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AN ANALYSIS OF CONSENT WITH SPECIFIC REGARD TO STEM CELL THERAPY AND RESEARCH

by

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DECLARATION OF ORIGINALITY

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SUMMARY

This thesis argues that stem cells cannot be properly regulated when understood in terms of medical treatment only. This is due to the uncertain scope and untested efficacy of stem cell therapy which renders treatment applications tantamount to research involving human subjects. This thesis therefore examines consent as regulatory instrument in context of stem cell related interventions and endeavours to introduce a sufficient consent model for such interventions. To this end, a clinical overview and explanation of stem cells is provided in order to establish an understanding of the field of science in need of regulatory control. This is followed by a background and introduction to consent, a discussion of specific aspects of consent and the National Health Act of 2003 and the Regulations made in terms of the Act to provide insight into consent as understood in South Africa. Consent in international instruments and international law is then examined. The law of the United Kingdom is also analysed by providing an examination of the legal systems in the United Kingdom which is then followed by a discussion of the Human Tissue Act of 2004 and the Human Tissue (Scotland) Act of 2006. Finally, dynamic informed consent is explained and introduced as the recommended consent format for the proper and valid regulation of stem cell therapy-research interventions. At the close of this thesis, the conclusions drawn throughout are compounded and pertinent recommendations are made regarding consent procedures and specifications.

KEY WORDS AND PHRASES

consent - stem cells - treatment - therapy
research - efficacy - biotechnology - experimentation
regenerative medicine - human subject - human participant - dynamic consent

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"They say you gotta stay hungry, hey baby I'm just about starving tonight,
I'm dying for some action, sick of sitting round here trying to write this book…"

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AN ANALYSIS OF CONSENT TO STEM CELL THERAPY AND RESEARCH

L Prinsen

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CHAPTER 1
INTRODUCTION

1 INTRODUCTION

"With how many things are we on the brink of becoming acquainted, if cowardice or carelessness did not restrain our inquiries."[1]

1.1 BACKGROUND

Through the course of history, humankind has sought out ever more inventive and newer techniques of keeping illness, disease, aging and even death at bay. Some would argue that in the discovery of stem cells, the quest for ultimate health has finally found its end.

Human tissues and organs are comprised of a combination of specialised cells determining the function of the organ or tissue. Unfortunately, these cells do not have the same lifespan as a human being and as such are in need of continuous regeneration or replacement and this is where stem cells become relevant. Stem cells are already found in the human body and when the specialised tissue or organ cells are damaged or destroyed, stem cells divide and replace these cells, meaning that the organ is maintained. To this end, stem cells have, for example, been applied in cancer treatment for years to reduce the symptoms of chemotherapy and restore the body's immune system. Working from this, numerous other types of stem cells have since been discovered and in the course of the last 20 years, stem cells have even been discovered that were thought to be non-existent such as in the brain and heart. The most controversial of these cells are those found in embryos known as embryonic stem cells. However, the ethical issues and objections to use of these cells were soon overcome with the discovery of induced pluripotent stem (iPS) cells, which are cells that have been reprogrammed to an embryonic state.[2] The discovery of iPS cells has, in fewer than ten years, allowed scientists to greatly impact biomedical research and an amazing technology is emerging, the boundaries of which are, however, unknown.[3] It is in this uncertainty that this thesis finds its footing and wherein the hypothesis posed in the course of this thesis is rooted.

[1] Shelly M (1818) *Frankenstein*: 50-51.
[2] See chapter 2 *infra* for an explanation of the science of stem cells.
[3] Mummery C, Van De Stolpe A, Roelen B & Clevers H (eds)(2014) *Stem cells: Scientific facts and fiction*: ix-x.

As often happens in the event of a new scientific discovery, things may go wrong and especially in a field of research such as stem cells which is so rapidly moving forward, facts and fiction may become confused. The science may be less robust than hoped for, the call of fame and fortune decreases personal integrity, and horrific practices come to light such as stem cell tourism. Different role players also enter the environment, each wanting a piece of the pie as physicians see new treatment options, entrepreneurs in biotechnology expect new commercial products and financial gains or opportunities and religious and political leaders debate the issues and concerns while manipulating them towards their own advantage. All the while the law must attempt to regulate and, to some extent, make sense of it all. This thesis therefore endeavours to provide a legal stance on the issue or, at least, a small part thereof.

As such, this thesis seeks to examine the role of consent in stem cell therapy and research. As the field of stem cells straddles both the scientific and the medical worlds it is therefore necessary, at this juncture, firstly to describe briefly the relationship between the law and science on the one hand, and the law and medicine on the other.

1.1.1 Science and the Law

Scientific development, although based on logic, is often an emotionally loaded pursuit. As such, an objective force such as the law is required to monitor science. In *Novum Organum*, Francis Bacon stated:[4]

> "The human understanding is not a dry light, but is infused by desire and emotion, which gives rise to 'wishful science.' For man prefers to believe what he wants to be true. He therefore rejects difficulties, being impatient to inquiry; sober things, because they restrict his hope; deeper parts of Nature [*sic*], because of his superstition; the light of experience, because of his arrogance and pride, lest his mind should seem to concern itself with things mean and transitory; things that are strange and contrary to all expectation, because of his common opinion."

The law and science, which includes medicine, are two of the most important features of modern life. The law assures fairness and freedom while science fuels progress which makes life more enjoyable. The relationship between these two pillars of modern life must therefore be briefly discussed.

Although both the law and science are of importance, they often seem to be in conflict with one another. This is due to the differing objectives of each discipline. Science strives towards progress while the law stresses process.[5] Science focuses on gaining knowledge and is therefore

[4] The *Novum Organum* or *Novum Organum Scientiarum*, meaning the new instrument of science, was published in 1620 and was written in Latin by Francis Bacon.
[5] Goldberg S & Gostin LO (2006) *Law and science*: 1.

based on cumulative knowledge, which has increased our understanding of nature and the physical world. The law on the other hand attempts to resolve social disputes in a peaceful manner and is fundamentally concerned with procedural questions. Where cumulative knowledge marches forward, the law may often move back and forth as the values of society change.[6]

The law may in fact have a deciding role in what scientific projects will be permitted, and as such legal systems must balance competing interests. For example, scientists may have an interest in pursuing their chosen career and in freedom of research but this will have to be balanced against the interests of the public, those of individuals and health as is the case in the context of this thesis. In South Africa, the Constitution plays an invaluable role in this balancing process.[7] Broadly speaking, where considerations regarding the implementation of new technologies arise, it will more often than not be the attitudes of society rather than the technical judgements of the scientific community which will be of importance.[8] The wish of bioethics for many years now, has been to place medical and scientific decisions in the hands of the patients and participants rather than the doctors or researchers and so consent as instrument has been greatly propagated. However, true to bioethical tradition, the principle has been better articulated than the practice thereof and although ethicists have been anxious to promulgate this doctrine, they have been less rushed in discovering the quality of its workings.[9] The law may offer some insight here.

Usually, scientific questions entail even more fundamental questions. This is especially true in the arena of stem cells. Scientists may be able to offer useful information on the medical application of such research but science alone will not be able to answer the questions raised about how such research should be permitted. The procedurally driven law may then step in and wrestle with the relevant interests and values, and determine whether such research is permissible and then in what manner it is to proceed. At times the law may have to limit research and technology as it must consider a host of values of which scientific progress is but one.[10] In general the legal system seems to support science where it relates to pure research but when the application of such research has an effect on the public it becomes more strict and prescriptive.

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[6] Goldberg & Gostin (2006) 2-3.
[7] See chapter 3 paragraph 6 *infra* for a discussion of the Constitution of the Republic of South Africa, 1996.
[8] Goldberg & Gostin (2006) 4.
[9] Schneider CE & Farrell MH (2000) "Information, decisions and the limits of informed consent" in Freeman M & Lewis ADE (eds) *Law and medicine: Current legal issues*: 107.
[10] Goldberg & Gostin (2006) 4.

Science then also supports the law, as accurate and honest technical information is often vital to the resolution of disputes and legal questions. An example of this may be seen in the determination of risk in medical treatment and scientific research. The legal system thus incorporates technical input in a variety of ways. Some, however, believe that new techniques are necessary to better consolidate the relationship between the law and science. It is suggested that a model of dynamic consent which will be introduced in the course of this thesis is one such new technique.[11] Medicine, as a specific scientific field, then also shares a certain relationship with the law. In fact, the relationship between the law and medicine has become so developed that it has spawned a specialised branch of law regulating this relationship which must be addressed at this juncture.

1.1.2 Medicine and the Law

According to Carstens and Pearmain there is immense teleological value in an approach which sees medical law as a branch of law on its own. This is due to the fact that the law is never an end in itself and only has meaning when viewed as a means. The law may therefore only be assessed as valuable and significant in light of how effective a means it proves to its particular end - the end being justice in the specific context in which it has been applied. The law is concerned with application and by recognising and formulating a body of law within a certain context, in this case medicine, it offers value and regulation to those who preoccupy themselves with that aspect on a daily basis.[12] This has led to the classification of the law related to matters of a medical nature as "medical law."

The term "medical law" is, however, not readily definable since the principles and practice of medicine encompass very wide ranging topics and activities.[13] Traditionally medical law has been used to describe instances involving medical malpractice or negligence. The term "health law" has also gained popularity and extends beyond traditional medical scenarios and therefore includes public health and other health related matters. This may extent to any matter which potentially impacts on health and may even include environmental health aspects.[14] It is submitted that these other health related matters may then include scientific endeavours which venture into the realm of health such as stem cells. There then also exists a third term, namely

[11] See chapter 9 *infra* for a discussion of dynamic consent.
[12] Carstens P & Pearmain D (2007) *Foundational Principles of South African medical law*: v.
[13] Strauss SA (2006) "Medical Law-South Africa" in Blanpain R & Nys H (eds) *International encyclopaedia of laws*: paragraph 42. The term "medical law" is most frequently used in South Africa and as such will be used in the course of this thesis.
[14] Nys H as mentioned in Van Oosten FFW (2006) "Medical Law-South Africa" in Blanpain R & Nys H (eds) *International encyclopaedia of laws*: paragraph 26-27.

"medical jurisprudence" which is the branch of science and medicine involving the study of medical knowledge to legal issues. This term is used in context of inquests for example where a medical practitioner must deliver expert evidence.[15]

This thesis, however, is not concerned with the semantics of the matter but rather with the relationship between the law, medicine and health. Medicine enables health and health requires medicine and for the purposes of this thesis these terms are so closely related that a hair-splitting distinction is unnecessary.

The law seeks to resolve disputes and provides the procedures whereby this may be done. It also often has a deciding role in what activities will be permitted and thus controls and balances various interests. The law regulates systems and protects those who participate within those systems. It may therefore be stated that the relationship between the law and medicine, like the relationship between the law and science, is one of support or prescription depending on the circumstances. In either instance, however, the law is necessary for the continued progress of the field and, as such, credence must be given to the word of the law. For this reason, the legal position pertaining to stem cells must be considered since human health procedures are undeniably moving towards biotechnology. This thesis is therefore an exploration of how the law, in the form of consent procedures, is able to support the development of stem cell therapy and research.

2 HYPOTHESIS AND PURPOSE OF THESIS

As was mentioned above, this thesis ultimately endeavours to explore law manifesting as consent as a support system for scientific progress. However, in order to do this, the object of support must be certain. This thesis hypothesises that stem cell therapy is too novel to support, or then to regulate, if understood in terms of medical treatment.[16] It is argued that the scope of stem cell therapy is so uncertain and since the efficacy thereof is still untested, that stem cell

[15] Mohr JC (1993) *Doctors and the law: Medical jurisprudence in nineteenth-century America*: 3.
[16] Traditionally, treatment is understood as meaning an intervention in a medical setting with the sole purpose of benefiting the patient and their health directly. Defining research is not an easy task, especially when it pertains to research which has a medical nature. Herring opines that the key distinction is whether the treatment is provided in order to derive knowledge or to benefit the patient. Where it is provided in a process of gaining knowledge, it would be classified as research. This distinction supports the hypothesis of this thesis as stem cell treatment is beneficial to the patient but the novelty of stem cell treatment alone provides a gain in knowledge meaning that any application thereof garners new information previously unknown. As no clear distinction between therapy and research may therefore be drawn regarding stem cells and considering the greatly uncertain scope thereof, it may be stated that stem cell treatment falls towards research rather than therapy. See Herring J (2014) *Medical law and ethics*: 600. According to the NHS Patient Safety Authority, treatment must be deemed as research where there is no "firm basis for support in the clinical community." See in general, NHS Patient Safety Authority (2008) *Defining research*.

therapy essentially amounts to stem cell research. Furthermore, since this therapy is applied to human beings, it is research involving human subjects. In other words, stem cell treatment is tantamount to research involving human research participants. In order to illustrate the dual nature of stem cell interventions, this thesis will thus often make use of the phrase "therapy-research" or "treatment-research." This argument will be supported in the course of this thesis which will illustrate the still greatly experimental nature of biotechnology and related interventions.

Working from this premise it may then be argued that a person involved in stem cell treatment-research also fulfils a dual or combined role. A patient is more than a mere patient and a physician is more than a mere physician. Such persons are also research participants and researchers or, more aptly in context of this thesis, "patient-participants" and "physician-researchers." As a result of this amalgamation of concerned persons, the regulatory instruments pertaining to the rights and duties of patients, research participants, doctors and researchers become relevant.

A further argument stemming from the above premise concerns the focal point of this thesis, namely consent. Traditionally the distinction between therapy and research is important in determining the appropriate model of consent to be utilised in an intervention. Interventions of a medical nature follow established consent practices and make use of informed consent due to the certain scope of the proposed intervention. Research related consent however may be more uncertain and complex and, as such, a model of broad consent is preferred. Returning to the hypothesis of this thesis that stem cell therapy is stem cell research due to the uncertain scope of the intervention, it may therefore be argued that neither informed nor broad consent are appropriate forms of consent in the context of stem cell therapy-research. It is argued that new trends and forms of medical science require new models of consent and that consent models may be merged in the same manner as the interventions and the persons involved, to create a new model of consent. This model of consent must, ideally, be a combination of the better parts of informed and broad consent, meaning that it offers an optimal amount of information and that its validity is not dependant on a fixed scope. It must be broad and informed, or then, dynamic in nature.

It is therefore the purpose of this thesis firstly to investigate the concept of consent and secondly to introduce a new and suitable model of consent in circumstances of stem cell related interventions, and herein lies the significance of this study.

3 MOTIVATION AND VALUE CONTRIBUTION

Research is not generally regulated unless it involves human participants, human gametes, human embryos, animals or data related to individuals. The tension which arises in regulating research therefore takes the form of attempting to promote medical and scientific advances which are only achievable through research on the one hand and the need to protect research participants and the public in general on the other.[17] A fine balance must therefore be kept and different rights and interests must be considered in a constant weighing of the positive and negative implications and aspects related to a certain research endeavour. The prominence of the human element is obvious and it is widely accepted that research involving humans must be carefully regulated and that it must be ensured that those who do participate in research are consenting. The law recognises the dangers involved in such research were it to be unregulated or conducted without proper consent.[18]

The motivation behind and original value contribution of this thesis therefore lies firstly in the novelty of investigating consent in context of stem cell therapy, research or then therapy-research on a doctoral level. This thesis is the first known legal academic study which focuses specifically on this particular issue related to stem cells and therefore contributes to the field of knowledge and debate in a significant manner. Secondly, it contributes to South African law, biotechnology regulation and legal thought by introducing the concept of a dynamic consent model. Thirdly, this thesis identifies certain areas of uncertainty pertaining to consent in the context of stem cells and offers valuable recommendations in clarifying these uncertainties. Fourthly, this thesis contributes to the development of this field on a documentary level as it is an inclusive and comprehensive collection of relevant legislative instruments regulating stem cells in South Africa to date of publication. Finally, this study contributes to the development of law by suggesting further topics of study, either post-graduate or post-doctoral, which fall outside of the ambit of this thesis.

4 RESEARCH METHODOLOGY

As is suggested by the title of this thesis, it is an analysis of the concept of consent as it relates to stem cell therapy and research or therapy-research as is hypothesised. In order to do this, a multi-layered approach will be followed and as such this thesis is a theoretical study

[17] Herring (2014) 600. It has been noted that society has a duty to engage in research. See also Fried E (2001) "Physician duties in the conduct of human subject research" *Accountability in Research* 8(4): 349-375.
[18] *Idem* 599.

predominantly based on a literature review of numerous primary and secondary legal and scientific sources which include:

1. The Constitution of the Republic of South Africa, 1996;
2. A comparative analysis of relevant South African and United Kingdom legislation and Regulations;
3. Relevant European Union Directives;
4. Relevant international instruments;
5. A study of South African and United Kingdom case law;
6. Legal academic writing in the form of books, textbooks and journal articles;
7. Legal postgraduate research studies in the form of theses and dissertations;
8. Relevant conference papers and lectures;
9. Scientific material pertaining to the science, manifestations, techniques and development of biotechnology;
10. Some ethical guidelines and other soft law instruments; and
11. Reputable online and electronic sources; but also
12. Face-to-face conversations with the developers of the Oxford Ensuring Consent and Revocation interface.

It must be noted that some of the chapters of this thesis are particularly lengthy. In order to fully address all the relevant aspects and reflect the most holistic and complete view of the topic of study of this thesis, limiting the potentially relevant literature was difficult. Where possible brevity was, however, applied. To this end the ambit of this thesis is limited to issues of consent and stem cells although various other concerns exist in this specific field of science including commercialisation of human material, patenting practices and intellectual property, moral objections, ethical concerns, questions regarding the classification of stem cell therapy, the regulation of the safety and efficacy of stem cells, issues surrounding storage, and the protection of information. It must also be noted that this is a legal study and by nature cannot be completely up to date on the most technical of scientific specifications and information. The science and manifestations of stem cells are therefore discussed with high reliance on electronic sources due to their high-tech nature but in general terms.

It must be noted that this thesis introduces a dynamic consent model which may be accompanied by an electronic interface. As a legal study, this interface is discussed in theory and a practical, working digital program has not been programmed as part of this research. Creation of such an interface requires multidisciplinary knowledge which falls outside the ambit of this thesis.

4.1 CHOICE OF LEGAL SYSTEMS

4.1.1 South Africa

This thesis will focus on South Africa's legal framework with regard to the law, stem cells, therapy and research while also addressing constitutional and medico-legal aspects of consent in order to identify and analyse shortcomings and areas in need of development within the national framework. Although some directly relevant South African sources on the topic of this thesis do exist, it is not sufficient in that this aspect of biotechnological regulation has not been properly explored or researched and leaves numerous questions unanswered. Section 39 of the Constitution, however, mandates the consideration of international and foreign law when interpreting the Bill of Rights and legislation as well as in developing the common and customary law. As such, this thesis relies heavily on foreign sources including international instruments and the relevant legislation of the United Kingdom.

4.1.2 International Instruments

Section 39(1)(b) of the Constitution expressly requires that international law must be considered in interpreting the Bill of Rights. This thesis therefore makes use of various international law documents in order to clarify the meaning of consent which is a constitutionally entrenched right in the Bill of Rights. A wider net is, however, also cast and other international instruments will also be analysed in the course of this thesis by virtue of South Africa's membership of the international bodies responsible for creating these instruments. Instruments relating to consent and biotechnology will receive particular attention.

4.1.3 The United Kingdom

The Constitution further states in section 39(1)(c) that foreign law may be considered in interpreting the Bill of Rights and as such the importance of the law of foreign jurisdictions ought not to be ignored. The concept of consent was properly introduced into South African medical law in the watershed case of *Castell v De Greeff* in 1994.[19] This case, however, strongly relied on the English case of *Sidaway v Bethlem Royal Hospital Governors* which had been decided in 1985.[20] This has the implication that the United Kingdom's regulatory regime

[19] *Castell v De Greef* 1994 (4) SA 408 (C).
[20] *Sidaway v Bethlem Royal Hospital Governors* [1985] 1 All ER 643.

concerning consent has massive informative value and may be insightful in solving the issues encountered in this field of study. A further aspect of consideration leading to the decision of making comparative use of this jurisdiction is the United Kingdom's long history of biomedical regulation which reaches back almost 40 years to the 1970's and the birth of the first *in vitro* fertilised baby. Their experience in this field can therefore not be ignored.

5 OVERVIEW OF PARTS AND CHAPTERS

This thesis is divided into Parts which are then subdivided into Chapters as follows:

Part A	:	Chapter 2	:	A CLINICAL OVERVIEW AND EXPLANATION OF STEM CELLS
Part B	:	Chapter 3	:	A BRIEF BACKGROUND OF AND INTRODUCTION TO CONSENT
	:	Chapter 4	:	SPECIFIC ASPECTS OF CONSENT
	:	Chapter 5	:	THE NATIONAL HEALTH ACT, ACT 61 OF 2003
Part C	:	Chapter 6	:	CONSENT IN INTERNATIONAL INSTRUMENTS
Part D	:	Chapter 7	:	THE LAW OF THE UNITED KINGDOM: AN INTRODUCTION TO THE LEGAL SYSTEMS OF THE UNITED KINGDOM
	:	Chapter 8	:	THE HUMAN TISSUE ACTS 2004 AND 2006, THE HUMAN TISSUE AUTHORITY AND OTHER RELEVANT REGULATORY INSTRUMENTS
	:	Chapter 9	:	DYNAMIC CONSENT
Part E	:	Chapter 10	:	CONCLUSION AND RECOMMENDATIONS

Following the winnowing methodology described above, each Part flows from a broader examination of the relevant topic to a narrowed-down, focussed discussion. It must be noted here that each individual Part and Chapter commence by providing a comprehensive account of the content to be discussed in the course of the Part or Chapter and, as such, what follows is a brief overview of the Parts and individual chapters of this thesis.

5.1 PART A: THE SCIENCE OF STEM CELLS

Part A of this thesis will introduce the scientific field of stem cells. The science which underlies the stem cell phenomenon will therefore be discussed in order to promote an understanding of that which the law must attempt to regulate. Part A of this thesis will have the purpose of facilitating, firstly, an understanding of stem cell therapy and research, and secondly, supporting

the hypothesis of this thesis that stem cell treatment is still largely experimental and therefore tantamount to research.

5.1.1 Chapter 2

Taking into account that this is a legal study, the most intricate technical details and information pertaining to the science of stem cells will not be discussed. This chapter will explain the potential of stem cells and their unique characteristics from which this potential is born. The different types of stem cells will be discussed as well as the sources from which these cells may be derived or created. This will be followed by an explanation of the procedures for the creation of stem cells which include somatic cell nuclear transfer and induced pluripotency. This will be followed by an explanation of the process of cell culture as well as stem cell banking. Lastly, aspects of tissue engineering will be explained which include bioscaffolding and printing. These aspects will all be explained in an endeavour to clarify this science in order to enable better regulation thereof. Diagrammatic figures will be provided throughout this chapter to ease comprehension of the concepts being addressed.

5.2 PART B: CONSENT IN SOUTH AFRICA

Part B of this thesis will be focused on the law and consent. The purpose of Part B of this thesis will be an inquiry into the understanding of consent in South Africa. This examination will flow from an abstract understanding of consent to one of concrete knowledge regarding the manifestation of consent in South Africa. This Part is comprised of chapters 3 to 5.

5.2.1 Chapter 3

This chapter will aim at providing insight into the doctrine of informed consent. In order to achieve this, this chapter will commence with a general discussion of the history, rationale and development of consent. This will then be followed by a chronological discussion of consent as found in South African case law in order to illustrate the development and incorporation of the concept within our law. The cases to be discussed are *Stoffberg v Elliot*, *Lymbery v Jefferies*, *Rompel v Botha*, *Ex Parte Dixie*, *Esterhuizen v Administrator Transvaal*, *Dube v Administrator Transvaal*, *Verhoef v Meyer*, *Richter v Estate Hammann*, *Phillips v De Klerk*, *Castell v De Greef*,

Oldwage v Louwrens, *Christian Lawyers' Association v National Minister of Health and Others* and the most recent case of *Sibisi NO v Maitin*.

The Constitution will be discussed with specific regard being given to section 12 which guarantees freedom and security of the person as well as providing for the right to bodily as well as psychological integrity. The last aspect to be addressed in this chapter will be the law of obligation as it pertains to consent. The law of contract and the law of delict will therefore be discussed briefly.

5.2.2 Chapter 4

This chapter will focus on a *capita selecta* of consent aspects relevant to this thesis. Attention will be given to consent in medical law which will include a discussion of the nature and scope of consent, the controversial nature of the doctrine of informed consent and the duty of disclosure. This will be followed by an examination of the requirements of valid consent and the traditional distinction between therapy and research and its impact on consent practices.

Specific pertinent aspects of consent will then be addressed. This discussion will focus on who must obtain and provide consent with reference to adults, the mentally ill and minors. The issue of when consent ought to be obtained and what the scope of the consent process ought to be is then discussed and lastly, the format wherein consent must be given is examined. Here, various different types of consent including express, implied, simple, specific, generic, blanket and especially broad consent will be given attention. The argument as posed in the hypothesis of this thesis will be elaborated on and strengthened in the course of this chapter and at the close, the model of dynamic consent introduced later in this thesis will be briefly introduced, and consent in the digital age will be made mention of.

5.2.3 Chapter 5

The whittling methodology used in this thesis will then also be used in this chapter to investigate the South African position relating to stem cells and consent. The purpose of this chapter will therefore be an investigation and dissection of relevant provisions of the National Health Act, Act 61 of 2003 and the Regulations made in terms of the Act. This chapter will provide some background information to the NHA and the legislation preceding the Act will also be discussed with specific regard to the development of consent in these Acts.

The discussion of the NHA will commence by discussing Chapter 2 of the Act which makes provision for the rights and duties of health care users and personnel. Particular attention will be given to sections 6, 7, 8, 9 and 11. Chapter 8 of the Act which provides for the control and use of blood, blood products, tissue and gametes in humans will then be analysed as an investigation and discussion of South African stem cell legislation at the time of publication of this thesis. National health research and information as provided for by Chapter 9 of the NHA will then be discussed and particular attention will be given to section 71 which makes provision for research or experimentation with human subjects. It will be shown throughout that the NHA is framework legislation and is therefore supplemented by Regulations.

Lastly, the Regulations will be addressed according to the commonality of their subject matter and will therefore be discussed as they pertain to the use of biological material, artificial fertilisation, the national health research ethics council and national health research committee, research on human subjects and participants, human stem cells, import and export, tissue and stem cell banks, general control as well as blood and blood products. Throughout the course of this chapter it will be shown that by making use of interpretation, the Act and Regulations already allow for a different consent format.

5.3 PART C: INTERNATIONAL POSITION OF CONSENT

Part C of this thesis will focus on international law. It will serve the dual purpose of thoroughly examining and discussing the relevant international instruments as well as exploring the manner in which domestic law and policy is informed by internationally accepted principles and standards. This will be done in taking account the comparative mandate established by the South African Constitution.

5.3.1 Chapter 6

At the onset of this chapter an overview and definition of international law will be provided to establish some certainty regarding the meaning of "international law instruments." This will be followed by an analysis of sections 39 and 231 of the Constitution to determine, illustrate and motivate a comparative study. The *Makwanyane* and *Bernstein* cases will also be mentioned.

The entities that create international instruments namely the United Nations; the United Nations Educational, Scientific and Cultural Organisation; the World Medical Association; the

World Health Organisation and the Council for International Organisations and Medical Sciences will be given some attention. The African Union is then also discussed.

A wide variety of instruments pertaining to both medical and research matters will be discussed in this chapter and include the Nuremburg Code, the International Bill of Rights, the Declarations of the Rights of the Child and on the Rights of Disabled Persons, the Convention on the Rights of a Child, the Universal Declaration on the Human Genome and Human Rights, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects, as well as the Universal Declaration on Bioethics, and Human Rights and the Convention on the Rights of Persons with Disabilities. The Declarations of Geneva and of Helsinki will also be discussed. Lastly, the African Charters on Human and Peoples' Rights and on the Rights and Welfare of the Child as well as the African Bioethics Resolution will be analysed. All the while, specific attention will be given to the provision pertaining to consent as found in these instruments and this Part will then conclude with the insights gained into consent through these instruments.

5.4 PART D: CONSENT IN THE UNITED KINGDOM

Part D of this thesis will pay attention to the specific foreign jurisdiction of the United Kingdom. The purpose of this Part will therefore be an analysis of the law existing in the UK and ultimately introducing a dynamic consent format. This discussion will also commence by first examining general and broad aspects of the United Kingdom's law which will then systematically be tapered down to particular legislative and regulatory documents. Finally, a solution to the consent concern will be introduced in a highly particular and specialised fashion. This thesis Part is comprised of chapters 7 to 9.

5.4.1 Chapter 7

This chapter will set out the different legal systems in play in the United Kingdom and provide an overview, explanation and some insight into the intricacies of each individual system. In order to understand specific legislation, regulating authorities and the Dynamic Consent and EnCoRe model which will be introduced in this thesis, the background and context of the United Kingdoms' legal system will be explained in a general sense in order to understand the specific regulatory framework discussed in the following chapter.

As such, this chapter will provide some history and background to the development of the law of the United Kingdom as a whole as well as of each of the individual jurisdictions, explain the

interplay between the different legal systems, identify the legislature, explain the court systems and point out the distinct jurisdictions and their relationships to one another.

This chapter will also entail a discussion of key consent related cases originating from the United Kingdom. Although the focal point of this thesis is legislation, a complete understanding of the regulatory regime pertaining to consent in general and stem cells in particular must be established. Case law enables such understanding and as consent forms the foundation of the Human Tissue Act of 2004 as well as the Human Tissue (Scotland) Act of 2006, the judicial interpretation and consideration thereof is important. This thesis also follows a multi-layer approach and case law forms a part thereof. The cases of *Bolam v Friern Hospital Management Committee*, *Sidaway v Bethlem Royal Hospital Governors*, *Gillick v West Norfolk and Wisbeck Area Health Authority*, *Re C (Adult Refusal to Treatment)*, *Pearce and Pearce v United Bristol Healthcare Trust*, *Re B (Consent to Treatment: Capacity)*, *Simms v Simms*, *Chester v Afshar* and *Montgomery v Lanarkshire Health Board* will therefore be discussed.

5.4.2 Chapter 8

This chapter will focus on the specific laws, policy documents and other legislative instruments regulating human tissues and cells and particularly the relevant consent in the United Kingdom. This will be done by examining both the 2004 and the 2006 Human Tissue Acts of which consent is the foundation.

This discussion will address the scope of the Acts, activities permitted under the particular Acts, the Acts' consent or authorisation provisions, the existence of any exemptions to the consent requirement and the offences under the Acts. A summary of the provisions regarding consent or authorisation will then be provided.

Additionally to the 2004 and 2006 Acts, numerous other legal instruments have an impact on the regulation of human tissue and cells which include the Human Tissue (Quality and Safety for Human Application) Regulations of 2007, the *Guide to Quality and Safety Assurance of Human Tissue and Cells for Patient Treatment*, the European Union Tissue and Cells Directives and certain Codes of Practice. Attention will therefore also be given to these instruments.

This chapter will further examine the Human Tissue Authority by discussing activities regulated by the Authority and the mechanisms whereby these activities are regulated, legislation pertaining to the Human Tissue Authority and the Codes of Practices issued by the Authority.

5.4.3 Chapter 9

This chapter seeks to make a contribution to South African law by introducing a new form of consent. This will be achieved by suggesting that different types of consent may be combined to develop a new format of consent. This chapter will therefore introduce dynamic consent as a new, appropriate consent model for stem cell treatment and research.

Dynamic consent will be introduced and explained by discussing the reasons for dynamic consent, its meaning, and its workings. Attention will also be given to the benefits and claims of superiority of a model of dynamic consent and the challenges facing this format. The characteristics of dynamic consent will then be discussed. Dynamic consent as a participant-centred initiative is also discussed as well as the functions and benefits of initiatives of this nature.

This is followed by an explanation of the two-way, circular working of dynamic consent and leads into a discussion of various projects and initiatives which make use of dynamic consent models. This is done with reference to First Genetic Trust, Private Access, 23andMe, PatientsLikeMe and especially the Ensuring Consent and Revocation project.

Attention will then be given to the Ensuring Consent and Revocation project, or EnCoRe project. In discussing the EnCoRe project, consideration will be given to the aims and features thereof, how it works as well as the challenges to this system.

At the conclusion of this chapter, dynamic consent in context of this thesis will be discussed and its proposal as contribution to South African law will be motivated.

5.5 PART E: CONCLUSION AND RECOMMENDATIONS

Part E of this thesis will contain the conclusions drawn in the course of this thesis and will make pertinent recommendations for the regulation of consent in interventions of a stem cell therapy-research related nature. This thesis Part is comprised of chapter 10.

5.5.1 Chapter 10

The final chapter of this thesis will summarise all the conclusions reached throughout the course of this thesis. The conclusions pertaining to consent in South Africa, the international position of consent and consent in the United Kingdom will be provided. Certain

recommendations will also be made in the course of this thesis and will be collectively set out according to who bears the responsibility of obtaining consent, the person from whom consent must be obtained, the timing of consent, the scope of consent, the format of consent, the drafting of the NHA and the Regulations made in terms of the Act and other aspects which may be identified in the course of this thesis. Lastly, recommendations pertaining to possible post-doctoral studies will be provided.

6 CONCLUSION

As was asked at the onset of this chapter, with how many things such as keeping illness, disease, aging and even death at bay are we on the brink of becoming acquainted, if carelessness or rather insufficient regulatory measures did not restrain our inquiries?

The discovery of stem cells has allowed for the emergence of an amazing technology and potentially revolutionary medical field. However, the boundaries thereof are still unknown and as is often the case in incidents of scientific discovery, things may rapidly go awry, ultimately impeding scientific progress. This also leads to legal uncertainty as the law is tasked with protecting and balancing the rights and interests of different groups while enforcing their obligations and attempting to regulate the confusion and offer clarity.

This thesis therefore finds its footing in this confusion and seeks to provide some certainty regarding the aspect of consent in context of stem cell related interventions. In order to do so, the concept of consent will be thoroughly examined in the course of this thesis and ultimately certain conclusions will be drawn regarding the topic of study and pertinent recommendations will be made.

In order to understand the field of study, however, some understanding of the science of stem cells is required. The following chapter of this thesis will therefore entail a clinical overview of stem cells which will then be followed by the legal study of this thesis as subdivided into certain Parts.

PART A
THE SCIENCE OF STEM CELLS

Part A of this thesis introduces the scientific field of stem cells. In other words, in this part of this thesis, the science which underlies the stem cell phenomenon will be discussed in order to promote an understanding of the science which the law attempts to regulate in general. More specifically, however, Part A is necessary to facilitate firstly, an understanding of stem cell therapy and research and secondly, to support the argument made in the hypothesis of this thesis that stem cell treatment is still largely experimental. This thesis argues that since the efficacy of stem cell therapy is still greatly uncertain and untested, this novel medical treatment may be deemed research involving human subjects. This has the implication that traditional consent formats are insufficient in rendering consent lawful.

In order to achieve the purpose of Part A, an explanation of the science and manifestations of stem cells will be provided. This includes the unique properties of stem cells and the various types of stem cells. The sources from where stem cells may be derived, which entails a discussion of multiple other aspects, will also be provided. Stem cell banking is addressed and lastly, tissue and organ engineering will be explained. Diagrammatic figures are used throughout Part A in order to ease comprehension of the concepts being addressed.

Part A of this thesis consists of the following:

CHAPTER 2 - A CLINICAL OVERVIEW AND EXPLANATION OF STEM CELLS

CHAPTER 2
A CLINICAL OVERVIEW AND EXPLANATION OF STEM CELLS

1 INTRODUCTION

"If knowledge can create problems, it is not through ignorance that we can solve them." These words by the late Isaac Asimov ring very true in context of stem cells, stem cell therapy, stem cell research and biotechnology.[1] The knowledge of stem cells, of the amazing potential of this technology, even of their mere existence has created great scientific, ethical, political and legal uproar and controversy. In the course of this thesis, some of these problem areas are discussed in detail and it becomes apparent that most of the issues surrounding stem cell technology result from a lack of knowledge and understanding, or the ignorance of what this science really and truly entails. This chapter has a dual purpose in that it endeavours firstly, to reduce ignorance of this subject and to provide knowledge thereof and secondly, to illustrate the still greatly experimental nature of this particular scientific phenomenon. This is important in context of the hypothesis and problem statement discussed in the previous chapter of this thesis.[2] It is argued that stem cell science is currently still so new and uncertain and that since the efficacy of stem cell therapy is still greatly untested, this novelty and unpredictability render stem cell treatments tantamount to research. As such, the traditional and well-known formats of obtaining consent in either therapeutic interventions and research participation are insufficient.

Biotechnology,[3] which in itself is revolutionary, has introduced several innovations and these have led to various new technologies and products. The first major discovery made under the umbrella of biotechnology was that of DNA and recombinant DNA which allowed researchers and scientists to splice DNA and in so doing, they were able to assemble genes in manners which allowed for the manufacturing of host proteins such as insulin which has become a commonplace treatment for persons suffering from diabetes.[4] The second revolution came in

[1] Asimov was an American author and biochemistry professor at Boston University, best known for his works of science-fiction and his popular science books.
[2] See chapter 1 paragraph 2 *supra*.
[3] Biotechnology is the branch of molecular biology which focuses on the use of microorganisms to perform specific functions. In context of this thesis it is used as an umbrella term which includes stem cell science and technology.
[4] To splice, in the most basic sense, means to connect or join. In context of DNA and genes it may therefore be understood as the technology or process used whereby recombinant DNA may be created by slicing together DNA molecules from multiple organisms. Recombinant DNA (rDNA) is therefore created in a laboratory by way of genetic

the form of genomics which allowed scientists and researchers to rapidly sequence and manipulate genetic information.[5] Regenerative medicine, also referred to as cell therapy, may then be described as the third revolutionary innovation and it is sure to lead to amazing discoveries, drug testing, treatments and therapies.

The emerging field of regenerative medicine is the branch of medical and scientific procedures founded on the concept of the production of new cells which are then used to replace or repair malfunctioning or damaged cells, tissues and organs and to treat disease and injury. Numerous currently untreatable and significant diseases are due to the loss of or malfunctioning of certain cell types in the human body such as Alzheimer's and Parkinson's disease, heart failure and immune system aging, known as immunosenescence. Also, medical conditions which result in cell damage caused by acute disease, trauma, infractions or burns may be treated by regenerative medicine and biotechnology.[6] This chapter will explain how this is possible.

Keeping in mind that this thesis is a legal study, the most intricate technical details and information will not be discussed. This chapter will, however, explain the potential of stem cells and the unique characteristics of the cells from which this potential is borne. The different types of stem cells are then discussed as well as the sources from which these cells may be derived or created. This is followed by an explanation of the procedures for such creation of stem cells. Once stem cells have been derived or created, something must be done either to multiply the cells or to preserve them. To this end, the process of cell culture is discussed as well as stem cell banking. And lastly, the fascinating realm of tissue engineering is explained as this is where stem cells travel from the laboratory, the theory, to patients, the application, by using the cells to build or print organs and tissues. All the above mentioned aspects will be explained and discussed in order to understand this science, thereby enabling better regulation thereof. As Goethe once stated, that which a man does not understand is that which he does not possess. Regulation of this technology is thus unattainable in the absence of an understanding thereof. Even more so, obtaining informed consent becomes impossible if the scope of what consent is being provided for is not understood. This is, after all, the ultimate focus of this thesis and must be addressed. Firstly, however it is interesting to discuss the history and background of stem cell research and therapy.

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recombination methods such as somatic cell nuclear transfer which will be discussed in the course of this chapter. See paragraph 3.6.1.2 *infra*.

[5] Genomics is a branch of genetics which makes use of recombinant DNA, bioinformatics and DNA sequencing to analyse the structure and functions of the genome.

[6] See in general, Advanced Cell Technology (2013) "Regenerative medicine" available online at http://www.advancedcell.com/our-technology/regenerative-medicine/ accessed 3/1/2013. See also BioTime (2013) "Regenerative medicine" available online at http://www.biotimeinc.com/regenerative-medicine/ accessed 3/1/2013.

1.1 HISTORY AND BACKGROUND

Due to the alarming rate at which biotechnological science is developing it is difficult to stay on the "cutting edge" of information if not directly involved in the laboratory.[7] This being said however, the evolution of this field of medical science is interesting in itself as it is only when we know where we are coming from that we know where we are going. It therefore becomes important to have knowledge of, at least, an abridged history and background of the scientific field which the law is attempting to regulate in some form or another. Some of the highlights in the development of this science are thus discussed here.[8]

During the 1950's, bone marrow experimentation revealed the existence of stem cells in the human body. This discovery led to the development of bone marrow transplantation, a therapy which is now commonly used in the treatment of blood disorders and cancers such as leukaemia. An aspect of the 1950's discovery of stem cells during experiments which was, and still is, of great importance was the awakening of hope in the potential of regeneration. After the successful completion of the first ever bone marrow transplant in 1956, scientists set out to identify embryonic cells with this same potential because of studies on early human development which had indicated that the human embryo was capable of forming all the cells of the human body.[9] This was the beginning of wonderful discoveries in the field of biotechnology.

Mice were predominantly used as research subjects and in the 1980's stem cells were extracted from such mice, followed by embryonic stem cells being derived from mouse blastocysts in 1981 and in 1988 hematopoietic stem cells which were withdrawn from adult mice were purified and characterised.[10]

In 1992 stem cells were identified in the human brain. In 1997 the world was introduced to Dolly the sheep, the first cloned animal and in 1998 nuclear transfer was used to clone over 50 mice.[11] Furthermore, scientists were able to isolate human embryonic stem cells and sustain these cells in culture without differentiation for the first time in 1998.[12]

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[7] See paragraph 5 *infra* for the newest developments in stem cell technology at the time of publication of this thesis.
[8] See in general, Stem Cell History (2013) "Stem cell research timeline" available online at www.stemcellhistory.com/stem-cell-research-timeline/ accessed 27/1/2013.
[9] Suggested further reading, Appelbaum FR, Thomas ED, Forman SJ & Blume KG (eds)(2009) *Thomas' hematopoietic cell transplantation*. Dr Thomas was the first person ever to perform a bone marrow transplant and is known as "the father of bone marrow transplantation." He was a 1990 Nobel Prize laureate and passed away at the age of 92 in 2012. See also in general, Munker R, Lazarus HM & Atkinson K (eds)(2009) *The BMT data book*.
[10] The National Academies (2006) *Understanding stem cells: An overview of the science and issues from the National Academies*: 2.
[11] Swanepoel M (2006) *Embryonic stem cell research and cloning: A proposed legal framework in context of legal status and personhood* (LLM thesis unpublished, University of Pretoria): 56.
[12] The National Academies (2006) *Understanding stem cells* 2.

Mouse embryonic stem cells were created by nuclear transfer in 2001 and in 2002 pancreatic cells were derived from these cells and used to cure diabetes in mice. Nerve cells which are lost when a person suffers from Parkinson's disease were produced for the first time ever in 2004.[13]

Human embryonic stem cells, implanted into mouse brains, differentiated into active nerve cells after implantation in 2005. The year 2006 held many incredible developments for biotechnology as the first-ever Morula-derived embryonic stem cells were extracted,[14] stem cells were grown in culture without any animal products[15] and induced pluripotent stem cells (iPS cells) were created using mouse cells.[16] In 2007 iPS cells were created using human cells[17] and in 2008 it was reported that the cancerous genes which are a negative consequence of induction, could be removed thus increasing the potential use of this technique for human application.[18]

Also in 2008, researchers at Harvard University published an article stating that they had successfully created disease-specific iPS cell lines for diseases such as Parkinson's disease and juvenile diabetes,[19] pluripotent stem cells were derived from spermatological cells and HES-like cells were derived from human hair.[20] In 2009 Andras Nagy and Keisuke Kaji were able to induce iPS cells without making use of viruses.[21] Also the first patient-specific iPS cells were created and a new method of producing HES-like stem cells was created without damaging the DNA of the cells.[22] The year 2010 was rather uneventful as the greatest highlight of the year was the reprogramming of fibroblasts without having to dedifferentiate the cells to a pluripotent state first.[23] In 2011 HES cells were cloned and in 2012 a new method of mesenchymal stem cell creation was developed.[24] Also Shinya Yamanaka, the pioneer of induced pluripotent stem cells,

[13] *Ibid*.
[14] Meaning that embryonic stem cells were extracted from a human embryo in the Morula stage of development. See paragraph 3.4 *infra* in this regard.
[15] The National Academies (2006) *Understanding stem cells* 16-17.
[16] See paragraph 3.6.1.3 *supra* for more on induced pluripotent stem cells.
[17] Stem Cell Network (2009) "Stem cell timeline" available online at http://www.stemcellnetwork.ca/index.php?page=stem-cell-timeline accessed 8/8/2011.
[18] Kaplan K (2009) "Cancer threat removed from stem cells" *Los Angeles Times*, 6 March available online at http://www.latimes.com/news.nationworld/nation/la-sci-stemcell62009mar06,0,63456.story accessed 10/5/2010.
[19] Regenerative Medicine (2012) "Stem cell timeline" available online at www.slideshare.net/Regenerative_Medicine/stem_cell_timeline accessed 27/1/2013.
[20] LabGrab (2011) "Stem cell highlights-From 1908 to present day" available online at http://www.labgrab.com/timeline/stem-cell-research-then-and-now accessed 27/1/2013.
[21] Regenerative Medicine (2012) online. See also paragraph 3.6.1.3 *infra*.
[22] LabGrab (2011) online.
[23] Regenerative Medicine (2012) online.
[24] Science Progress (2009) "Timeline: A brief history of stem cell research" available online at http://scienceprogress.org/2009/01/timeline-a-brief-history-of-stem-cell-research/ accessed 27/1/2013.

received a Nobel Prize.[25] In 2013 Shoukharat Mitalipov and his colleagues successfully created human embryonic stem cells from fetal cells by way of therapeutic cloning.[26]

In Japan 2014 was the year in which Charles Vacanti of Harvard Medical School and Haruko Obokata of the Riken Centre for Developmental Biology in Kobe, Japan, announced that any cell could potentially be "rewound" to a pre-embryonic state in just 30 minutes by making use of their simple technique. In this same year, Masayo Takahashi of the Riken Centre also proposed to commence patient selection for the first-ever clinical trial for human age-related blindness therapy making use of induced pluripotent stem cells.[27] In the United Kingdom, it was reported that scientists were creating custom-made body parts from stem cells.[28]

In 2015, researchers claimed to have developed patient-specific heart cells from stem cells as well as fully functional kidneys.[29] To date, it has been reported that stem cell therapy has to some extent reversed blindness and has been used to replace sections of the human brain.[30]

1.2 THE POTENTIAL OF STEM CELLS

Stem cells have certain unique characteristics and because of this they offer the prospect of cell-based therapies.[31] Cell-based treatments include the reparation or replacement of damaged tissue. Practically speaking, this would entail the treatment of neurodegenerative diseases such as Alzheimer's, diabetes or Parkinson's.[32] Also, and perhaps more astounding is the potential for utilising stem cells in organ engineering whereby actual organs such as hearts, kidneys and livers, may be built or grown.[33]

Furthermore, the fields of cancer research, drug testing and embryonic development research may derive benefit from stem cell research and therapy and gene therapy may become a practicable and revolutionary medical treatment.[34]

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[25] See paragraph 3.6 *infra* for more on Yamanaka.
[26] Coghlan A (2014) "Stem cell timeline: A history of a medical sensation" *New Scientist* available online at https://www.newscientist.com/article/dn24970-stem-cell-timeline-the-history-of-a-medical-sensation/ accessed 13/5/2016.
[27] *Ibid*.
[28] Stem Cell Tracker (2016) "Stem cell research timeline" *Stem cell history* available online at http://www.stemcellhistory.com/stem-cell-research-timeline/ accessed 13/5/2016.
[29] *Ibid*.
[30] *Ibid*.
[31] See paragraph 2.1 *infra* for more on the unique properties of stem cells.
[32] Holland S, Lebacqz K & Zoloth L (eds)(2001) *The human embryonic stem cell debate: Science, ethics and public policy*: 3.
[33] Gavaghan H (2001) "The promise of stem cells" *Bulletin of the World Health Organisation* 79(8): 800. See also paragraph 5 *infra* for a discussion on tissue and organ engineering.
[34] Stem cell research, or more broadly, cell-based treatments are a *condictio sine qua non* of the benefits which would befall the improvement of infertility treatment; development of further knowledge regarding factors giving rise to

Stem cell therapy holds the potential for the future treatment of diabetes, Parkinson's disease, Alzheimer's disease, spinal cord injury, heart failure or failure of bone marrow[35] as it may be applied in the treatment of degenerative, malignant or genetic diseases and even injuries caused by inflammation, infection or trauma.

In order to fully understand the wonder that is stem cells and stem cell research and therapy and why stem cells are fast becoming one of the most talked about subjects in both medicine and research, and to be able to grasp the importance of a solid regulatory framework, it is essential to have an understanding of the intricacies of this science. The greatly experimental nature of this branch of science must however also be recognised. What follows in the remainder of this chapter is thus an explanation of the science and the manifestations of stem cells, the process of cell banking and its application in the practice of tissue engineering.

2 SCIENCE AND MANIFESTATIONS

In the following section certain characteristics of stem cells will be explained. This includes the unique properties of stem cells and the various types of stem cells. This explanation attempts to illustrate the distinction between stem cells and any other human cells or rather, it attempts to illustrate why stem cells have drawn so much attention and justify such intense study and research.

2.1 UNIQUE PROPERTIES OF STEM CELLS

A stem cell is unlike any other cell in the human body and it is this disparity which has sparked interest in this field of scientific study. It is furthermore the reason for the importance of this technology and wherein the potential miracle promised by stem cells lies. Stem cells possess three unique properties which separate them from other cells. These qualities, each of which deserve some attention and are briefly discussed further hereafter, are:

1. The ability to proliferate and self-renew for long periods of time;
2. The unspecialised nature of stem cells; and
3. The ability to give rise to specialised cell types.

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congenital disease; the development of more effective contraceptive methods; and pre-implantation detection of gene or chromosome abnormalities. See in this regard Tanner JM (2005) "Medici stry nog oor foetuses se pyn" *Perspektief*: 4 and also Carstens P & Pearmain D (2007) *Foundational principles of South African medical law*: 198.

[35] Lerou PH & Daley Q (2005) "Therapeutic potential of embryonic stem cells" *Blood Reviews* 19: 321. See also The National Academies (2006) *Understanding stem cells* 13-17, National Institutes of Health (2009) *Stem cell basics*: 1-2 and Swanepoel (2006) 39-41.

2.1.1 Proliferate And Self-Renew

Stem cells have the unique ability, unlike other bodily cells, to replicate repeatedly. This process of repeated replication is commonly referred to as proliferation.[36] Stem cells could almost be described as immortal since a small subset of stem cells may produce millions of cells should they be allowed to proliferate in culture over the course of months.[37] The immortality of a stem cell is more eloquently referred to as homeostasis.[38] Cells in general become more specialised naturally and thus have therapeutic value. Should these cells, however, remain unspecialised and capable of producing more unspecialised cells, these cells are referred to as being capable of "long term self-renewal."

2.1.2 Unspecialised Nature

Stem cells may best be described as "blank slates" which do not possess a tissue-specific structure or encoding which requires of the cell to perform a certain specialised function such as heart muscle or nerve cells.[39] In other words, an unspecialised cell has no specific function and may be "programmed" to perform a necessary or desired function. Such cells may be found in embryos, fetuses and in some adult tissues.

2.1.3 Give Rise To Specialised Cell Types

Differentiation is the process whereby blank, unspecialised stem cells produce or give rise to specialised cells.[40] Cell differentiation is triggered by the cell's internal and external signals.[41] The internal signals are controlled by the genes in the DNA[42] of the cell which carries and instructs the functions and structures of the cell. The external signals are more dependent on circumstantial factors such as the micro-environment of the cell and physical contact with surrounding cells and the chemicals which these neighbouring cells secrete.[43] The scientific control of this process will certainly become a key element in any future cell-based therapy. This

[36] Proliferation is discussed in further detail in the course of the discussion pertaining to induced pluripotent stem cells. See paragraph 3.6.1.3 *infra*.
[37] See paragraph 3.5 *infra* for a discussion regarding the process of cell culture.
[38] Laurie G (2004) "Patenting stem cells of human origin" *European Intellectual Property Review* 26(2): 60.
[39] Castell JH (2001) "Lengthening the stem: Allowing federally funded researchers to derive human pluripotent stem cells from embryos" *University of Michigan Journal of Law Reform* 34(3): 551.
[40] Differentiation may be defined as "the process whereby an unspecialised early embryonic cell acquires the features of a specialised cell such as a heart, liver or muscle cell." See The National Academies (2006) *Stem cells and the future of regenerative medicine*: 69.
[41] As of yet, very little is known about this process.
[42] DNA or deoxyribonucleic acid is "a nucleic acid and primary constituent of chromosomes." See Family Medical (2000) *Medical dictionary*: 69.
[43] Swanepoel (2006) 37.

process is utilised in the production of pluripotent stem cells, but it is then reversed and referred to as de-differentiation.[44]

2.2 TYPES OF STEM CELLS

According to the National Institute of Health, stem cells are defined as "cells with the ability to divide for indefinite periods in culture and to give rise to specialised cells."[45] This definition thus contains three distinguishable elements. Firstly, the ability to divide for an indefinite period of time. Secondly, the process of cell culture is involved and lastly, stem cells give rise to specialised cell types. The "ability to divide," as mentioned in the definition refers to the process of cell division whereby a single cell exponentially divides to create more cells.[46] A cell will split, or divide into two cells which then further divide to create four cells, which then divide to create eight, then sixteen and so forth. There are two main forms of cell division namely mitosis and meiosis.[47]

Mitosis is the type of division undergone by most bodily cells by which tissues are repaired and grown. It consists of the division of a single cell to create two genetically identical cells which are referred to as "daughter cells" which each have a full set of chromosomes. Meiosis, on the other hand, is the division as found in the maturation process of gametes and results in the sex cells eventually containing only half the number of chromosomes of the parent cell. During fertilisation the full number of chromosomes is restored in the embryo in a unique combination. As a result of a process during meiosis called "crossing-over," daughter cells vary genetically.[48] Meiosis furthermore consists of two phases of division which are then further divided into four stages namely: prophase, metaphase, anaphase and telophase.[49] Culture is the process whereby cells are grown in a laboratory setting and is discussed in the course of this chapter.[50]

The last element of the definition pertains to the formation of specialised cell types and requires some in-depth explanation. Where an egg cell undergoes natural gestation *in utero*, the various different cell types which are found in the human body[51] develop from a single cell and thus share an origin. Blood cells, neural cells, brain cells, liver cells *etcetera* all come from the original

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[44] See paragraph 3.6.1.3 *infra* for a discussion on induced pluripotent stem cells.
[45] National Institutes of Health (2009) "Stem cell basics: Glossary" available online at http://www.stemcells.nih.goe/staticresources/info/basics/SCprimer2009.pdf accessed 5/8/2009.
[46] National Institutes of Health (2009) "Glossary" online.
[47] See in general, Alberts B, Johnson A, Lewis J, Raff M, Roberts K & Walter P (2002) *Molecular biology in the cell: Landmarks in the development of tissue and cell culture cell*.
[48] See in general, Youds JL & Boulton SJ (2011) "The choice in meiosis-Defining the factors that influence crossover or non-crossover formation" *Journal of Cell Science* 124: 501-513.
[49] Family Medical (2000) 161 & 167.
[50] See paragraph 3.5 *infra*.
[51] There are more than 200 types of cells in the human body.

cell: the embryo. The process whereby a cell becomes more specialised is referred to as cell differentiation and in layman's terms, this may be expressed as the level of commitment a single cell has to a certain form. This is controlled by the cell's interaction with the chemical and physical conditions surrounding the cell.[52] This is accomplished by the signalling of pathways involving proteins embedded in the surface of the cell. It could be said that the cell is given a "developmental map" by its surrounding environment. This signalling of pathways is referred to as the "expressing or repressing" different subsets of genes. Gene expression is the activation of genes while repression is the deactivations of genes.[53] As a cell becomes more specialised or differentiated, the possible subsets of genes which it is able to express becomes more limited. Differently stated, the cell's plasticity reduces.[54] Plasticity is the cell's potential to differentiate. It may further be stated that plasticity is the ability of the cell to differentiate into a cell type other than the type of tissue in which it may be found normally.

Depending on the differing sources from where stem cells originate, the plasticity of the cell will also differ and this allows for a hierarchical division of stem cells based on the cell's level of differentiation. This hierarchy may also be referred to as the cell's potency.[55] In terms of this hierarchy, stem cells may be divided into the following categories which will be discussed: totipotent stem cells, pluripotent stem cells, multipotent stem cells, bipotent stem cells and unipotent or monopotent stem cells.[56]

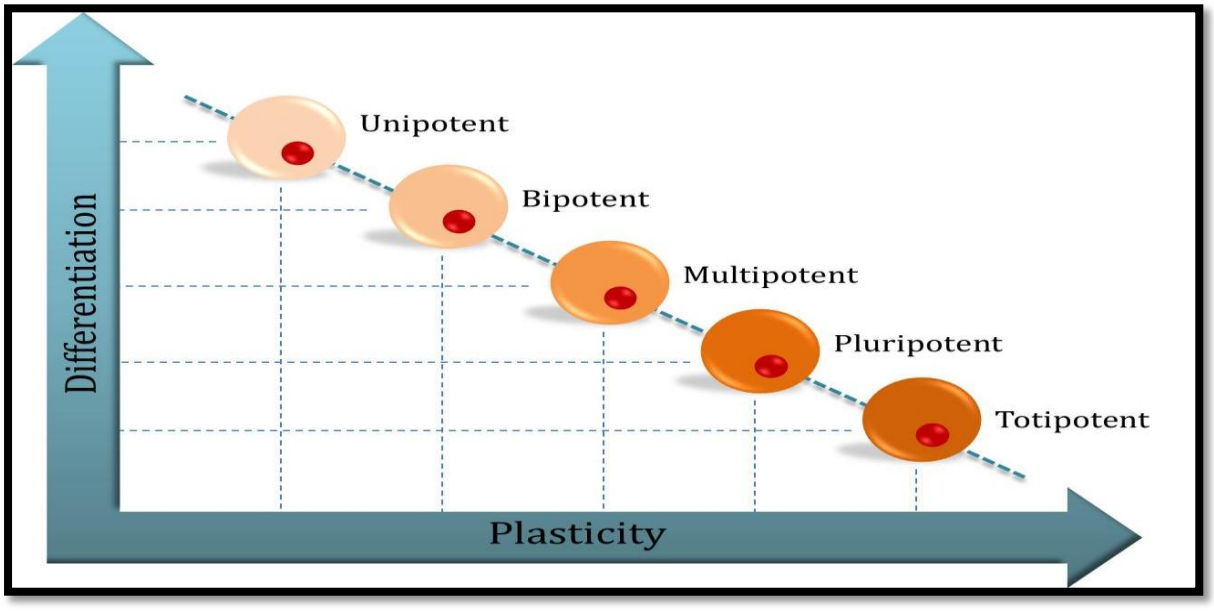

Figure A: Stem cell hierarchy

[52] National Institutes of Health (2009) 20.
[53] For example, red blood cells express the genetic creator of haemoglobin, the protein which transports oxygen throughout the body while neural cells do not. Swanepoel (2006) 33 footnote 37 & 38.
[54] The National Academies (2006) *Stem cells and the future* 71.
[55] Potency is the cell's ability to become a specialised cell.
[56] Swanepoel (2006) 34.

2.2.1 Totipotent

The human body contains various different cells which include germ cells, egg and sperm cells and somatic cells.[57] Germ cells are gametes, meaning ova or sperm, or cells which directly give rise to gametes and are either any germ cell, whether ovum or spermatozoon, or a mature male or female reproductive cell.[58] An egg cell may also be referred to as oocyte and may be defined as "a cell in the ovary that undergoes meiosis to produce an ovum, the female reproductive cell."[59] Sperm cells are "the mature, male reproductive cells or gametes."[60] A sperm cell consists of a head with a Haploid nucleus containing half the chromosome number and an acrosome which helps to penetrate the egg cell. Below the head of the sperm cell is mitochondria which provides energy to sperm and a tail whereby it propels itself forward. Somatic cells are all the other cells found in the body of an organism, other than the germ cells, and are made up of two sets of chromosomes.[61]

After fertilisation, the union of an egg cell and a sperm cell, the fertilised egg begins the process of cell division which is the method whereby a single cell divides to create two cells.[62] Should any one of these cells be isolated and cultured and allowed to continue its development, a new embryo would form from this single cell.[63] Totipotent cells possess unlimited capability and are able to differentiate into an embryo,[64] placenta[65] and tissue. It may further contribute to all the cell types in the human body[66] which includes *inter alia*, heart cells, brain cells and liver cells.[67] Three days after division starts, the period of totipotency however ends and the cells become more specialised, thus decreasing in potency.[68] The cells therefore become pluripotent.

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[57] Somatic cells are also referred to as adult cells.
[58] Holland, Lebacqz *et al*. (eds)(2001) 244.
[59] Family Medical (2000) 184.
[60] *Idem* 239.
[61] Holland, Lebacqz *et al*. (eds)(2001) 245.
[62] National Institutes of Health (2009) "Glossary" online.
[63] This explains how twins are formed. Twins are thus the result of a process wherein genetically identical organisms arise from the symmetrical division and separation of totipotent cells. See in general, Revolution Health (2010) "Where do twins come from?" available online at http://www.revolutionhealth.com/healthy-living/pregnancy/first-concerns/multiples/facts accessed 22/4/2010.
[64] An embryo is "the first stage of development of the fetus after the fertilised ovum is implanted into the uterus until the second month." See Family Medical (2000) 77. The embryo may also be defined as "the developing organism from the time of fertilisation until the end of the eighth week of gestation, when it becomes known as the fetus." See also The National Academies (2006) *Stem cells and the future* 68.
[65] Placenta may be defined as "the organ attaching the embryo to the uterus." The placenta is only a temporary feature which comprises maternal and embryonic tissue and allows oxygen and nutrients to be carried from the mother's blood to the fetus. It is expelled after birth. See Family Medical (2000) 77. See also Kidson S (2009) *Working with human ES and iPS (induced pluripotent stem) cells in SA* presented at the Stem Cell Seminar, Innovation Hub, University of Pretoria, Pretoria, 27 May. Hereafter referred to as the Stem cell seminar.
[66] Holland, Lebacqz *et al*. (eds)(2001) 245.
[67] Miller J (2003) "A call to legal arms: Bringing embryonic stem cell therapies to market" *Albany Law Journal of Science & Technology* 13(2): 558.
[68] Slabbert MN (2003) "Cloning and stem cell research: A critical overview of the present legislative regime in Australia and the way forward" *Journal of Law and Medicine* 10(4): 515.

2.2.2 Pluripotent

During the early stages of embryonic development, pluripotent stem cells which generate all cell types which are able to self-renew in both the fetus and adult, but which cannot develop into a complete organism, may be found.[69] Pluripotent cells are able to form differentiated cells and even tissues. Although the gene expression is different to that of a pluripotent stem cell, the genome remains the same and unchanged.[70]

On approximately the fourth day after fertilisation, the blastocyst forms. The blastocyst is an embryo of roughly 150 cells produced by cell division following fertilisation[71] and is comprised of an outer layer named the trophoblast,[72] a fluid-filled cavity called the blastocoel[73] and a cluster of cells inside the blastocyst referred to as the inner cell mass.[74]

The inner cell mass is the source from which embryonic stem cells are derived.[75] The cells produced by the blastocyst are pluripotent and thus have the ability to develop into any of the various cells in the human body, whether endoderm, mesoderm[76] or ectoderm.[77] Pluripotent cells cannot, however, become a fetus should they be implanted into the womb of a woman.[78] As a pluripotent cell becomes more specialised and less potent during further development, it becomes multipotent.

2.2.3 Multipotent

Multipotent cells, which are capable of becoming a few types of tissue, form during fetal development and may be found in adults as most adult cells are multipotent in nature. These

[69] Holland, Lebacqz *et al*. (eds)(2001) 244.
[70] Kidson (2009) Stem cell seminar.
[71] National Institutes of Health (2009) "Glossary" online.
[72] *Ibid*. The trophoblast is "the outer layer of the blastocyst. It is responsible for implantation [into the uterine wall during normal gestation] and develops into extra-embryonic tissues, including the placenta, and controls the exchange of oxygen and metabolites between mother and embryo."
[73] "The fluid-filled cavity inside the blastocyst, an early... stage of the developing embryo." See National Institutes of Health (2009) "Glossary" online.
[74] *Ibid*. See also The National Academies (2006) *Stem cells and the future* 67.
[75] See paragraph 3.4 *infra* for a further discussion on embryonic stem cells derivation from the blastocysts.
[76] MedicineNet.com (2010) "Endoderm" available online at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=endoderm accessed 3/5/2010. See also MedicineNet.com (2010) "Mesoderm" available online at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=mesoderm accessed 3/5/2010.
[77] Ectoderm is the outermost of the three germ layers forming the embryo. It gives rise to various important tissues and structures which include the outer layer of the skin and its appendages such as the sweat glands, hair, nails, the teeth, the lens of the eye, parts of the inner ear, the nerves, brain, and spinal cord. This is known due to classic human embryology. Stem cell research has indicated that certain cells within the ectodermal structures retain their ability to differentiate into other tissues. See MedicineNet.com (2010) "Ectoderm" available online at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=ectoderm accessed 3/5/2010.
[78] See Moore KL & Persaud TVN (2003) *Before we are born: Essentials of embryology and birth defects*: 41-48 & 60.

cells are more specialised than pluripotent cells but less specialised than bipotent and unipotent cells. Prime examples of multipotent cells which are capable of becoming different types of cells are umbilical cord stem cells and bone marrow cells which are able to create blood cells.[79] Multipotent cells thus have a certain, specified function and may be regarded as being organ-specific. As stated previously, multipotent cells may be found in the adult human body but, unfortunately, only in smaller quantities.[80]

2.2.4 Bipotent

Bipotency, as indicated by the name, means that a cell may become two things.[81] A bipotent cell will thus develop into either endoderm or mesoderm.[82] Mesoderm is the layer of the three germ layers which are found in early embryonic development and is situated between the ectoderm and the endoderm. It subsequently gives rise to muscle, connective tissue, cartilage, bone, blood and bone marrow, gonads and various other tissues. Endoderm is the innermost layer of the three germ layers. It subsequently gives rise to the epithelium, tonsils, the thyroid gland, the larynx, trachea, and lungs to name but a few.[83]

2.2.5 Uni- Or Monopotent

Unipotent or monopotent cells, as indicated by the usage of "uni" or "mono" will only ever create one cell type. Most of the cells found in the human body may be categorised as unipotent and are fully differentiated.[84] An example of such a unipotent cell is a skin cell, as a skin cell will always create more skin cells. A unipotent cell therefore has almost no plasticity and will only ever create more of its own type of cells.

3 THE SOURCES OF STEM CELLS

The sources and potential sources from where stem cells may be derived are varied. In order to globally grasp stem cell research and stem cell therapy, it is important to have knowledge of

[79] Kidson (2009) Stem cell seminar.
[80] Slabbert (2003) 515.
[81] Kidson (2009) Stem cell seminar.
[82] Bradbury J (2005) "A culture of bipotency" *Development* 132(19): e1905.
[83] Encyclopeadia Britannica (2012) "Mesoderm" available online at http://www.britannica.com/EBchecked/topic/376720/mesoderm accessed 18/8/2012. See also Encyclopeadia Britannica (2012) "Endoderm" available online at http://www.britannica.com/EBchecked/topic/186938/endoderm accessed 16/8/2012.
[84] Kidson (2009) Stem cell seminar.

these sources. Some of the controversy wherein stem cells and related technology is shrouded is often rooted in the sources of stem cells and each source has its own unique ethical and moral hurdles to overcome. The sources are also indicative of the experimental nature and open "scope" of stem cell technology. The sources of stem cells include the following:[85]

1. Cadaveric fetal tissue or embryonic germ cells. These cells are derived from the remains of spontaneous or elective abortion;
2. Cord blood. Cord blood is derived from the umbilical cord directly after birth;[86]
3. Cloned chimera embryos. This is where the somatic cell of a human is implanted into an enucleated animal egg cell;[87]
4. Human embryonic stem cells. Such cells are created in the process of *in vitro* fertilisation;[88]
5. Adult cells. Adult cells are most commonly derived from bone marrow, blood or skin of a donor;[89] and
6. Cloned human embryos. Cloned embryos are created by the process of somatic cell nuclear transfer.[90]

In the course of this thesis, attention will mostly be given to embryonic stem cells and the more prominent forms of adult stem cells as manifested in somatic cell nuclear transfer and induced pluripotent stem cells. What follows is a discussion of all the sources of stem cells listed above as it is necessary to have a complete idea of the sources of stem cells.

3.1 CADAVERIC FETAL TISSUE

The withdrawal of fetal stem cells in particular, but also any tissue in general, is contentious and emotionally loaded and relates to various ethical concerns. After an abortion, it is possible to obtain cadaveric fetal tissue. An abortion may have occurred spontaneously or electively. It is preferable to obtain material from an electively aborted fetus as spontaneous abortions often

[85] Slabbert (2003) 516 and Carstens & Pearmain (2007) 191.
[86] See paragraph 4.1.1 *infra* for a detailed discussion of the withdrawal of cord blood from the umbilical cord.
[87] "Enucleated" means that the nucleus of the cell has been removed.
[88] *In vitro* means "in glass" and is the opposite of *in vivo* which is a biological, natural process. See Family Medical (2000) 133.
[89] Adult stem cells are utilised in the process of induced pluripotency. For more, see paragraph 3.6.1.3 *infra*.
[90] Somatic cell nuclear transfer is discussed in further detail in paragraph 3.6.1.2 *infra*.

contain weaknesses which caused the miscarriage or ectopic pregnancy[91] which resulted in abortion.[92] Cells may be derived from fetuses aborted five to nine weeks after fertilisation.

3.2 CORD BLOOD CELLS

Cord blood stem cells, postnatal stem cells and haematopoietic stem cells may be withdrawn from the umbilical cord after birth.[93] It must be noted that the umbilical cord is regarded as an especially important source of mesenchymal cells and it has been suggested that a national cord blood "bank" be established in order to facilitate the development and harness the potential of cord blood stem cells. Such cells could be utilised in therapeutic procedures on the donor of the cells and any other patient and could further provide scientists with a source of cells to be used in research.[94]

3.3 CHIMERIC EMBRYOS

Animals are often used in medical research as well as research examining the developmental processes in organisms and in diseases.[95] It has been common practice, before tests are done using human subjects, to implant human cells into mice in order to test and assess the safety and efficacy of new medicines and treatments.[96] In context of stem cell research and therapy, animal testing is utilised to ensure incorporation of stem cells into tissue, to assess whether there are any harmful consequences and to observe whether stem cells function in cooperation with the other functions of the tissue after implantation. Animal studies may further illustrate the differentiation of cells during normal development.[97]

An organism which contains cells or tissues from different species is referred to as a chimera. The word "chimera" comes from the Greek word *Khimaira*. The Khimaira was a mythological creature which was composed of parts of different animals: a lion, a goat and a snake. The Khimaria was depicted as a lion with a goat's head rising from its back and the tail of the lion

[91] An ectopic pregnancy is where the fetus develops outside of the uterine wall. See MedlinePlus (2012) "Ectopic pregnancy" available online at http://www.nlm.nih.gov/medlineplus/ency/article/000895.htm accessed 31/8/2012.
[92] Castell (2001) 549-550.
[93] Swanepoel (2006) 45 & 55.
[94] The National Academies (2006) *Understanding stem cells* 14.
[95] *Idem* 10. By implanting human cells which result in certain diseases into a mouse blastocyst, scientists are able to observe how and when the cells start to show signs of disease.
[96] Heyer J, Kwong LN, Lowe SW & Chin L (2010) "Non-germline genetically engineered mouse models for translational cancer research" *Nature Reviews Cancer* 10: 470-480.
[97] Scientists may, for example, implant human cells into a developing mouse in order to observe any processes involved in the organisation and building of different tissues of which the human body is comprised.

turning into a snake. Today, the phrase chimera is used to denote an animal consisting of different parts and then normally in a scientific context. A chimera is therefore an organism which possesses two or more genetically different groups of cells which originate from different organisms. The process of somatic cell nuclear transfer is used to create chimeric embryos as the somatic cell of a human is implanted into an enucleated ovum of an animal.[98] These embryos may then be used in cell-based therapies[99] and could offer relief to the usage of spare IVF embryos[100] as they may lessen the demand for such spare eggs.[101]

As this practice involves the combining of genetic material from different species, there are obvious underlying objections thereto.[102] The argument may, however, be made that ethical issues regarding the moral status of a hybrid embryo are less contentious and difficult to overcome than the issues surrounding the moral status of an embryo or, for that matter, human experimentation.[103]

3.3.1 Ethics and Experimentation

The creation of chimeras has unique ethical implications which must be briefly discussed.[104] The German philosopher Immanuel Kant was of the opinion that man does not owe any duty towards animals and that animals are a mere means to man's end. Man does not have a direct duty towards animals but rather an indirect duty towards humanity.[105] Researchers, however, have the duty towards society to respect life and thus to treat all living beings, be they animal or human, with the necessary and appropriate respect. This means that animals should not be used in research where the animals will be harmed or sacrificed if there exists an alternative method, such as computer-generated models, which will achieve the same results.[106]

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[98] See paragraph 3.6.1.2 *infra* for an explanation of the process of somatic cell nuclear transfer.
[99] See in general, Newman SA (2003) "Averting the clone age: Prospects and perils of human developmental manipulation" *Journal of Contemporary Health Law* 19(2): 431-464.
[100] Swanepoel M (2007) "Constitutional, legal and ethical issues regarding the regulation of cloning in South Africa" *SA Publiekreg/SA Public Law* 22(2): 341.
[101] Slabbert (2003) 518. See also Zelony A (2005) "Don't throw the baby out with the bathwater: Why a ban on human cloning might be a threat to human rights" *Loyola of Los Angeles International and Comparative Law Review* 27(3): 541-564 and Adams NA (2004) "Creating clones, kids and chimera: Liberal democratic compromise at the crossroads" *Issues in Medicine and Law* 20(1): 3-27.
[102] See paragraph 3.3.1 *infra*.
[103] Dhai A, McQuiod-Mason & Rodeck C (2004) "Ethical and legal controversies in cloning for biomedical research: A South African perspective" *South African Medical Journal* 94(11): 908.
[104] See in general, Adwell M (2011) "UK researchers urge regulations for animal-human genetic hybrids" available online at http://www.the9billion.com/2011/07/28/uk-researchers-urge-regulations-for-animal-human-genetic-hybrids/ accessed 27/1/2013.
[105] Kant I (1930) "Duties toward animals" in Huhse H & Singer P (eds)(2006) *Bioethics: An anthology*: 564.
[106] Health Professions Council of South Africa (2008) "General ethical guidelines for health researchers" *Guidelines for good practice in the health care professions: Booklet 6*: 9.

For this reason, health researchers have a duty towards animals to accept responsibility for the care of the animals used in research and to respect the welfare of the animals as well as take active measures, like using procedures which minimise the incidence and the severity of pain and suffering experienced by the animals. Researchers must also demonstrate that the research is justifiable and scientifically-based and that the research follows the ethical and regulatory guidelines established at an institutional level. Researchers should use, when appropriate, inanimate objects rather than animals. Where the use of an animal species is absolutely necessary, lower animal species less susceptible to pain and suffering should be used if the integrity of the research will not be compromised by doing so. No more animals than necessary may then be used.[107]

Animal testing is a contentious and emotional subject and researchers must always keep the importance of the knowledge sought and the importance of using animals in search of this knowledge in mind. The Medical Research Council provides the following in this regard: [108]

1. The research must preferably benefit humans, animals and the environment;
2. Only where no appropriate alternative exists, may animals be used;
3. Optimal standards of animal care and health must be observed in order to provide quality results to enhance credibility and reproducibility;
4. The three "R" principles must be adhered to during the planning and conducting of the research studies: replacement, reduction and refinement;
5. Animal usage is dependent upon public confidence in mechanisms and processes used to ensure that the experiments are humane and justified; and
6. Laboratory animals are protected under law in South Africa and the use of animals for educational, research and testing must be accordingly justifiable.[109]

The Regulations relating to Research on Human Subjects[110] is relevant to this thesis as it deals with animal research in context of biotechnology wherein animals are used for human applications. The National Health Act, Act 61 of 2003 is, not surprisingly, mute on this subject.[111] Chapter 3 of the Human Subjects Regulations deals with research which involves animals and states that where animals are used in research which will ultimately benefit humans, the

[107] *Idem* 11.
[108] See in general, Medical Research Council of South Africa (2003) *Guidelines of ethics for medical research: Use of animals in research and training (Book 3)*.
[109] See in general, Health Professions Council of South Africa (2008) "General ethical guidelines for biotechnology research" *Guidelines for good practice in the health care professions: Booklet 7*: 26-28.
[110] Regulations Relating to Research on Human Subjects of 23 February 2007. Hereafter referred to as the 2007 Human Subjects Regulations. See chapter 5 paragraph 5.5 *infra* for more on these Regulations.
[111] See chapter 5 of this thesis for more on the shortcomings of the National Health Act, Act 61 of 2003. Suggested further reading, Prinsen L (2013) "Flawed law: A critical analysis of the faults and shortcomings of chapter 8 of the National Health Act of 2003" *Obiter* 34(3): 522-532.

research proposal for such research must be submitted to an animal research ethics committee. The proposed researcher must further, complaisant to the National Department of Agriculture, consult with and comply with the regulations and guidelines for the research.[112]

It should also be mentioned that some are of the opinion that research on animals is permissible only as long as the animal has no level of human consciousness and thus any research which makes it possible to produce a brain, the home of consciousness, must be conducted with caution. The National Academies has prohibited the following:

1. Introduction of human cells into the blastocyst of non-human primates;
2. The introduction of any animal or human cell into a human blastocyst; and
3. The breeding of human-animal chimeras in the event that human genetic material may be contained in the animals' reproductive cells.[113]

The risks and potential risks of species combining is still greatly uncertain but for now, the use of chimeric mice in research is essential since human testing may not be conducted unless conclusive animal testing has been performed.

3.4 HUMAN EMBRYONIC STEM CELLS

Human embryonic stem cells or HES cells[114] are "primitive (undifferentiated) cells derived from a five-day pre-implantation embryo that are capable of dividing without differentiation for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers."[115] Due to the characteristic of cell division without differentiation, HES cells may be described as immortal and possess unlimited developmental potential.[116] HES cells are capable of proliferating indefinitely in cell culture and for this reason, are able to produce an endless source of specified adult cells such as blood or bone cells.[117]

As may be deduced from the name, embryonic stem cells are derived from embryos. More specifically, HES cells are derived from early embryos during the blastocyst stage of development. It must be noted that the embryos used for deriving stem cells are not naturally fertilised ones, as spare embryos which have not and will not be used for *in vitro* fertilisation are

[112] Regulation 9 of the 2007 Human Subjects Regulations.
[113] The National Academies (2006) *Understanding stem cells* 21-22.
[114] "HES cells," "ES cells" and "embryonic stem cells" are used interchangeably in the course of this thesis.
[115] National Institutes of Health (2009) "Glossary" online.
[116] Holland S (2005) "Many suspect that new kinds of adult stem cells may be found that are as versatile as those found in embryos" *National Geographic Magazine* 208(1): 18-20.
[117] University of Wisconsin-Madison (2001) "Embryonic stem cells: Research at the University of Wisconsin-Madison" available online at http://www.news.wisc.edu/packages/stemcells/facts.html accessed 6/8/2011.

the most utilised source of HES cells.[118] Another source of embryonic stem cells is aborted fetuses. This is the cause of various great ethical issues which surround stem cell research and therapy.[119]

It is necessary to understand the development of an embryo in order to fully understand the embryo as a source of stem cells. An embryo is the developing organism from the moment of fertilisation[120] of an egg cell up to the eighth week of development. After the eighth week of development the embryo is referred to as a fetus.[121] Stated differently, an embryo is the product of *in vivo* or *in vitro* fertilisation[122] of an egg cell by a sperm cell.[123]

The following is an explanation of the process of embryonic development. Since both natural and artificial fertilisation has been mentioned in this chapter, both will be discussed. Firstly, *in vivo* fertilisation and development to birth is discussed and secondly, *in vitro* fertilisation to embryo transfer is discussed. Development from fertilisation to birth may be divided into seven stages:[124]

1. Fertilisation of the egg cell. Fertilisation, of a female egg by male sperm, occurs inside the oviduct of the uterus and usually within 12 hours after ovulation[125] but no later than 24 hours, as the oocyte[126] starts to degenerate after such time. Male sperm also have a general life span of around 48 hours inside the female genital tract.[127] Fertilisation entails various biological processes and ultimately culminates in the formation of a zygote[128] carrying the required genetic information necessary to create an individual. Half the genes are provided for by each parent.[129]

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[118] Slabbert (2003) 517.
[119] The implementation of processes such as somatic cell nuclear transfer and induced pluripotency have reduced some of these issues but entail some of their own, unique issues.
[120] Fertilisation may be described as "the union of male and female gametes." See The National Academies (2006) *Stem cells and the future* 67. The moment at which fertilisation occurs is difficult to determine since it cannot be observed within the human body. See also Moore & Persaud (2003) 2 and Swanepoel (2006) 43.
[121] National Institutes of Health (2009) "Glossary" online. A fetus is described as "an unborn child after the 8th week of development," according to Family Medical (2000) 93. In the course of this thesis, fetus will be spelt as such although the spelling "foetus" is also generally accepted.
[122] *In vitro* fertilisation or IVF is "the process of fertilising an ovum outside the body." The term "test-tube baby" is sometimes used and was coined after the first successful live birth utilising this technique in 1978 in the United Kingdom. See Family Medical (2000) 133.
[123] Swanepoel (2006) 43.
[124] The first three stages are relevant to this thesis and have been illustrated in *Figure B infra*.
[125] Ovulation is the process whereby an egg cell is released from the ovary after which it travels down the Fallopian tube and into the uterus. See Family Medical (2000) 189.
[126] An oocyte is a cell in the ovary. It produces an ovum which is the female reproductive cell. See Family Medical (2000) 184.
[127] Holland (2005) 18. See also Moore & Persaud (2003) 26.
[128] "The cell produced by the fusion of male and female germ cells (gametes) during the early stages of fertilisation." After the zygote has passed down the Fallopian tube, it implants itself into the uterine wall and becomes an embryo. See Family Medical (2000) 283.
[129] Odendaal HJ (1989) *Ginekologie* 21-23.

2. Cell division. Approximately 36 hours after fertilisation, the process of cell division commences. During this developmental stage, all the cells are identical and totipotent. This means that, given the correct environment, each single cell has the ability to develop into an individual.[130] The zygote then divides exponentially in that it first divides into two blastomeres, which then divide into four, these four become eight. This eight cell stage entails a process during which the cells are reshaped and form what is referred to as the Morula[131] or "morus mulberry."[132] The Morula enters the uterus three days after fertilisation and here the fluids inside the cavity of the Morula increase and the trophoblast separates from the inner cell mass. The inner cell mass is a "cluster" of cells inside the blastocyst. These cells give rise to the embryonic disk of the later embryo and ultimately the fetus."[133] The inner cell mass is, most importantly, the source of embryonic stem cells.
3. The fertilised embryo develops into a collection of around 100 to 150 undifferentiated cells referred to as the blastocyst. The blastocyst is sometimes referred to as a "pre-implantation embryo" in the context of *in vitro* fertilisation, or an "early embryo." The blastocyst consists of three layers of which the outermost layer, the trophoblast, later forms the extra embryonic structures such as the umbilical cord and the placenta.[134] The inner cell mass of the blastocyst is the primary source of embryonic stem cells and therefore cells may be harvested and cultured to obtain such stem cells.[135]
4. A week after fertilisation, the embryo containing undifferentiated or pluripotent cells, implants into the womb. This process is normally completed before the second week after fertilisation and in the event that this does not occur the blastocyst ceases all further development.[136]
5. Two weeks after fertilisation the embryo consists of roughly 2000 cells which start to differentiate and become specialised. The primitive streak, which forms the central nervous system, also begins to develop at this developmental stage.[137]

[130] The National Academies (2006) *Stem cells and the future* 13.
[131] Moore & Persaud (2003) 31.
[132] This is due to the mulberry-like appearance of the cell cluster.
[133] The National Academies (2006) *Stem cells and the future* 70.
[134] The umbilical cord connects the embryo or later the fetus to the placenta and is usually connected close to the centre of the fetal surface. The placenta is the primary source of nutrients and aids in gas exchange between the mother and fetus. The placenta and umbilical cord together function as transportation system. After birth, the placenta is expelled from the uterus and it is then referred to as the afterbirth. See Moore & Persaud (2003) 35 & 105.
[135] See *Figure C infra* for an explanation of cell culturing.
[136] The Merck Manuals Online Medical Library Home Edition for Patients and Caregivers (2009) "Stages of development" available online at http://www.merckmanuals.com/home/sec22/ch257/ch257c.html accessed 5/5/2011.
[137] Odendaal (1989) 23.

6. About eight weeks after fertilisation individual organs become apparent and the embryo becomes a fetus. Organ growth and differentiation[138] as well as that of tissues and other bodily systems now take the primary developmental role.[139]
7. Normally after nine months, roughly 38 weeks, from fertilisation, the fetus is born as a baby. At this stage haematopoietic cells may be harvested from the umbilical cord blood which remains in the umbilical cord and postnatal stem cells may be withdrawn from the placenta and afterbirth.[140]

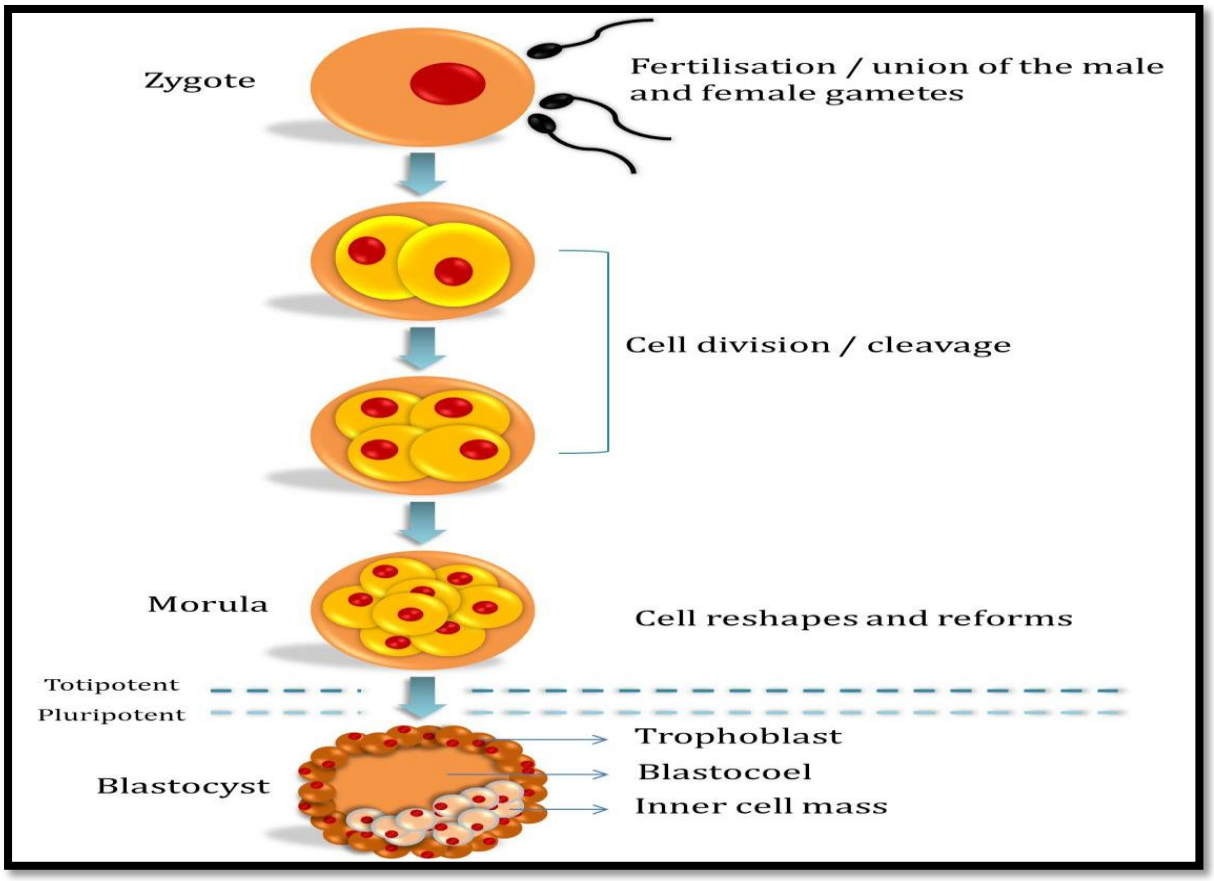

Figure B: Early embryonic development

The process of *in vitro* fertilisation (IVF) has five stages:[141]

1. Ovarian stimulation. A woman is required to use hormones for a period of eight to fourteen days which stimulates the woman's ovaries to produce numerous eggs and not just one during her menstrual cycle. Successful IVF more often than not requires

[138] Stem cells usually produce an intermediate cell prior to becoming fully differentiated and this precursor cell is referred to as a progenitor cell. Progenitor cells are differentiated to some extent as they are committed to a specified cell type and give rise to differentiated cells during cell division.
[139] Moore & Persaud (2003) 78.
[140] See paragraph 4.1.1 *infra*.
[141] Jeffries M "*In vitro* fertilisation overview" available online at http://health.howstuffworks.com/pregnancy-and-parenting/pregnancy/fertility/in-vitro-fertilization1.htm accessed 10/1/2013.

fertilisation of multiple eggs since some of the fertilised eggs may not develop normally after fertilisation. Ultrasound and blood tests may be used to determine when the eggs are ready for retrieval.

2. Retrieval. Once the eggs are ready to be retrieved, the process of transvaginal ultrasound aspiration is used to remove the eggs. This is a minor surgical procedure wherein a physician locates the eggs by way of ultrasound and then inserts a needle into the follicles of the fallopian tube and removes the eggs with suction. If it is not possible to locate the eggs by ultrasound, laproscopic surgery may be required. This is a technique whereby a small incision is made in the abdomen of the woman to locate the eggs with a fiber-optic lens.
3. Insemination. After the eggs have been retrieved they are examined to determine whether or not the eggs have the potential for successful pregnancy. The viable eggs are then placed in an IVF culture medium. While the eggs are in the culture medium the sperm with which it is to be fertilised is separated from the semen of the father or donor. The most motile[142] sperm is then added to the eggs in an incubator.
4. Fertilisation and embryo culture. Normally the sperm cell penetrates and fertilises the egg in a matter of hours. This may be confirmed visually as two pronuclei should become visible. The pronuclei form the basis of embryo formation as they unite and form the nucleus of the zygote. Approximately two days after fertilisation a two-to-four-cell embryo appears, on the third day this has divided into a six-to-ten-cell egg and this continues until the egg reaches the blastocyst stage. The egg may be implanted as soon as one day after fertilisation but no later than six days and normally takes place on the second or third day after fertilisation so the blastocyst stage is usually not observed.
5. Embryo transfer. Around the second or third day after fertilisation, the embryo or embryos are transferred to the woman's uterus. This is done by suspending the embryos in fluid and drawing them into a transfer catheter[143] which is then guided into the vagina, past the cervix and into the uterus. The embryos are then allowed to attach to the uterine wall from where natural development takes place.

Before continuing with the discussion pertaining to adult stem cells, it becomes necessary to explain the process of cell culturing as it is relevant to the processes whereby adult stem cells are rendered suitable for stem cell therapy and research. These processes are discussed in the course of this chapter.[144]

[142] In layman's terms, this means the "best swimmers."
[143] This is a thin, long and flexible tube with a syringe on the end.
[144] See paragraph 3.6.1 *infra*.

3.5 CULTURE

Cell culturing is the removal of cells from their biological environment and the subsequent growth of these cells in an artificial environment.[145] This process dates back to the early twentieth century when the original purpose of culturing cells was the study of normal physiological events such as neural development under a microscope. Animal cell culture only became routine around the 1940's and 1950's due to the need for viral vaccines necessitated by the Polio epidemic.[146] Recombinant DNA technology, known as genetic engineering, was developed in the 1970's using bacteria but it soon became apparent that complex proteins were not producible in bacteria as the necessary sugar chains did not form. The need for large-scale commercial production of such proteins thus gained importance at this stage.[147] In 1975 Köhler and Milstein produced the first-ever hybrid cell lines and in 1976 Sato published a series of papers stating that different cell lines require different combinations of hormones and growth factors in order to grow in a serum-free medium. Martin and Evans, in 1986, isolated and cultured pluripotent embryonic mouse stem cells and in 1998 Thomson and Gearhart isolated human embryonic stem cells.[148]

An advantage of cell culture is the consistency and reproducibility which it provides. A disadvantage, however, is that cell characteristics may change from those of the starting population.[149] Cell culture is used to:[150]

1. Investigate the normal physiology and biochemistry of cells;
2. Undertake tests of the effects of chemical compounds or drugs on certain cell types;
3. Synthesize large scale biological materials; and
4. Study the parallel or sequential combination of different cells in order to generate artificial tissues.[151]

In context of this thesis, culture is essentially used to increase or amplify the available number of cells to be used in therapy[152] of both embryonic stem cells as well as adult cells which have been induced to be pluripotent stem cells. Culture is also used during tissue engineering which

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[145] GIBCO & Invitrogen (2012) *Cell culture basics handbook* available online at http://biology.usf.edu/cmmb/research/data/Handbook%20for%20cell%20culture%20basics%20(Gibco).pdf accessed 15/11/2012.
[146] In 1949 it was shown that it was possible to grow the poliovirus in large quantities in a culture of human cells and that the vaccine could then be derived from this.
[147] Chaundry A (2011) "Cell culture" *The Science Creative Quarterly* 6 available online at http://www.scq.ubc.ca/cell-culture/ accessed 14/11/2012.
[148] Alberts, Johnson *et al*. (2002) Table 8.3.
[149] Chaundry (2011) online. See also GIBCO & Invitrogen (2012) online.
[150] *Ibid*.
[151] This is known as tissue engineering and is discussed in paragraph 5 *infra*.
[152] International Society for Stem Cell Research (2012) "Stem Cell Primer" available online at http://www.isscr.org/public/ISSCRstemCellPrimer.pdf accessed 15/11/2012.

is discussed in the course of this chapter. Embryonic stem cells are more readily coaxed into amplification in culture without losing their plasticity whereas adult cells are more difficult to increase in number without losing their capabilities. Some exceptions to this are mesenchymal stem cells[153] or induced pluripotent stem cells.

As mentioned previously, both embryonic as well as certain adult stem cells may be cultured and thus this process is relevant to this thesis chapter and an understanding of the process is therefore required. The inner cell mass of the blastocyst in the case of HES cells or the dedifferentiated adult cells in the case of induced pluripotent stem cells, are isolated from their natural or biological environment and planted into a petri dish which contains a feeder layer and a culture medium. The feeder layer, consisting of embryonic mouse skin cells,[154] serves a dual purpose as it provides for an adhesive layer to which the planted cells are able to attach and proliferate and it furthermore provides the growing cells with necessary nutrients.[155] The culture medium provides all further nourishment to the cells[156] and also contains antibiotics or fungicides which inhibit contamination.[157]

After the cells have been planted or seeded in the petri dish, they are allowed to proliferate and spread across the inner surface of the dish for a number of days.[158] This stage is known as "primary culture."[159] Once the dish is crowded with cells, which is known as confluency,[160] the cells are removed from the dish either by trypsinization[161] or by mechanical means[162] and

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[153] *Ibid.*
[154] These cells are treated to stop differentiation and recently scientists have started investigating ways of culturing stem cells without the feeder layer in order to mitigate the risk of viruses being passed from the layer to the stem cells. See National Institutes of Health (2012) *Stem cell information*: III. It is now being proposed to use autologous cells for the feeder layer. In this regard see Takahashi K, Narita M, Yokura M & Yamanaka S (2009) "Human induced pluripotent stem cells on autologous feeders" *PLos ONE* 4(12): 8067.
[155] It is interesting to mention that not all cells require an adhesive layer to which they attach in order to grow and proliferate. Cells which do require such a feeder layer are cultured in what is referred to as "adherent" or "monolayer" culture and the cells thus require a solid or semi-solid surface to adhere to. Other cells are capable of growing and proliferating while floating in culture medium and this is referred to as "suspension culture." See GIBCO & Invitrogen (2012) online.
[156] In earlier culturing practice used in cloning, serum or serum replacer, with or without human recombinant basic fibroblast growth factor bFGF, was used rather than culture medium. Suggested further reading, Amit M, Carpenter MK, Inokuma MS, Chui C, Harris CP, Waknitz MA Itskovitz-Eldor J & Thomson JA (2000) "Clonally derived human embryonic stem cell lines maintain pluripotency and proliferative potential for prolonged periods of culture" *Developmental Biology* 227: 271.
[157] According to Phelan, the choice of culture medium plays an important role in the growth of cells in culture and various recipes exist whereby a medium may be concocted which suits the needs of a specific laboratory. Laboratories may choose to prepare their own medium or buy a commercial medium which is available either as ready-to-use sterile liquid, a concentrate or in a powdered form. See Phelan MC (1998) "Basic techniques for mammalian cell tissue culture" *Current Protocols in Cell Biology* 1.1.1.
[158] National Institutes of Health (2012) III. According to Phelan this takes about 2 to 3 days. See Phelan (1998) 1.1.1.
[159] GIBCO & Invitrogen (2012) online.
[160] Phelan (1998) 1.1.1.
[161] Trypsinization is a process whereby trypsin, a proteolytic enzyme which breaks down proteins, is used to dissociate or loosen adherent cells from the vessel, the petri dish, in which the cells are being cultured. When trypsin is added to a cell culture it breaks down the proteins enabling the cells to adhere to the vessel. Trypsinization is normally used to passage cells to a new vessel. For a more detailed explanation of this process see Jayadev S (1991)

planted into a new dish and allowed once again to proliferate to confluency where the cells are replanted into even more new dishes. The new cycle of culturing is referred to as subculturing[163] and each subsequent new cycle of subculturing is referred to as a passage.[164] After six months of culturing and subculturing an embryonic stem cell line is regarded as having been established if the cells are capable of proliferating without differentiating and thus remaining pluripotent.[165]

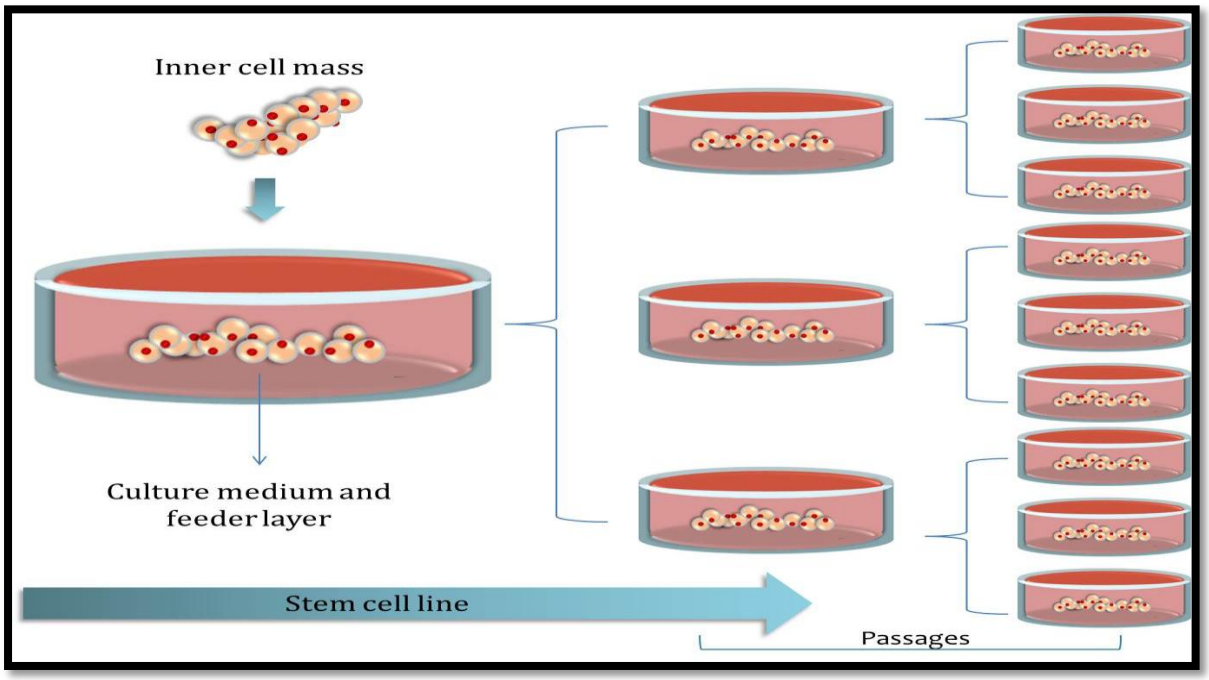

Figure C: Stem cell culturing

Naturally the cells are tested at various points during the culture process in order to establish their safety as well as to ensure that the cells exhibit the required characteristics of a undifferentiated cell. No standard battery of tests exists and therefore laboratories use a variety of differing tests. These include:[166]

1. Growing and subculturing cells for long periods of time to ensure that the cells are able to self-renew over such periods. This is done by inspecting the cells under a microscope;

"Trypsinization of adherent cells" available online at http://www.duke.edu/web/ceramide/protocols/0005.html accessed 15/11/2012.
[162] Phelan (1998) 1.1.1.
[163] After the first subculturing, the primary culture is referred to as a cell line or subclone and has a limited life span; it is finite. As cells continue to be passaged the cells with the highest growth capacity become dominant which leads to uniformity amongst the cells and due to a process called transformation the cells become immortal or infinite and develop a continuous cell line. See GIBCO & Invitrogen (2012) online.
[164] National Institutes of Health (2009) 5.
[165] *Idem* III.
[166] *Ibid*.

2. Utilising specific techniques to determine the presence of certain surface markers which are only found in undifferentiated cells. The presence of the protein Oct-4 is also useful in testing the characterisation or lack thereof in a cell;[167]
3. Microscopically examining the chromosomes of the cells allows the observer to assess whether or not the cells are damaged or whether the number of chromosomes have altered;[168]
4. Cells may be frozen, thawed and replanted to establish whether or not the cells are still capable of being cultured; and/or
5. Testing for pluripotency by either allowing spontaneous differentiation in cell culture; manipulating the cells, known as directed differentiation,[169] to differentiate into a certain cell type or injecting the cells into an immunosuppressed mouse to test for the formation of a tetratoma which indicates that the cells are able to differentiate into different cell types.[170]

After the cells have been cultured and tested the cells may be stored. Frozen storage of cells is of vital importance as an established cell line is a valuable resource and replacing such a line, which may be damaged by laboratory equipment failure or contamination, is expensive and time-consuming.[171] The moment a surplus of cells is available due to the process of subculturing, these cells should be cryogenically frozen as a seed stock which is protected and not used for general laboratory work. Working stocks may be prepared and replenished from the seed stock. Seed stocks may then be replenished from cryopreserved working stocks should the seed stocks become depleted.[172] Cryopreserving cultured cells is best done in liquid nitrogen in complete medium and a cryopreservative agent[173] which reduces the freezing point of the medium which allows for slower cooling. This in turn reduces the risk of the formation in the medium of ice crystals which are capable of damaging or killing the cells. Before cells can be used for therapeutic purposes, the frozen cells should obviously be thawed. This process could be stressful to the cells and thus good technique and fast work are essential in ensuring a high survival rate.[174]

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[167] Oct-4 is a transcription factor, also used in the process of induced pluripotent stem cells which is discussed in paragraph 3.6.1.3 *infra*, which activates or deactivates genes in cells. Without Oct-4 a cell would thus be "turned on" and differentiate.
[168] Genetic mutations in the cells are not visible using this method, however.
[169] This may be achieved by altering the chemical composition of the cells or the culture medium, by altering the surface of the dish to change the environmental factors surrounding the cells or gene modification via injection.
[170] A tetratoma is a benign tumor which contains a combination of differentiated or partly differentiated cells.
[171] Preservation of cells is also discussed in paragraph 4 *infra* in the course of the discussion pertaining to cell banking practices.
[172] GIBCO & Invitrogen (2012) online.
[173] Such as dimethylsulfoxide.
[174] For a detailed guide on the thawing process see GIBCO & Invitrogen (2012) online.

The use of embryonic stem cells, as mentioned, is the primary cause of vast ethical and moral discord surrounding stem cell therapy and research. For this reason, it is of imperative importance to not only acknowledge or mention the alternatives to HES cells, but to discuss and explain these in detail. The following section of this chapter thus focuses of adult stem cells and related procedures.

3.6 ADULT STEM CELLS

Adult stem cells or somatic cells are undifferentiated cells which may be found in small numbers in differentiated tissue and are able to self-renew and differentiate to form all the specialised cell types of the tissue from which it was originally derived.[175] During the 1960's researchers discovered that bone marrow is comprised of at least two different types of cells and from this discovery, adult stem cell research was born.[176] The first is haematopoietic stem cells which are stem cells from which all red and white blood cells evolve[177] and the second type of cell is bone marrow stromal cells which are mixed population cells which generate bone, cartilage, fat and fibrous connective tissue.[178] Currently, adult stem cells have evoked great excitement in the scientific and medical community, since researchers have discovered that adult stem cells are found in more tissue types than originally anticipated.[179] Stem cells, as previously mentioned, vary in regard to their level of plasticity and for this reason a stem cell originating from a specific tissue type could give rise to cells naturally occurring from a different tissue.[180] For this to be achieved however certain reprogramming processes are undertaken such as somatic cell nuclear transfer and induced pluripotency[181] and the appropriate laboratory conditions are essential.[182]

The origin of adult stem cells in mature tissue, in contrast to embryonic stem cells which are defined by their origin, is still unknown.[183] Biologically, adult stem cells as found in mature

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[175] The National Academies (2006) *Stem cells and the future* 67. See also Campbell A (2005) "Ethos and economics: Examining the rationale underlying stem cell and cloning research policies in the United States, Germany and Japan" *American Journal of Law and Medicine* 31(1): 48-63.
[176] Weise E (2007) "Stem cell discovery hailed as milestone" available online at http://www.usatoday.com/tech/science/genetics/2007-11-20-stem-cells-skin-cells_N.htm accessed 5/05/2009. See also Pagán Westphal S (2002) "Ultimate stem cell discovered" available online at http://www.newscientist.com/article/dn1826-ultimate-stem-cell-discovered.html accessed 5/05/2011.
[177] The National Academies (2006) *Stem cells and the future* 69.
[178] Swanepoel (2006) 53 footnote 150.
[179] Murnaghan I (2012) "Adult stem cells" available online at http://www.explorestemcells.co.uk/AdultStemCells.html accessed 17/11/2012.
[180] Weiss R (2005) "The stem cell divide" *National Geographic Magazine* available online at http://ngm.nationalgeographic.com/ngm/0507/feature1/index.html# accessed 6/05/2011.
[181] See paragraphs 3.6.1.2 and 3.6.1.3 *infra*.
[182] Murnaghan (2012) "Adult stem cells" online.
[183] *Ibid*.

tissue[184] serve the purpose of maintaining and repairing the host tissue.[185] It has been suggested that adult stem cells remain dormant within a particular area of a tissue for numerous years without dividing and that division is then triggered by disease or tissue damage.[186] Adult stem cells, however, are found only in small numbers in such mature tissue and identifying these cells may prove difficult. Even amongst scientists some discord exists as to the best manner of identifying adult stem cells in mature tissue and a number of methods may be employed such as:[187]

1. Labelling cells in culture after the cells have been removed from a living animal and then examining the behaviour of the cells when replanted into a different animal to determine whether the cells repopulate the tissue from which they originate;
2. Using markers to label cells in live tissue and then determining which cells are created by the labelled cells; and/or
3. Isolating, culturing and then manipulating the cells by the addition of growth factors to determine whether they differentiate.

Some further problems surrounding adult stem cells are in regard to the decreased capacity for self-renewal and so these cells do not proliferate to the same degree as HES cells. Also, due to age, adult stem cells may contain more DNA abnormalities caused by factors such as the environment, DNA replication errors and toxins.[188]

In spite of the various difficulties, adult stem cells have numerous benefits or potential benefits. Firstly, these cells may potentially replenish specialised cells when used therapeutically. Stem cell therapy may be employed to control and guide the growth of stem cells within a laboratory and these cells may then potentially be applied to replace dysfunctional cells within the body. Some examples of these hoped-for treatments include treatment of Parkinson's disease by replacing the dopamine producing cells in the brain which would reduce the progression of the disease. A further potential treatment is the development of insulin producing cells to be used on diabetes patients. Another treatment entails repairing heart tissue damaged by heart attacks by the use of stem cell therapy.[189] An important benefit of adult stem cells is that their use is more widely accepted than that of HES cells. This then negates several of the ethical and moral issues surrounding stem cell research and therapy. Also, adult stem cell therapy reduces the risk

[184] Tissue thought to contain adult stem cells includes skin, bone marrow, blood vessels, the brain, the liver and skeletal muscle.
[185] Stayn J (2005) "The new Massachusetts stem cell research law" *Boston Bar Journal* 49(4): 17.
[186] Murnaghan (2012) "Adult stem cells" online.
[187] Walsh P (2005) "Stemming the tide of stem cell research: The Bush compromise" *John Marshall Law Review* 38(3): 1063-1066.
[188] Murnaghan (2012) "Adult stem cells" online.
[189] *Ibid*.

of rejection and thus overcomes immunological challenges since the donor of the cells is also the recipient.[190] The issue of smaller numbers may be overcome by culturing adult stem cells for periods of time. This is related to the procedures whereby adult stem cells are reprogrammed and some attention must be given to somatic cell nuclear transfer and induced pluripotency at this juncture.

3.6.1 Created Cells

The following is a discussion of the procedures whereby stem cells are reprogrammed or reverted back to a pluripotent state. In order to reprogram a cell, one of three processes could be utilised, namely cloning, somatic cell nuclear transfer and induced pluripotency. Cloning is discussed firstly, in spite of it being regarded as a dated and passé topic, since it does form part of the greater landscape of biotechnology which we are currently discussing and it is, unfortunately, the source of much of the controversy surrounding stem cells and is inextricably bound and associated to public notions of stem cell research and therapy.

3.6.1.1 Cloning

Cloning may be defined as "to generate identical copies of a region of a DNA molecule or generating genetically identical copies of a cell, or organism."[191] In 1997,[192] the world was taken by storm when Ian Wilmut, Keith Campbell and colleagues from the Roslin Institute in Scotland announced that they had successfully cloned a sheep named Dolly.[193] Dolly was born on the 5th of July 1996 and was cloned by making use of the process known as nuclear transfer. Her name, according to Wilmut, was given to her as she was cloned from a mammary gland cell and the scientists could not think of more impressive mammary glands than those of Dolly Parton.[194] The unnamed sheep from which she had been cloned had died several years prior to Dolly's creation.[195] She became the most famous sheep in the world and amongst others was featured in TIME Magazine and was named *Science*'s breakthrough of the year. Not only was Dolly the first

[190] *Ibid*.
[191] National Institutes of Health (2009) "Glossary" online.
[192] Suggested further reading on the history of cloning, Vos S (2004) "Dolly and the clone wars: Timeline" available online at http://novaonline.nvcc.edu/eli/evans/his135/events/dolly96/Dolly_Module.html#Timeline accessed 17/11/2010.
[193] Wilmut I, Schnieke AE, McWhir J, Kind AJ & Campbell KHS (1997) "Viable offspring derived from fetal and adult mammalian cells" *Nature* 385: 810.
[194] BBC News (2003) "Dolly the sheep clone dies young" *BBC News*, 14 February available online at http://news.bbc.co.uk/2/hi/science/nature/2764039.stm accessed 17/11/2012.
[195] Human Genome Project Information (2012) "Cloning fact sheet" available online at http://www.ornl.gov/sci/techresources/Human_Genome/elsi/cloning.shtml accessed 17/11/2012.

animal to be cloned but she was the first clone created from an adult cell and much media attention was given to this particular sheep. During her life she was bred with a Welsh Mountain ram and produced six lambs.[196] She developed arthritis in 2001 and on the 14th of February 2003, Dolly was euthanized as she suffered progressive lung disease.[197] This sparked some concern as Finn Dorset sheep usually have a lifespan of 11 to 12 years and it was said that cloned animals are born with health problems.[198] During a post mortem examination it was found that she had developed a form of lung cancer named Jaagsiekte which is common amongst sheep.[199] The birth, life and death of this one sheep proved to the world that cloning of animals was possible and therefore has great significance.[200]

Today, cloning is a tired issue and almost all that could be said on this subject has been said. It is still however relevant when taking into consideration that the same process is employed in cloning as is in somatic cell nuclear transfer and thus "cloning" is used, or could be used, in stem cell therapy and regenerative medicine. Naturally there are ethical concerns which come about in this arena, especially given that stem cell lines could be derived from specially created embryos. It is important to note that cloning may take two forms, namely reproductive and therapeutic. The distinction between these forms will now be briefly explained.

3.6.1.1.1 Reproductive cloning

Reproductive cloning is the process whereby somatic cell nuclear transfer[201] is used to produce a normal, full grown organism which is genetically identical to the organism which donated the somatic cell nucleus.[202] In other words, the DNA from an unfertilised egg is removed and replaced with DNA from a donor. The egg is cultured to the point where it is possible to implant it into a surrogate mother where it then develops until birth.[203] This process creates an embryo containing genetic information in the form of DNA and should this embryo be implanted into a uterus and allowed to grow it would undergo normal development and become an independent being. Reproductive cloning could therefore be described as cloning with the goal of the birth of

[196] The first lamb produced by Dolly was named Bonnie and was born in April 1998. In 1999 twins were born named Sally and Rosie and in 2000 Dolly gave birth to triplets Lucy, Darcy and Cotton. See The Roslin Institute (2003) "Dolly's family" available online at http://www.roslin.ed.ac.uk/publicInterest/DollyFamily.php accessed 17/11/2012.
[197] BBC News (2003) online. See also Williams N (2003) "Death of Dolly marks cloning milestone" *Current Biology* 13(6): 209.
[198] *Ibid*.
[199] Kuehn BM (2003) "Goodbye Dolly: First cloned sheep dies at six years old" *American Veterinary Medical Association* 222(8): 1060.
[200] McKinnell RG & Di Bernadino MA (1999) "The biology of cloning: History and rationale" *Bioscience* 49(11): 875.
[201] See paragraph 3.6.1.2 *infra* for a detailed explanation of this procedure.
[202] National Institutes of Health (2009) "Glossary" online.
[203] International Society for Stem Cell Research (2012) "Reproductive cloning" available online at http://www.isscr.org/public/reproductive_cloning.pdf accessed 22/11/2012.

an individual who is genetically identical to a person or animal from a previous generation[204] since the DNA of the "new" individual is actually replicated from the donor of the genetic material.

The use of somatic cell nuclear transfer as primary procedure gives rise to certain fears regarding the power scientists hold. The concern exists that scientists and researchers will overstep the boundaries of therapeutic cloning and create human beings.[205] To date, however, no human being has been created by cloning. In spite of this, the possibility that it might happen frightens the public, policy makers, scientists and researchers as well as legislators. The scientific community fervently opposes reproductive cloning but supports therapeutic cloning and for this reason it should be permitted albeit under careful and stringent control.[206] Since reproductive cloning is hugely controversial, unethical and morally frowned upon, it has been internationally and nationally prohibited.[207]

3.6.1.1.2 Therapeutic cloning

Therapeutic cloning is the process wherein somatic cell nuclear transfer is used to produce cells which match a patient exactly.[208] This is done by combining the nucleus of a somatic cell, donated by the patient who will be treated by the cloned cells, and an enucleated egg which is then allowed to develop up until the blastocyst stage. From this, scientists are able to harvest cells which match the patient and thus eliminate the risk of immune rejection. These cells are almost tailor made to suit the patient's body, needs and immune system.

From the definitions provided in the previous paragraphs, it becomes apparent that both reproductive and therapeutic cloning make use of the process of somatic cell nuclear transfer and thus the distinguishing moment or factor, where cloning becomes either reproductive cloning or therapeutic cloning, occurs around the blastocyst stage of development. At this stage one of two actions is possible. Either the embryo is allowed to develop to term, which would then constitute reproductive cloning, or the cells are removed from culture, thus stunting any further development and are applied in treatment and therapy, thus constituting therapeutic

[204] Prinsen L (2010) *An analysis of the proposed regulatory framework for the procurement and distribution of stem cells* (LLM thesis unpublished, University of Pretoria): 32.
[205] This is connected to the nature protection framework of ethical debate surrounding stem cells. See in general, Prinsen (2010) 122-124.
[206] Murnaghan I (2012) "Therapeutic cloning" available online at http://www.explorestemcells.co.uk/TherapeuticCloning.html accessed 29/11/2012.
[207] Suggested further reading, Human Genetics Alert (2004) "Reproductive cloning: Ethical and social issues" available online at http://www.hgalert.org/topics/cloning/cloning.PDF accessed 22/11/2012.
[208] National Institutes of Health (2009) "Glossary" online.

cloning. The fundamental difference between therapeutic and reproductive cloning therefore lies in the purpose of the cloning procedure and the action taken following somatic cell nuclear transfer and development to the blastocyst stage.[209]

Some problems associated with therapeutic cloning are that numerous attempts are often necessary to create a single viable egg. This is due to the fact that the somatic nucleus is weakened during the process of nuclear transfer. Therapeutic cloning may furthermore receive criticism as the embryo is destroyed in the process after the stem cells are extracted from it.[210] This has led to cloning being compared to abortion as both entail the destruction of potential life and has sparked controversy and concerns regarding the ethical and moral implications of cloning.[211]

Although cloning in general and reproductive cloning especially is very controversial, various arguments in favour of therapeutic cloning exist and it has therefore not been banned in the same manner as its reproductive counterpart.[212] Some of the benefits of therapeutic cloning should be mentioned here. Firstly, the cells which are removed from the blastocyst are pluripotent and are therefore programmable to become any cell in the human body and disease-affected organs or tissues could be treated by replacing the damaged or dysfunctional cells. Secondly, when using therapeutic cloning the risk of immunological rejection is alleviated since the genetic material of the eventual recipient of the treatment is used *ab initio*. The body of the recipient thus recognises the "new" cells as its own.

HES cells are ideal for application in research as they possess desirable characteristics such as the fact that they are undifferentiated. Adult stem cells are committed to specialised tissue types and are less in number which means that their developmental potential is restricted in comparison with embryonic stem cells. Due to this, the creation of embryonic-like cells is important and in some instances, these pseudo embryos will have to be created for research purposes. The following section of this chapter deals with two further processes wherein cells are created which have the same level of (pluri)potency as HES cells.

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[209] Prinsen (2010) 32.
[210] See in general, Murnaghan I (2012) "Creating embryonic stem cells without embryo destruction" available online at http://www.explorestemcells.co.uk/creating-embryonic-stem-cells-embryo-destruction.html accessed 29/11/2012.
[211] Murnaghan (2012) "Therapeutic cloning" online.
[212] Gusman A (2005) "An appropriate legislative response to cloning for biomedical research: The case against a criminal ban" *Annals of Health Law* 14(2): 265. See also Goldberg D (2006) "Cloning around with cells" available online at http://www.abc.net.au/science/slab/stemcells/default.htm accessed 7/5/2011.

3.6.1.2 Somatic cell nuclear transfer

Somatic cell nuclear transfer (SCNT) is a process whereby the nucleus of a somatic cell is transferred into an egg from which the nucleus has been removed.[213] Differently stated, SCNT is a process wherein an enucleated egg is combined with the nucleus of an adult or somatic cell to create an embryo. This process may be used for therapeutic or reproductive applications. This is illustrated when taking into consideration the above discussion regarding cloning, both therapeutic and reproductive, wherein it was mentioned that the process of cloning entails utilising the technique of somatic cell nuclear transfer.[214] In fact, somatic cell nuclear transfer is more commonly known as cloning and for this reason it is a very contentious subject. The fear exists that this process will be misused for reproductive cloning. Further issues touch on ethical considerations, informed consent questions and issues regarding the destruction of a blastocyst.[215]

It must be emphasised, however, that the production of HES cells by way of SCNT is not the same thing as reproductive cloning and this distinction relates to the difference between therapeutic cloning, or "research cloning" and reproductive cloning. In instances of therapeutic cloning, somatic cell nuclear transfer is used to develop disease-specific stem cells.[216] Reproductive cloning is where nuclear transfer is used to create an embryo which is intended to be implanted and allowed to develop to term inside the womb of a person or animal.[217] Animal reproductive cloning has become common practice but it must be restated and emphasised that human reproductive cloning is actively and widely prohibited and discouraged.[218]

On the positive side, stem cells derived from nuclear transfer hold considerable promise in the field of regenerative medicine as well as cell-based drug discoveries.[219] These embryos provide not only a potential source of embryonic stem cells but also any other cell type. Further benefits include that the cells derived from such embryos would be histocompatible with the patient's cells[220] and the cells are expected to have a normal life span.[221]

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[213] The National Academies (2006) *Stem cells and the future* 71.
[214] National Institutes of Health (2009) "Glossary" online.
[215] The National Academies (2006) *Understanding stem cells* 7.
[216] See in general, Ma M, Sha J, Zhou Z, Zhou Q & Li Q (2008) "Generation of patient-specific pluripotent stem cells and directed differentiation of embryonic stem cells for regenerative medicine" *Journal of Najing Medical University* 22(3): 135-142.
[217] Refer to the discussion of how Dolly the sheep was created in paragraph 3.6.1.1 *supra*. This is a real-life example of the application of somatic cell nuclear transfer as used in reproductive cloning.
[218] The National Academies (2006) *Understanding stem cells* 7.
[219] French AJ, Adams CA, Anderson L, Kitchen JR, Hughes MR & Wood SH (2008) "Development of human cloned blastocysts following somatic cell nuclear transfer with adult fibroblasts" *Stem Cells* 26(2): 485.
[220] This means that the cells will be accepted by the patient's body and will thus remain functional. Suggested further reading, Cibelli JB, Kiessling AA, Cunniff K, Richards C, Lanza RP & West MD (2004) "Rapid communication: Somatic cell nuclear transfer in humans: Pronuclear and early embryonic development" *The Journal of Regenerative Medicine* 2(5): 25.

3.6.1.2.1 The process of SCNT

The process of somatic cell nuclear transfer entails the removal of the nucleus from a somatic or adult cell. The nucleus contains all 46 chromosomes which determine a person.[222] Every cell in the human body contains 23 pairs of chromosomes, which excludes the sperm and ova, of which half is derived from each parent. A chromosome is comprised of a double helix, which is a coiled double filament of DNA, which carries the genetic information of a cell in a linear fashion. The DNA contained in this cell determines the characteristics of an individual. A basic example of this is the determination of the individual's sex since 22 of the chromosomes are identical in males and females but the 23rd pair differs. Males have an x-chromosome and females have a y-chromosome.[223]

After the nucleus has been extracted from the somatic cell, the remaining biological cellular material is discarded. An unfertilised egg is then enucleated, meaning that the egg cell's nucleus is removed, and it is then referred to as an oocyte. The somatic cell nucleus which was previously removed is then implanted into the oocyte.[224] The oocyte is shock-stimulated into beginning the process of cell division and embryogenesis.[225]

At this point the egg cell contains the DNA, thus the genetic code, of the donor cell and is reprogrammed thereby. The egg cell is placed in culture and develops into a blastocyst with almost identical DNA to the original donor of the somatic cell.[226]

Somatic cell nuclear transfer may therefore be used to create patient-specific pluripotent cells and so eliminate the risk of immune rejection. The cells created by SCNT are genetically matched

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221 Wilmut I & Paterson L (2003) "Somatic cell nuclear transfer" *Oncology Research Featuring Preclinical and Clinical Cancer Therapeutics* 13(6): 303.

222 This may be defined as "the rod-like structures, present in the nucleus of every body cell, that carry the genetic information or genes." See Family Medical (2000) 46.

223 Family Medical (2000) 46.

224 It must be noted that researchers are not permitted to create organ deficient human embryos, embryos which lack the ability to grown organs, and so pigs provide a suitable growth environment. This was achieved by injecting blood stem cells into pigs which in turn made the pigs produce human blood. Pigs are anatomically close to humans as the internal cavity of a pig is similar but smaller to that of a human. See in this regard RedOrbit (2011) "Using stem cells to grown organs" *RedOrbit: Your Universe Online* available online at http://www.redorbit.com/news/health/2066454/using_stem_cells_to_grow_organs/ accessed 7/7/2012. This process is also sometimes referred to as "Blastocyst complementation" as pioneered by Professor Hiromitsu Nakauchi from the Centre for Stem Cell Biology and Regenerative Medicine, University of Tokyo. This technique revolves around the growth of human organs for transplant inside the body of a pig. Induced pluripotent stem cells, harvested from tissue such as skin, may be used in this process. See Gray R (2011) "Pigs could grow human organs in stem cell breakthrough" *The Telegraph*, 19 June available online at http://www.telegraph.co.uk/science/science-news/8584443/Pigs-could-grow-human-organs-in-stem-cell-breakthrough.html accessed 7/7/2012.

225 Embryogenesis is "the processes leading to the development of an embryo from egg to completion of the embryonic stage." See Lackie JM (2012) *The dictionary of cell and molecular biology*: 208.

226 Peters T (2007) *The stem cell debate*: 13. See also The National Academies (2006) *Understanding stem cells* 6.

to the donor and genetically customised cell lines may therefore be created to target certain specific diseases.[227]

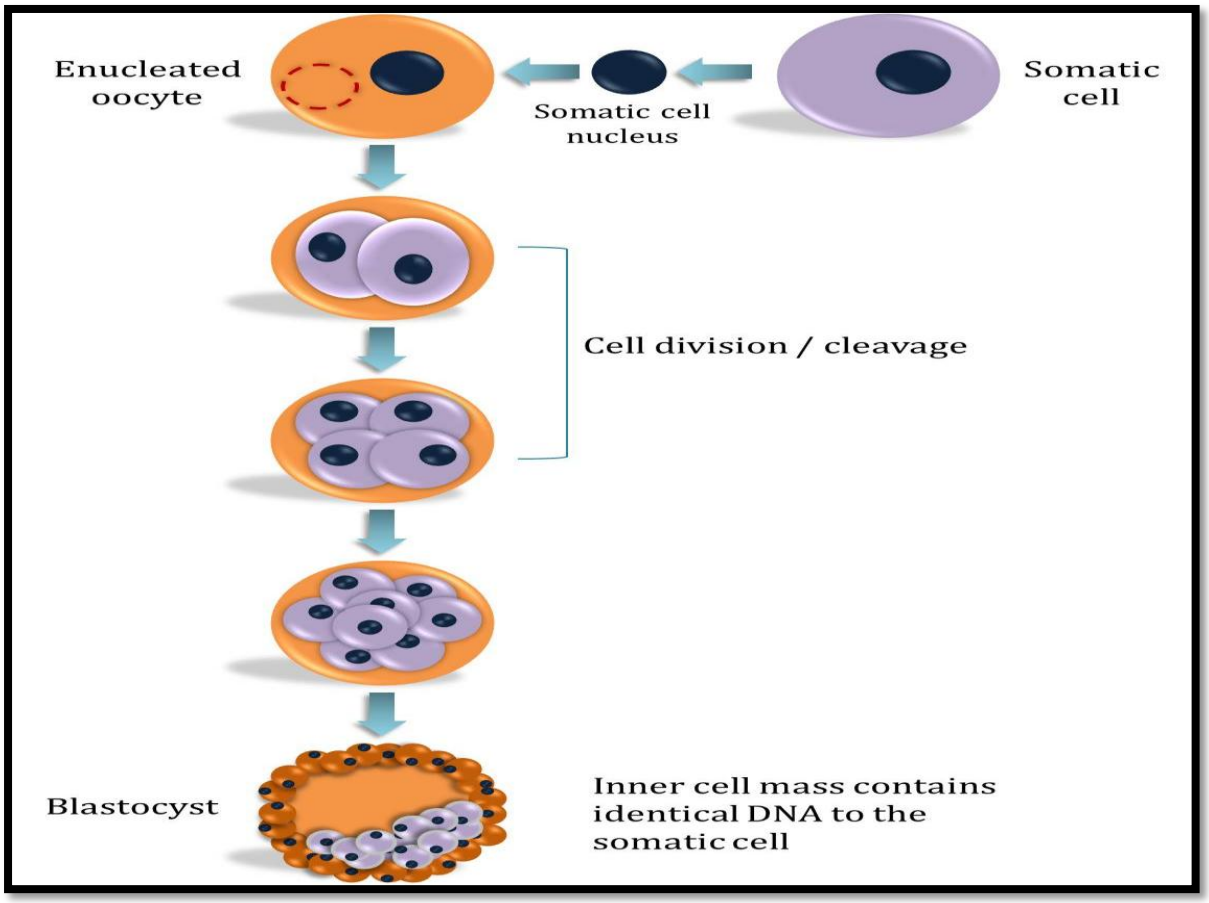

Figure D: Somatic cell nuclear transfer

3.6.1.2.2 Utilisation of SCNT in stem cell research

SCNT may be utilised in stem cell research with the objective of obtaining stem cells which are genetically matched to the somatic cell donor. Genetic customisation plays a hugely important role in creating disease-specific cell-based-therapies and in eliminating immune system rejection in medical treatment.

Immunological rejection is of particular importance in context of stem cell based therapy as the human body rejects any matter or cells which it does not recognise as its own. This function exists mainly in order for the body to protect itself from infections and diseases. Currently, there

[227] Semb H (2005) "Human embryonic stem cells: Origin, properties and applications" *Acta Pathologica, Microbiologica et Immunologica Scandanavia* 13(11-12): 734. See also Hadjantonakis AK & Papaioannou VE (2002) "Can mammalian cloning combined with embryonic stem cell technologies be used to treat human disease?" *Genome Biology* 3(8): 1023.

are three ways of overcoming the problem of immunological rejection. The following may be used:[228]

1. Immune-suppressing drugs. Such drugs have a history of being utilised in organ transplantation for many years. The drugs do, however, leave the patient open to infection and disease and the patient is required to take these drugs for the remainder of his life;
2. Matching tissue. This method is also not free of problems as finding a matching donor is highly unlikely;[229] and
3. The tissue or cells from the patient himself. This method is the surest method of avoiding immune rejection and involves creating a zygote from the patient's adult cell's nucleus and growing these cells to the blastocyst stage. The cells cultured from this blastocyst may then be used for implantation or therapy.

3.6.1.2.3 Limitations and controversy

Additionally, to the potential ability to renew the activity of damaged cells or growing new organs and replacing them as mentioned previously, the use of SCNT created stem cells may hold advantages over stem cells derived from *in vitro* fertilised embryos since the risk of rejection is reduced or may even be eliminated. SCNT is furthermore of great value in research surrounding dedifferentiation as it is currently the only method whereby the marking of DNA-affecting factors during differentiation may be identified and removed.[230] A further amazing advantage of somatic cell nuclear transfer lies in the field of infertility treatment. Sterile couples will be able to have children which will have either the mother or father's genetic pattern.[231] This may also aid male homosexual couples to have children with the genetic material of both parents.[232]

[228] Swanepoel (2006) 58 footnote 171.
[229] Stem cell culturing holds the potential of creating a stockpile of cells which represent the entire population and which may be banked for future use.
[230] Swanepoel (2006) 58. The genetic and epigenetic changes which occur during certain phases of development may be observed as the process of cloning, SCNT, amplifies processes and makes these processes observable. See in this regard The National Academies (2012) "Pros and cons of human cloning: National Academies Report debates the pros and cons of human reproductive cloning" available online at http://www.yenra.com/pros-and-cons-of-human-cloning/ accessed 11/12/2012.
[231] Farnsworth J (2000) "To clone or not to clone: The ethical question" available online at http://thefarnsworths.com/science/cloning.htm accessed 11/12/2012.
[232] In such instances a donor egg cell may be enucleated and implanted with the DNA from a somatic cell of one of the males. It is then fertilised *in vitro* by sperm of the partner male and implanted into a surrogate female. After normal development and birth a child may then be born with the genetic makeup of both the parents.

In spite of the numerous advantages of SCNT, there are however certain limitations.[233] During the process of nuclear transfer, enormous stress is placed on the egg cell and the nucleus and this leads to high losses of created cells.[234] Also, mitochondrial DNA cannot be completely transferred and this leads to imperfect copies of the cells which contribute to immune rejection. The cells further suffer a loss of genetic variation.[235] The process of SCNT cannot be automated as the biochemistry involved in the reprogramming or dedifferentiating of cells is still somewhat uncertain and it is therefore labour intensive.[236] This is in line with the hypothesis of this thesis and illustrates the experimental nature of biotechnology, even in a relatively well established technique such as nuclear transfer. The use of somatic cell nuclear transfer may also have unknown psychosocial effects on families in the case of fertility application and on society as a whole.[237]

Furthermore, numerous ethical and moral issues exist. These issues, some unique to SCNT and some shared by all biotechnology techniques, include *inter alia* the fear of reproductive cloning eventually being allowed as a consequence of this science[238] and socio-economic concerns. The socio-economic issues are related to the "sources" of human egg cells, women, and the fear that underprivileged, poor, uneducated or vulnerable women could be exploited in the commercialisation of egg cells.[239]

Science has, however, progressed greatly[240] and induced pluripotent stem cells become relevant at this point as this procedure has the potential to completely nullify SCNT cells, meaning that all the above mentioned issues and concerns, limitations and objectives may be circumvented.

3.6.1.3 Induced pluripotent stem cells

In 2006, induced pluripotent cells were first created by using mouse cells and in 2007 this procedure was undertaken for the first time using human cells. This development is of paramount significance as iPS cells have the ability to be used in future research, to be therapeutically applied and may entirely replace the use of embryonic stem cells in research

[233] Suggested further reading, Sumer H, Liu J, Tat P, Hefferman C, Jones KL & Verma PJ (2009) "Somatic cell nuclear transfer: Pros and Cons" *Journal of Stem Cells* 4(2): 85.
[234] Campbell KH, McWhir J, Ritchie WA & Wilmut I (1996) "Sheep cloned by nuclear transfer from a cultured cell line" *Nature* 380(6569): 64.
[235] Farnsworth (2000) online.
[236] Campbell, McWhir *et al.* (1996) 64.
[237] Farnsworth (2000) online.
[238] This fear is, however, unfounded as reproductive cloning is nationally and internationally prohibited and discouraged by legislators, scientists and the public. See The National Academies (2006) *Understanding stem cells* 7. This is also related to the "slippery slope argument." Suggested further reading, Prinsen (2010) 123.
[239] Suggested further reading, Prinsen (2010) 127-130.
[240] See in general, Science Magazine (2007) "Life science technologies: Stem cells-Beyond somatic cell nuclear transfer" available online at http://www.sciencemag.org/site/products/lst_20070420.xhtml accessed 10/12/2012.

and therapy and in so doing decrease the controversy and opposition to human stem cell research.

Induced pluripotent stem cells or iPS cells are a type of pluripotent stem cell which are similar to embryonic stem cells and are formed by the introduction of certain embryonic genes into a somatic cell.[241] Differently stated, this means that they are cells which are artificially derived from somatic or adult cells which are normally multi- or unipotent and are then reprogrammed to a pluripotent state by forcing the expression of particular genes which are essential to the maintenance of all pluripotent cells.[242] iPS cells are therefore deemed to be identical to natural pluripotent cells such as embryonic stem cells.[243]

Induced pluripotent cells are, however, not used without risk and thus its application in humans is somewhat limited. Reprogramming of genetic material may activate cancer-causing genes known as oncogenes. This problem may be avoided in future by the development of induction by way of specific proteins. This process is referred to as protein induced pluripotency.

3.6.1.3.1 The production of iPS cells

As suggested by the name, induced pluripotent stem cells entail a process of cell induction. Induction, in turn, involves de-differentiation of cells which is achieved by transfection of the cells. De-differentiation, in layman's terms, means that the cells are reverted back to a less specialised cell type. Transfection is a procedure wherein a cell is infected with viral vectors such as retroviruses[244] or purified viral nucleic acid, causing the subsequent replication of the cell.

The genes currently used to de-differentiate cells are Oct3/4, c-Myc, Sox2 and Klf4. This combination of genes is the result of extensive developments in this field which have taken two generations of research to achieve. These generations must be discussed briefly.

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[241] National Institutes of Health (2009) "Glossary" online.
[242] Kidson (2009) Stem cell seminar.
[243] Baker M (2007) "Adult cells reprogrammed to pluripotency, without tumors" *Nature Reports Stem Cells* available online at http://www.nature.com/stemcells/2007/0712/071206/full/stemcells.2007.124.html accessed 14/04/2010. See also Kastenberg ZJ & Odorico JS (2008) "Alternative sources of pluripotency: Science, ethics and stem cells" *Transplantation Review* 22: 215-222.
[244] A retrovirus is an "RNA virus (a virus composed not of DNA but of RNA)." Retroviruses contain an enzyme referred to as "reverse transcriptase" which provides them with the unique property of transcribing RNA, their own, into DNA. This DNA is able to integrate into the chromosomal DNA of the host cell and be expressed. HIV, human immunodeficiency virus, which causes AIDS, is an example of a retrovirus. See MedicineNet.com (2010) "Retrovirus" available online at http://www.medterms.com/script/main/art.asp?articlekey=5344 accessed 3/5/2010.

3.6.1.3.1.1 First generation iPS cells

As mentioned previously, induced pluripotent stem cells were first generated in 2006 using mouse fibroblasts,[245] retroviruses and certain genes which are essential to embryonic stem cells. This discovery was made by Shinya Yamanaka[246] of Kyoto University,[247] who won the Nobel Prize in Physiology or Medicine in 2012 along with Sir John B. Gurdon[248] for discovering that mature cells could be reprogrammed back to an immature state.[249]

The genes used by Yamanaka's team were Oct3/4, c-Myc, SoX2 and Klf4 and the cells were isolated by $Fbx15^{+}$[250] cells. Unfortunately, cell lines produced in this manner demonstrated DNA errors and no viable chimeras were produced during the test phases which entailed injecting the DNA into developing embryos.[251]

3.6.1.3.1.2 Second generation iPS cells

By June 2007 the issues surrounding DNA errors were resolved and Yamanaka's team as well as researchers and scientists from the Michigan Institute of Technology (MIT), Harvard University and the University of California published their findings stating that mouse cells had been successfully reprogrammed without such errors. Viable chimeras were furthermore produced.[252]

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[245] A fibroblast may be defined as "a cell ubiquitous in connective tissue that makes and secretes collagen." See MedinceNet.com (2010) "Fibroblast" available online at http://www.medterms.com/script/main/art.asp?articlekey=24766 accessed 3/5/2010.
[246] See in general, Yamanaka see Nobelförsamlingen-The Nobel Assembly at Karolinska Institute (2012) "Shinya Yamanaka" available online at http://www.nobelprize.org/nobel_prizes/medicine/laureates/2012/yamanaka.html accessed 10/8/2012. See also Nair P (2012) "Profile of Shinya Yamanaka" *Proceedings of the National Academy of Science* 109(24): 9223-9225.
[247] SABioscience (2009) "Induced pluripotent stem cells-Quick facts" *Pathways Magazine Issue 9* available online at http://www.sabiosciences.com/pathwaymagazine/pathways9/induced-pluripotent-stem-cells-quick-facts.php accessed 6/5/2011. See also Pei XT (2010) "iPS cells: Alternative pluripotent cells to embryo stem cells" *Science China Life Sciences* 53(1): 154-156.
[248] John B. Gurdon may be regarded as the father of cloning science as he pioneered the first SCNT research and experiments and discovered that the specialisation of adult cells is reversible in 1962. For more see Nobelförsamlingen-The Nobel Assembly at Karolinska Institute (2012) "Sir John B. Gurdon" available online at http://www.nobelprize.org/nobel_prizes/medicine/laureates/2012/gurdon.html accessed 10/8/2012. See also Williams R (2008) "Sir John Gurdon: Godfather of cloning" *The Journal of Cell Biology* 181(2): 178-179.
[249] Nobelförsamlingen-The Nobel Assembly at Karolinska Institute (2012) "Press Release" available online at http://www.nobelprize.org/nobel_prizes/medicine/laureates/2012/press.html# accessed 10/8/2012.
[250] This is a protein which is expressed in undifferentiated embryonic cells. See in general, Takahashi K & Yamanaka S (2006) "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors" *Cell* 126(4): 663-676.
[251] Freund C, Davis RP, Gkatzis K, Ward-Van Oostwaard D & Mummery CL (2010) "The first reported generation of human induced pluripotent stem cells (iPS cells) and iPS cell-derived cardiomyocytes in the Netherlands" *Netherlands Heart Journal* 18(1): 51-54.
[252] Akst J (2009) "iPS cells yield live mice" available online at http://www.the-scientist.com/blog/display/55835/ accessed 7/11/2011.

The solution to the problem, it turned out, required the replacement of $Fbx15^{+}$ with Nanog. Nanog is an important gene found in embryonic stem cells and plays a major role in pluripotency.[253] Although this new process was an improvement, the technique was still flawed as c-Myc is an oncogenic gene which means that it is cancer-causing and the development of cancerous tumors was discovered in some of the chimeric mice.[254]

3.6.1.3.2 Human iPS cells

November of 2007 marked a milestone in iPS science when two independent groups published their findings on the creation of induced pluripotent stem cells created from adult human cells. The first group was James Thomson and Junying Yu from the University of Wisconsin[255] and the second was by Yamanaka and his team at the University of Kyoto.[256] Both the American and Japanese groups had used the same essential genes which had been used in the previous mouse studies. Yamanaka and team had, however, utilised a further retroviral system.[257] Thomson and Yu made use of Oct4, SoX2, Nanog and Lin28 along with a lentiviral system.[258]

Some concerns were raised regarding the therapeutic potential of induced cells since these iPS cells are inclined to form cancerous tumors resulting from the transfection system whereby genes are randomly inserted into the host genome. Both groups expressed the need and importance of developing a new method of delivery.[259]

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[253] Takahashi & Yamanaka (2006) 663. See also Okita K, Ichisaka T & Yamanaka S (2007) "Generation of germline-competent induced pluripotent stem cells" *Nature* 448: 313-317; Wernig M, Meissner A, Foreman R, Brambrink T, Ku M, Hochedlinger K, Bernstein BE & Jaenisch R (2007) "*In vitro* reprogramming of fibroblasts into a pluripotent ES-cell-like state" *Nature* 448: 318-324 and Maherali N, Sridharan R, Xie W, Utikal J, Eminli S, Arnold K, Stadtfeld M, Yachechko R, Tchieu J, Jaenisch R, Plath K & Hochedlinger K (2007) "Directly reprogrammed fibroblasts show global epigenetic remodeling and widespread tissue contribution" *Cell Stem Cell* 1(1): 55-70.

[254] See in general, Ruggero D, Montanaro L, Ma L, Xu W, Londei P, Cordon-Cardo C & Pandolfi P (2004) "The translation factor eIF-4E promotes tumor formation and cooperates with c-Myc in lymphomagenesis" *Nature Medicine* 10: 484-486.

[255] Yu J, Vodyanik MA, Smuga-Otto K, Antosiewicz-Bourget J, Frane JL, Tian S, Nie J, Jonsdottir GA, Ruotti V, Stewart R, Slukvin II & Thomson JA (2007) "Induced pluripotent stem cell lines derived from human somatic cells" *Science* 318(5858): 1917.

[256] Takahashi K, Tanabe K, Ohnuki M, Narita M, Ichisaka T, Tomoda K, Yamanaka S (2007) "Induction of pluripotent stem cells from adult human fibroblasts by defined factors" *Cell* 131: 1-12.

[257] Retroviruses are "a family of RNA viruses containing a reverse transcriptase enzyme which allows the viruses' genetic information to become part of the genetic information of the host cell upon replication." See The Free Medical Dictionary (2009) "Retroviral" available online at http://medical-dictionary.thefreedictionary.com/retroviral accessed 7/6/2011.

[258] A lentivirus may be defined as "any member of a genus of retroviruses that have long incubation periods and cause chronic, progressive, usually fatal diseases in humans and other animals. Species include the types of human immunodeficiency virus." See MedicineNet.com (2010) "Lentiviral" available online at http://medical-dictionary.thefreedictionary.com/lentiviral accessed 3/5/2010. See in general, SABiosciences (2009) "Lentivirus-based signalling pathway reporters" *Pathways Magazine Issue 9* available online at http://www.sabiosciences.com/pathwaymagazine/pathways9/lentivirus-based-signaling-pathway-reporters.php accessed 6/5/2011.

[259] Swaminathan N (2007) "Stem cells: This time without the cancer" *Scientific American News*, 30 November available online at http://www.sciam.com/article.cfm?id=stem-cells-without-cancer accessed 6/6/2011.

In 2008, Konrad Hochedlinger and his research team at Harvard University announced that they had successfully overcome the problem of tumor and cancer formation by making use of an adenovirus to transport the necessary genes into the DNA of laboratory mice.[260] The result of this new and improved technique was the formation of cells which were identical to HES cells.[261]

Currently, the iPS cell production procedure requires donor cells to be isolated and cultured using the same methods as are used in the case of embryonic stem cells.[262] The genes which are associated with embryonic stem cells as mentioned above are then transfected into the donor cells via viral vectors. This sets in motion a process of cell replication and proliferation and the cells are cultured and subsequently harvested in a manner similar to the technique utilised for embryonic stem cells.[263]

A small subset of the transfected cells will become morphologically and biochemically similar to pluripotent cells and will generate embryonic stem cell-like cells which are usable in the same manner as natural HES cells.[264]

[260] An adenovirus is "a DNA virus, composed of over 40 serotypes. Many serotypes cause ocular infection, including epidemic keratoconjunctivitis caused by serotypes 8, 19 and 37. Other infections include follicular conjunctivitis with or without pseudomembranes and epithelial keratitis. The adenovirus can be identified using, among others, conjunctival swabs for viral antigen." See The Free Medical Dictionary (2009) "Adenovirus" available online at http://medical-dictionary.thefreedictionary.com/adenovirus accessed 7/6/2011.
[261] Stadtfeld M, Nagaya M, Utikal J, Weir G & Hochedlinger K (2008) "Induced pluripotent stem cells generated without viral integration" *Science* 322: 945. See also Stein R (2008) "Scientists find way to regress adult cells to embryonic state" *Washington Post*, 26 September available online at http://www.washingtonpost.com/wp-dyn/content/article/2008/09/25/AR2008092502099.html accessed 6/7/2009. suggested further reading on the Hochedlinger method, Ahn JY (2010) "Are iPS cells and ES cells identical twins or distant cousins?" available online at http://www.biotechniques.com/news/Are-iPS-cells-and-ES-cells-identical-twins-or-distant-cousins/biotechniques-302742.html?service=print accessed 2/11/2010.
[262] See paragraph 3.5 *supra* for the discussion on the process of cell culture.
[263] See *Figure C supra*.
[264] National Institutes of Health (2009) 2 & 13-14. See also Baker (2007) online.

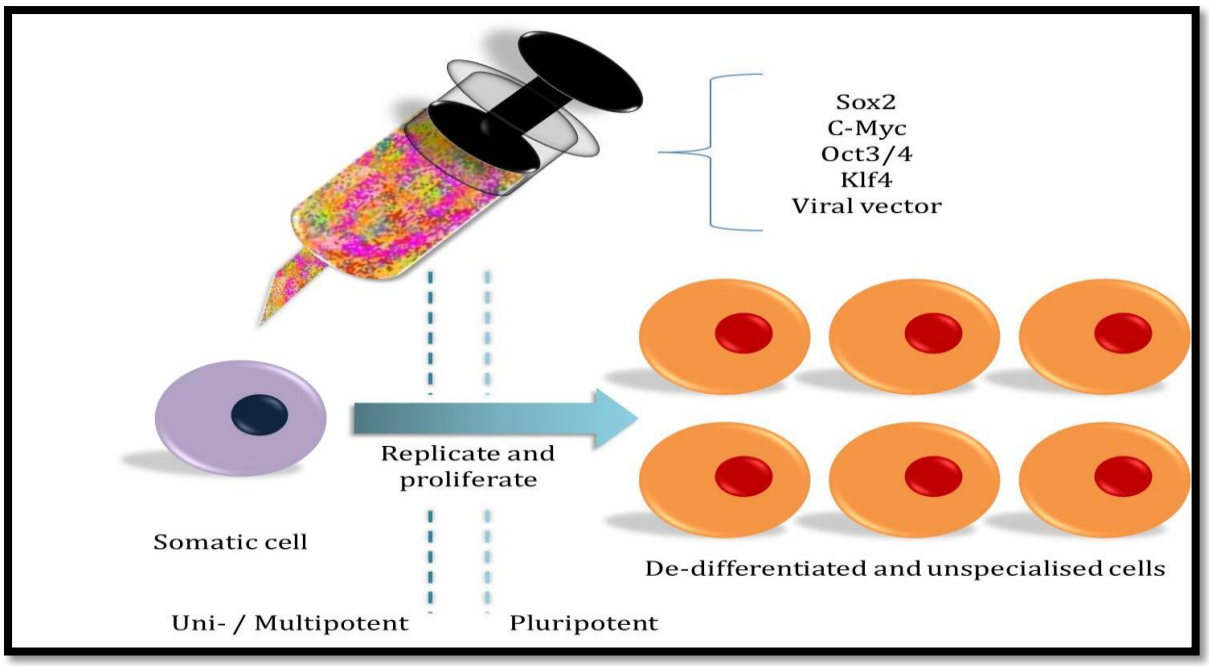

Figure E: Induced pluripotent stem cells

At this juncture it becomes relevant to discuss the four genes used for the induction of cells as without these genes the process of induced pluripotency would not be possible. The genes Oct3/4, c-Myc, SoX2 and Klf4 are thus discussed here:[265]

1. Oct3/4 aims at maintaining pluripotency and therefore it is a crucial transcription regulator.[266] When Oct3/4 is absent in a blastomere or an embryonic stem cell, differentiation of the trophoblast occurs. Oct3/4 is exclusively used for induction purposes as other members of the Oct gene family do not deliver the same results in pluripotency management.
2. c-Myc, a member of the Myc gene family, is a proto-oncogene. In other words, c-Myc may be implicated in cancer formation and use of this gene is bothersome. By making use of other Myc genes such as N-Myc and L-Myc however, pluripotency may be induced as efficiently as it is when using c-Myc but with a decreased risk of tumor formation.
3. SoX2, like Oct3/4, is a transcription regulator which maintains the pluripotency of cells. SoX genes, however, differ from Oct3/4 in that the SoX gene is normally associated with multi- or unipotent cells and therefore lacks the exclusivity factor.
4. Klf4 is a gene which contains the protein Krueppel-like factor 4 and this is used to indicate the stem-like capacity of a cell. It therefore aids in the generation of induced pluripotent stem cells.

[265] Darr H & Benvenisty N (2006) "Factors involved in self-renewal and pluripotency of embryonic stem cells" in Starke K & Freiburg B (eds) *Handbook of experimental pharmacology: Stem cells* 2: 8-12.
[266] A transcription regulator controls the rate of gene transcription.

Genetic markers play an important role in the process of creating iPS cells. In this regard Nanog and Lin28 must be mentioned. Nanog, a transcription factor,[267] is a protein which promotes pluripotency and is involved extensively in self-renewal of undifferentiated embryonic stem cells.[268] Lin28 is a mRNA[269] binding protein expressed by HES cells and it is also associated with cell differentiation and proliferation.[270]

3.6.1.3.3 Similarities between HES cells and iPS cells

The similarity of iPS cells to naturally pluripotent HES cells is where its miraculous medical potential lies. It is in fact believed that as this science progresses, HES cells will become obsolete as new kinds of adult stem cells will be found and induced to pluripotency, which will then be as versatile as the cells derived from embryos.[271] Human cells which have been induced to pluripotency have normal karyotypes,[272] express telomerase,[273] express cell surface markers and genes which characterise embryonic stem cells and which maintain the developmental potential which allows an HES cell to differentiate into any cell or tissue.[274] Three primary categories of similarity exist between iPS cells and HES cells and deserve some attention.[275]

The first relates to the cellular biological properties of an induced pluripotent cell, or differently stated, the morphology or appearance of the iPS cell which is identical to an embryonic cell. The surface markers are also the same. Induced pluripotent cells thus express genes which are usually expressed by embryonic stem cells. The growth properties[276] and telomerase activity is also alike. The second area of compatibility regards pluripotency itself and iPS cells, like HES cells, have the ability to differentiate into fully differentiated cells and tissues. Lastly, the

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[267] A transcription factor is a protein which binds to specific DNA sequences and thus controls the flow of genetic information from DNA to mRNA. It is sometimes referred to as a sequence-specific DNA-binding factor.
[268] Chambers I, Colby D, Robertson M, Nichols J, Lee S, Tweedie S & Smith A (2003) "Functional expression cloning of Nanog, a pluripotency sustaining factor in embryonic stem cells" *Cell* 113(5): 643-655.
[269] RNA or ribonucleic acid may be defined as "a complex nucleic acid present mainly in the cytoplasm of cells but also in the nucleus." RNA is involved in the production of proteins and may be found in three forms: ribosomal (r), transfer (t) and messenger (m) RNA. It forms the genetic material in certain viruses. See Family Medical (2000) 225. Cytoplasm is defined as "the substance within the cell wall that surrounds the nucleus and contains a number of organells." See Family Medical (2000) 61.
[270] See in general, Wilbert ML, Huelga SC, Kapeli K, Stark TJ, Liang TY, Chen SX, Yan BY, NathansonJL, Hutt KR, Lovci MT, Kazan H, Vu AQ, Massirer KB, Morris Q, Hoon S & Yeo GW (2012) "Lin28 binds messenger RNAs at GGAGA motifs and regulates splicing factors abundance" *Molecular Cell* 48(2): 195-206.
[271] Holland as mentioned in Weiss (2005) online.
[272] This has to do with the appearance of a cell and the structure and form of the nucleus and DNA inside the cell.
[273] This is an enzyme found in certain chromosomes and which is activated during cell division.
[274] Yu, Vodyanik *et al*. (2007) 1917.
[275] See in general, Zhao X, Li W, Lv Z, Liu L, Tong M, Hai T, Hao J, Guo C, Ma Q, Wang L, Zeng F & Zhou O (2009) "iPS cells produce viable mice through tetraploid complementation" *Nature* 461: 86-90. See also Kang L, Wang J, Zhang Y, Kou Z & Gao S (2009) "iPS cells can support full-term development of tetraploid blastocyst-complemented embryos" *Cell Stem Cell* 5: 1-4 and Boland MJ, Hazen JL Nazor KL, Rodriquez AR, Gifford W, Martin G, Kupriyanov S & Baldwin KK (2009) "Adult mice generated from induced pluripotent stem cells" *Nature* 461: 91.
[276] Such as self-renewal, proliferation and cell division.

epigenetic reprogramming of induced pluripotent stem cells is similar to that of embryonic stem cells. This means that the activity of certain genes may be altered without changing the structure of the genes or the DNA as a whole.[277]

These similarities translate into an amazing alternative to the use of embryonic stem cells and they are therefore more ethically acceptable than SCNT. Stem cell research and the future of this field of medical science will most certainly focus its attention on this procedure and for this reason its importance should not be underestimated or overshadowed. Other stem cell related technologies which are sure to gain prominence and importance are the areas of stem cell banking as well as tissue and organ engineering which includes scaffolding and three-dimensional organ and tissue printing. This will be discussed in the course of this thesis. At this point, however, it is necessary to realise that every coin has two sides. The wonder and miracle, the promise and positive aspects of iPS cells have now been discussed and it thus becomes prudent to discuss the negative and critiqued aspects thereof. This is done in order to form a complete picture of iPS cells in particular and stem cell research in general. The following section of this study will thus pay attention to the worrying reality of iPS cells as opposed to their amazing potential. In the greater context of this thesis, this also brings to light the experimental and uncertain nature of biotechnology in general and stem cells in particular.

3.6.1.3.4 Theory versus practice

In the above discussion of iPS cells, these cells appear to be the solution to all the problems facing stem cell research and therapy. And although this is true in theory, when placed into a practical milieu, certain issues become clear and this leads to the realisation that all is not well in the world of iPS cells. The following section of this thesis will thus focus on the critique which may be levelled at induced pluripotent stem cells. It will entail a discussion of some of the taboo topics surrounding this technique, ethical issues which remain unsolved by the use of iPS cells over HES cells and lastly, the challenges still facing induced pluripotent stem cell technology will be discussed.

[277] See in general, Narsinh KH, Plews J & Wu JC (2011) "Comparison of Human induced pluripotent and embryonic stem cells: fraternal or identical twins" *Molecular Therapy* 19(4): 635-638.

3.6.1.3.4.1 iPS cell taboos

Taboos must, for the discussion at hand, be understood as those topics surrounding iPS cells which the scientific and medical community is disinclined to discuss publicly. This might be because these issues, if openly discussed and brought to light, may cast a negative shadow on induced pluripotent cells and leave a blemish on the so far positive public reaction these cells have evoked. As with any argument, seeing both sides is necessary and for this reason it is important to discuss these "unpleasantries" here:[278]

1. Most laboratories still make use of a retroviral transduction method to create iPS cells despite the fact that it has become less relevant and there do exist different, non-retroviral methods to create such stem cells;
2. Each iPS cell line is epigenetically and functionally unique despite being genetically identical to others and this causes various challenges in genetic studies and disease modelling. This is due to an inherent stochastic[279] element involved in producing iPS cells. This then makes phenotyping[280] iPS cells difficult and disease testing and modelling complicated;[281]
3. Creating real induced pluripotent stem cells is a very difficult process;
4. The process whereby iPS cells are created is a time-consuming one. This means that patient specific cells cannot be used in patient-specific therapy in cases of acute injury such as a stroke, brain injury or heart attack;
5. iPS cells are expensive. When taking into account the time, equipment, ingredients and skilled manpower required to create iPS cells, it is not surprising that this process is an expensive one. So expensive in fact, that it is unlikely ever to become a widely used form of treatment;[282]

[278] Knoepfler Lab Stem Cell Blog: Building Stem Cell Bridges to Cures (2012) "Top 10 taboo topics about iPS cells: The elephant in the lab series" available online at https://www.ipscell.com/2012/05/top-10-taboo-topics-about-ips-cells-the-elephant-in-the-lab-series/ accessed 10/12/2012.
[279] This means elements which are non-determinable, sporadic and random.
[280] The word phenotyping is derived from the Greek words *phainein* meaning "to show" and *typos* meaning "type." This suggests a process whereby the composite characteristics of a cell are observed by studying its morphology, development, biochemical or physiological properties behaviour and/or products. Phenotypes result from the expression of genes and their interaction with surrounding environmental factors.
[281] For example, when attempting to map genetic elements which are linked to a certain disease phenotype making use of iPS cells, the inherent functional variability which is epigenetic could render this task impossible in spite of the genetic identicalness of the cells.
[282] According to the Knoepfler Lab Stem Cell Blog the costs of creating iPS cells are as follows: roughly $20 000 per line in the pre-clinical studies. For clinical grade cell lines, per line, it would be a further $100 000.

6. Many of the research papers published on the subject of iPS cells are not of much importance as they do not address fundamental issues and do not contribute substantially to the field and development of iPS cells;[283]
7. iPS cells are unstable. iPS cells are able to change overnight and thus they are also able to change in culture over time. This means that although cells become more stable due to cell evolution and selection of a homogeneous population, it may not be legitimate to compare data from the same cell line after too many passages;[284]
8. The field of iPS cells is very competitive. For purposes of this discussion this may be relevant as this would result in slow or no sharing of information before publications are sent into the world. This could thus contribute to an overwhelming mass of information without any new developments being contained therein. Or perhaps publications could contain information which another research group has already disproven, thus wasting development and progress time;
9. An unfortunately high proportion of published iPS cell methodological protocols are very difficult to recapitulate. This means that processes are difficult to repeat and thus some papers which are published contain a once off "fluke" method of creating iPS cells; and
10. iPS cells may likely never replace HES cells.[285]

At this juncture it may be informative to discuss some of the ethical issues surrounding induced pluripotent stem cells.

3.6.1.3.4.2 Remaining ethical concerns

Currently, very little has been written on the ethical issues pertaining to induced pluripotent stem cells. However, the ethical issues surrounding iPS cells are often shared by embryonic stem cells and the reason for this is that iPS cells are slated to be the alternative to the use of HES cells and due to their shared abilities, these cells are compared with one another on more

[283] This, it was found in the course of researching iPS cells for this thesis, is true. There exists an abundance of papers, articles and websites which a researcher is able to access yet most of these publications state what the previous ones have also stated.
[284] This information is dated the 10th of May 2012. In an article by Stanford University of Medicine dated that 19th of November 2012 it was, however, stated that iPS cells are not as unstable as previously thought. The study was first published on the 18th of November 2012 in *Nature*. See also Medical News (2012) "Induced pluripotent stem cells not as genetically unstable as previously thought" available online at http://www.news-medical.net/news/20121119/Induced-pluripotent-stem-cells-not-as-genetically-unstable-as-previously-thought.aspx accessed 10/12/2012.
[285] This is related to the difference in HES and iPS cells when used in drug development testing and disease modelling and testing.

levels than a purely biological one.[286] Scientists are still in disagreement on how iPS cells and HES cells will compare in certain instances. Some of the issues on which total agreement has not been reached are whether or not HES and iPS cells have a similar ability to be used in drug and disease testing and what fertility applications induced pluripotent cells will have.

iPS cells are irrefutably an astonishing discovery and development and they have gained much popularity in medical and scientific circles due to the potential they hold. The promise of replacing embryonic stem cells in research and therapy play no small role in this excitement and it is believed that the use of HES cells will be rendered obsolete by iPS cells. In spite of this, some questions remain. Is it possible to decide whether or not induced pluripotent stem cells will replace embryonic stem cells at this point in time when this research and technique is still relatively young? Will the use of iPS cells rather than embryonic cells resolve the ethical issues surrounding this research? In order to attempt to answer these questions, it is important to consider some of the ethical issues surrounding iPS cells. The most contested issues are those regarding efficacy and patient safety, large-scale accessibility and questions surrounding the moral status of iPS cells.

The first concern which must be dealt with is the issue of the safety and efficacy of any future cell therapy, specifically regarding immune rejection and safety standards. Immune response is a factor which must be discussed. As with organ transplants, the body may reject cells. The hope exists that since iPS cells may be created from cells derived from the eventual patient themselves, the induced cells will be recognised by the patient's body as their own and thus not rejected. Custom-made cells produced to treat individual patients would, however, be time-consuming, slow and costly.[287] In order to solve this problem, it is suggested that public stem cell banks should be considered. This would allow for a collection of diverse cells from where a match may be acquired faster than having to start the entire procedure from scratch for every new patient who requires this therapy. A public bank would, however, not solve the problem of potential immunological rejection.

[286] It is suggested that this leads to a circular ethical debate wherein the issues surrounding HES cells are solved by the proposition of using iPS cells only to discover that iPS cells have the same issues which needed to be solved in the first place. This thesis falls under the legal sciences and not under the realm of human sciences, philosophy or ethics and thus these issues are not resolved here, but merely discussed as is. It is however strongly suggested that more research be conducted on this topic and real, or at least satisfactory, answers found.
[287] EuroStemCell (2012) "Ethics and reprogramming: Ethical questions after the discovery of iPS cells" available online at http://www.eurostemcell.org/factsheet/ethics-and-reprogramming-ethical-questions-after-discovery-ips-cells accessed 12/12/2012.

Clinical trials using iPS cells have not started and for this reason "clinical grade" iPS cells have not yet been grown.[288] "Clinical grade" is the quality standard which is required for use in patients. This implies good manufacturing practice as well as optimal quality and safety.[289] Determining this clinical grade is however difficult. Tumor formation and aging of the cells as a result of reprogramming are some of the challenges facing scientists attempting to grow cells with controlled properties and this is hindering the development of a quality standard. Solutions have been suggested but require further research and this means that clinically approved cells are not yet available for human application.[290] In other words, iPS cell applications in humans may, at best, be regarded as experimental in nature and as such it is research involving a human subject.

The second important ethical consideration is related to patient access to cell therapy. This issues goes further than questions regarding whether this treatment will be available only to the rich, private healthcare user or will it also be available to those who depend on the public healthcare sector and this is a real concern. Either way, iPS cell therapy requires a well-developed healthcare system which has the necessary infrastructure to produce and distribute cells. It furthermore requires trained specialists who are able to retrieve, process and produce, manage, transport and deliver such cells.[291]

Lastly, it should be mentioned that some questions remain regarding the moral status of the cells. One might think that this debate is superfluous and has no real merit since induced pluripotent cells may be used as an alternative to the use of embryonic cells and that this warrants the use of these cells. In order for this thesis, however, to be complete, it is necessary to mention the arguments which may be made in this regard and that is that iPS cells could, in theory, be programmed to produce an egg cell or sperm cells and thus have the potential to create new life. Furthermore, iPS cells may be inserted into an embryo and contribute to the development of that embryo. If embryonic stem cells have moral status due to the fact that they may develop into a human being or if inserted into an embryo, could contribute to that embryo,

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[288] No mention is made of this requirement in South African legislation or regulations. It is, however, compulsory in Europe by the European Medicines Agency (EMEA) and the United States of America by the Food and Drug Administration (FDA).
[289] Suggested further reading on this and a discussion of proposed methods of manufacturing such clinical grade cells, Unger C, Skottman H, Blomberg P, Dilber MS & Hovatta O (2008) "Good manufacturing practice and clinical-grade human embryonic stem cell lines" *Human Molecular Genetics* 17(1): 48-53. See also Rajala K, Lindroos B, Hussein SM, Lappalainen RS, Pekkanen-Mattila M, Inzunza J, Rozell B, Miettinen S, Narkilahti S, Kerkelä E, Aalto-Setäla K, Otonkoski T, Suuronen R, Havotta O & Skottman H (2010) "A defined and xeno-free culture method enabling the establishment of clinical-grade human embryonic, induced pluripotent and adipose stem cells" *PLos ONE* 5(4): 10246. See in general, Chatterjee P (2012) "'There must be another way'-Shinya Yamanaka" available online at http://www.biospectrumasia.com/biospectrum/influencers/23502/there/page/3#.UMkB128U8Qo accessed 12/12/2012.
[290] EuroStemCell (2012) online.
[291] *Ibid*.

and if this then rings true of induced pluripotent cells, the argument could be made that iPS cells deserve the same moral status as HES cells. This argument could be taken to the extreme and it could thus be stated that if iPS cells receive moral status, the cells from which they are derived, skin or blood cells for example, should also receive some status.[292] It is suggested, however, that this is farfetched as it is the same as saying that there is no difference between a lump of clay and a pottery bowl.

The ethical concerns mentioned here and the previously discussed taboo topics are indicative of the difficult environment wherein the science of induced pluripotent stem cells finds itself. These may be seen as coming from the past and into the present and are not the only issues facing this scientific technique. The following section of this study is a discussion of further challenges still facing iPS cells, currently and in the future.

3.6.1.3.4.3 Challenges facing iPS cells

Induced pluripotent stem cells are a convoluted and confusing field of study and this, it seems, is not something which will become better with time. Some of these problems which exist currently, and are sure to continue in the foreseeable future, include the similarity between iPS cells and cancer cells, regulatory issues, induced pluripotent stem cell memory, iPS cell mutations, iPS cell epigenomic warts as well as issues regarding costs and timeliness.[293]

The similarity to cancer and the tendency to cause cancer have been discussed previously. Also, the fact that regulatory measures are seriously lacking is not new to this discussion and will be discussed at length at a later stage. The cost and time involved in the development of iPS cells have been discussed above.[294]

Cells, when cultured for a prolonged period, may lose the memory of their former being, for example a fibroblast. This memory is stored in the epigenome[295] and may fade greatly but not

[292] *Ibid*.
[293] Knoepfler Lab Stem Cell Blog: Building Stem Cell Bridges to Cures (2012) "Top 7 challenges facing iPS cells in late 2012" available online at https://www.ipscell.com/2012/10/top-7-challenges-facing-ips-cells-in-late-2012/ accessed 12/12/2012.
[294] This will not be repeated as it is unlikely that the process of iPS cells will become less expensive or less time consuming in future.
[295] The epigenome is comprised of chemical compounds which modify or mark the genome in a manner which directs its functions. Epigenetic marks do not form part of the DNA of the cell but may be passed from cell to cell during cell division. See National Human Genome Research Institute (2012) "Glossary" available online at http://www.genome.gov/Glossary/index.cfm?id=529 accessed 11/1/2012.

completely. It now seems that iPS cells retain some form of memory and this may have far reaching clinical impacts.[296]

A further issue is that of cell mutation. This occurs during reprogramming where the epigenome undergoes a metamorphosis and the genome thus becomes vulnerable to injury or damage. This mutation tends to collect in the cancer-related sectors of a cell and this raises concerns regarding the clinical application of these cells.[297]

A concern which is related to cell memory and mutation is that of epigenomic warts. These are incomplete or aberrant reprogramming events which manifest at the epigenomic level. These errors in the cell, in essence rendering them non-embryonic stem cell-like, range from incorrect DNA sequences to misplaced or absent methylation[298] to unusual histone modification patterns.[299] Once again the experimental nature of this field of science is also emphasised and so, the need for a proper consent regime is illustrated.

In conclusion, it is obvious that more research, into both HES and iPS cells, is required. Only then should the true potential of the cells be weighed, techniques and methods finalised, moral implications and ethical differences assessed and final judgements made. The similarities between HES and iPS cells are astounding and thus they serve as alternatives to one another while removing the ethical question marks which have been drawn over SCNT. The future development of this field of study will definitely move towards iPS cells. Stem cell banks, as previously mentioned, will also become more relevant and will gain importance in the field of biotechnology. It therefore becomes pertinent to discuss banking of stem cells.

[296] Suggested further reading, Daley G (2010) "Epigenetic memory in induced pluripotent cells" *Nature Biotechnology* 28(8): 848-855. See also Nature Biotechnology (2010) "Press releases-August" available online at http://www.nature.com/nbt/press_release/nbt0810.html accessed 11/1/2012.
[297] Knoepfler Lab Stem Cell Blog: Building Stem Cell Bridges to Cures (2012) "Top 7 challenges facing iPS cells in late 2012" online.
[298] Methylation is a biochemical process which entails the addition of a methyl group. See Iqbal K, Jin S, Pfeifer P & Szabo PE (2011) "Reprogramming of the paternal genome upon fertilisation involves genome-wide oxidation of 5-methylcytosine" *Proceedings of the National Academy of Sciences* 108(9): 3642-3647.
[299] Suggested further reading, Lennartsson A & Ekwall K (2009) "Histone modification patterns and epigenetic codes" *Biochimica et Biophysica Acta* 1790(9): 863-868 and Cedar H & Bergman Y (2009) "Linking DNA methylation and histone modification: Patterns and paradigms" *Nature Reviews Genetics* 10: 295-304.

4 STEM CELL BANKING

A cell bank is a facility which stores frozen tissue samples for later therapeutic or research purposes.[300] A stem cell bank is therefore a cell bank which specialises in the storage, known as banking, of stem cells. Previously, mostly umbilical cord blood had been banked, as umbilical cord blood was deemed the most accessible and ethically unchallenged source of stem cells.[301] Currently, however, stem cells may also be harvested and banked by making use of adipose tissue and peripheral blood.[302]

This thesis focuses on both the procurement and distribution of stem cells and attention must be given to the process of banking as "distribution" indicates the use of stem cells for therapy, research or educational purposes and the practice of stem cell banking. Storage is also an important factor in the consent process and requires attention as consent must be obtained to store material. Attention must, for this reason and in order to form a global understanding of the science of stem cells, be given to stem cell banking.

4.1 BANKABLE MATERIAL AND THE PROCESS OF BANKING

For the purposes of this thesis attention will be given to cord blood, adipose tissue and peripheral blood as bankable material. The material discussed here is, however, not a *numerous clauses* and it should be noted that various different cells, tissues and materials, such as human milk, may be stored in a banking facility.[303]

4.1.1 Cord Blood

Cord blood, until recently, was regarded as medical waste but may now be utilised for the harvesting of stem cells which could in later years be applied in therapeutic treatments.[304] After

[300] See in general, Hug K & Hermerén G (2010) *Translational stem cell research: Issues beyond the debate on the moral status of the human embryo*: 225-237. See also Svendsen C & Ebert AD (2008) *Encyclopedia of stem cell research*: 269-370.
[301] Prinsen L (2010) 42.
[302] Adipose tissue stem cells are stem cells which are derived from fat and peripheral blood is the blood found in the bloodstream of the human body.
[303] See in general, the Regulations relating to Human Milk Banks of 3 July 2015. Suggested further reading, Prinsen L (2015) "Meeting the standard: An overview of European biobank regulation and a comparison of the current South African position" *African Journal of International and Comparative Law* 23(1): 54-73.
[304] Kent A (2008) "Cord blood: Medical waste?" *Obstetrics & Gynaecology Forum* 18(4): 109-111. See also Fasouliotis SJ & Schenker JG (2000) "Human umbilical cord blood banking and transplantation: A state of the art" *European Journal of Obstetrics & Reproductive Biology* 90: 13-25 and Cox SR (2008) "Cord blood banking: What's it all about?" *Journal of Midwifery & Women's Health* 53(2): 161. Stem cells derived from cord blood may be used in the therapeutic treatment of leukaemia and other diseases affecting the immune system.

the birth of an infant, the umbilical cord is cut and the placenta as well as the remainder of the cord blood is discarded. Blood, rich in stem cells, remains in the cord and cord blood stem cells may then be harvested from this blood.

Collection is done by the attending obstetrician or midwife by clamping the umbilical cord, still attached to the placenta,[305] and inserting a needle into the umbilical cord vein.[306] As much blood as possible, usually about 100ml, is then extracted via a tube into a blood bag.[307] Cord tissue may also be collected at this time. An undamaged section of the umbilical cord, roughly 15cm, is cut from the cord, cleaned and placed in a sterile container.[308] The collection is then packaged by placing it in a temperature-controlled bag or container and is taken to the banking facility's laboratory directly from the place of birth.[309]

On arrival at the laboratory the blood and tissue are logged into the management system of the banking facility and at this point, will be issued with a registration number or code in order to ensure traceability. Certain tests and procedures are then performed on the blood as well as on the tissue. Tissue is dissected into smaller samples which are placed into cryo vials and preserved with cryo-protectant agents after which they are slowly frozen and stored. Cord blood is separated into three layers, namely red blood cells, plasma and the "buffy coat" where the stem cells are found.[310] A process of volume reduction is used to reduced and separate the red blood cells and the plasma so that only the buffy coat remains. After this, a cryopreservative[311] is added to the buffy coat which increases the porosity of the cells and prevents any damage to the cells which may occur during the freezing process.[312]

The cells are hermetically sealed in a cryogenic bag, meaning that the cells are sealed in an airtight bag which is then encased in an aluminium casing which provides protection during freezing as it enables a consistent heat path. After this the cells are frozen slowly at a controlled rate and stored. Storage of both the cord blood stem cells as well as the cord tissue takes place

[305] At this stage the placenta is still inside the woman's womb.
[306] This is a non-invasive, pain free procedure and takes around three to seven minutes. No aftercare is necessary. See in general, Moran M (2001) "Banking on umbilical cord blood," *WebMD* available online at kidshealth.org/parent/pregnancy_newborn/pregnancy/cord_blood.html accessed 28/6/2012 and Nemours Foundation (2004) "Banking your newborn's cord blood" *KidsHealth* available online at http://my.webmd.com/content/Article/14/3606_537.htm accessed 28/6/2012.
[307] The blood bag as well as the container wherein cord tissue is transported is provided by the banking facility in the "Collection Kit."
[308] Netcells (2012) "Baby stem cells-Cord blood and tissue: Procedure" available online at http://www.netcells.co.za/baby-procedure.php accessed 28/6/2012.
[309] See in general, Chao NJ, Emerson SG & Weinberg KI (2004) "Stem cell transplantation (Cord blood transplantation)" *Hematology* 1: 354-371.
[310] The buffy coat contains white blood cells as well as platelets. See The Free Dictionary (2012) "Buffy coat" available online at http://medical-dictionary.thefreedictionary.com/buffy+coat accessed 28/6/2012.
[311] Dimethyl Sulfoxide, known as DMSO.
[312] Napolitano M, Lo Coco L, Saccullo G, De Francisci G, Reina A, Allegro D, Fadda R, Di Liberto D, Mancuso S, Valore L, Vaccarella G, Agliastro R, Dieli F & Siragusa S (2013) "Functional *in vitro* studies of buffy coat pooled platelets cryopreserved in Dimethyl-Sulphoxide with a new system" *Blood* 122(21): 1158.

in vaults in the vapour phase above liquid nitrogen.[313] Once stored, the material may be kept in storage for decades.[314] Should the cells be required for later therapeutic use, the material need only be retrieved from such storage.[315]

4.1.2 Adipose Tissue

Adipose tissue is fat found in the body and contains mesenchymal stem cells.[316] Mesenchymal stem cells are ideal for stem cell therapy as they are rather robust, differentiate into various types of tissue and easily replicate. These stem cells are thus of great use in both the research and therapeutic arena and may be applied in skin regeneration, neurology, orthopaedics, cardiology, as well as sports injury repair and cosmetic surgery.[317]

Adipose tissue is collected by way of a liposuction procedure under local or general anaesthetic. During this procedure, around 100ml of adipose tissue is harvested as well as about 50 to 100ml blood which is required to extract serum which is necessary for the processing of the tissue. The tissue and blood are taken to the banking facility's laboratory where it is, after being logged and coded, processed in order to isolate the mesenchymal stem cells. Once the cells have been isolated, the cells are placed in a culture medium and allowed to proliferate for about five days. When the cells have sufficiently proliferated they are removed from culture, cryopreserved in much the same manner as umbilical cord blood stem cells but at a temperature of -1960°C and stored in cryovials.[318]

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[313] This means the cells are stored at around -196°C. This temperature is above -135°C at which biological processes cease and ageing is halted. See Netcells (2012) "Baby stem cells-Cord blood and tissue: Procedure" online.
[314] This was found in a study conducted by Broxmeyer and colleagues according to Cryo-Save (2012) "FAQ" available online at http://www.cryo-save.co.za/frequently-asked-questions/#q11 accessed 5/7/2012.
[315] According to Gunning, cord blood banking entails advantages and risks. The advantages are that cord blood units are more readily available than bone marrow; the collection of cord blood carries few risks; potential donor numbers are high; graft-versus-host disease risks are decreased; cord blood does not have to be HLA matched in order to be used and the risk of infectious disease is eliminated as the blood is tested and screened for any such diseases. Disadvantages of banking include prolonged platelet fragmentation; that the cell dose found in umbilical cord blood is insufficient for the treatment of adults and hereditary diseases, which may not be detected at birth, may be transmitted to the recipient of the material. See Gunning J (2005) "Umbilical cord cell banking: Implications for the future" *Toxicology and Applied Pharmacology* 207: s538-s543. See also Warwick R & Armitage S (2004) "Cord blood banking" *Best Practice and Research Clinical Obstetrics and Gynaecology* 18(6): 995-1011.
[316] Mesenchymal stem cells are also found in smaller numbers in bone marrow and the Wharton's Jelly of the umbilical cord tissue.
[317] Netcells (2012) "Adult stem cell banking: About adipose (fat) tissue stem cells" available online at http://www.netcells.co.za/adult-adipose-tissue.php accessed 28/6/2012.
[318] Netcells (2012) "Adult stem cell banking: Procedures" available online at http://www.netcells.co.za/adult-procedure.php accessed 28/6/2012.

4.1.3 Peripheral Blood

Stem cells found in the bloodstream are called peripheral blood stem cells and these cells may be used in bone marrow transplants. This is especially important in the treatment of persons who have undergone chemotherapy and radiation as part of cancer treatment. Bone marrow enables the human body to create blood cells, which are essential to survival as blood carries oxygen within the body,[319] fights infections[320] and is able to clot in the case of a wound, preventing the body from losing too much blood.[321] During the treatment of cancer, all rapidly developing cells are destroyed by chemotherapy or radiation but bone marrow cells are also destroyed as they develop at a faster rate than other cells in the body. Peripheral stem cells, along with bone marrow stem cells, may therefore be transplanted into a patient in order to restore the ability to produce blood. It should be noted that three different stem cell transplants exist which are relevant to this discussion:[322]

1. Autologous transplants: this is where the recipient of the stem cells is also the donor thereof. A person thus receives his/her own stem cells;[323]
2. Allogenic transplants: this is where the donor of the material is the recipient's brother, sister or parent. In some cases, an unrelated donor may also match the recipient. Allogenic transplants may therefore be seen as transplants from one person to another;[324] and
3. Synergenic transplants: the donor of the material and the recipient thereof are identical twins.[325]

Peripheral stem cells are collected by a procedure known as apheresis.[326] This procedure requires the donor to take medication starting five days prior to the procedure, which increases

[319] Red blood cells carry oxygen to the organs and tissues in the human body.
[320] White blood cells fight any infections which enter the human body.
[321] This is done by platelets.
[322] Netcells (2012) "Adult stem cell banking: About peripheral blood stem cells" available online at http://www.netcells.co.za/adult-peripheral-blood.php accessed 28/6/2012.
[323] Autologous transplants have certain advantages and disadvantages. The advantages may be blood type matching, the risk of exposure to an infectious disease is eliminated as well as the risk of allergic reactions. In short it could be stated that rejection of the transplant is eliminated. The disadvantages may be higher costs due to the individualised processing, record keeping and management of the material as well as the fact that mostly, donations are discarded if not used and are not added to the general supply of materials which may be utilised by society at large. See The Free Dictionary (2012) "Autologous blood transfusion" available online at http://encyclopedia.thefreedictionary.com/autologous accessed 28/6/2012.
[324] An important factor in the transplantation is the requirement that the donated material should match as closely as possible that of the donor. Persons have differing protein sets named leukocyte-associated antigens, or HLA antigens. This is the name of the major histocompatibility complex of human beings. The higher the rate whereby the HLA antigens of persons match, the greater the chances of acceptance by the recipients' body will be towards the transplanted material. This also reduces the risk of "grafts-versus-host disease."
[325] Identical twins have identical genetic makeup and thus transplants between such twins are accepted by the receiving twin's body.
[326] For a detailed discussion on this procedure see Stöppler MC (2012) "Apherisis (Hemapherisis, Pherisis)" available online at http://www.medicinenet.com/hemapheresis/article.htm accessed 28/6/2012.

the number of stem cells within the blood stream.[327] Blood is then withdrawn through a vein in the arm and stem cells are mechanically removed from the blood which flows back into the body. This process takes around four to six hours.[328] The cells are taken to a laboratory after removal from the blood and are tested for viability and are counted. The cells are diluted and added to a cryopreservative, also dimethyl sulfoxide (DMSO) as used in cord blood storage, in order to prevent crystallisation of the cells during the freezing process. The storage bags wherein the cells are kept are placed in a control rate freezer where the temperature is reduced to -1800°C. After this temperature has been reached, the storage bags containing the cells are placed in liquid nitrogen storage tanks and frozen at -1920°C.[329]

Since the stem cells derived from peripheral blood are intended for therapeutic treatment *ab initio*, the cells are dosed with high doses anticancer drugs and are then transplanted intravenously into the recipient. The cells migrate to the bone marrow and start producing new red blood cells, platelets and white blood cells by way of a process known as "engraftment."[330]

4.2 ISSUES SURROUNDING BANKING

Banking of stem cells is not without its own controversy and complications. Certain health care practitioners, for example, believe that the cord blood should be allowed to flow into the infant in order to prevent anaemia or later illness; liposuction is a dangerous procedure and renders a person vulnerable to infections and diseases as well as dehydration and the medication which must be ingested prior to the withdrawal of peripheral blood is loaded with side effects. When further taking into consideration that stem cells may be derived from various other sources, the argument may therefore readily be made that banking is an unnecessary health risk.[331] Furthermore, the high costs of storage are not always justified when the likelihood of use is weighed against such costs.[332] Issues related to data are also relevant.

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[327] One such medication is Neupogen. See Pollack A (2008) "Questioning the allure of putting cells in a bank" *New York Times*, 29 January available online at http://www.nytimes.com/2008/01/29/health/29stem.html?_r=1&pagewanted=all accessed 1/7/2012.
[328] The aperesis procedure causes some discomfort as well as light headedness, numbing around the lips and cramps but does not require anaesthesia. The medication which is taken, however, causes muscle and bone aches, headaches, nausea, fatigue and insomnia which only stop two to three days after the medication is no longer being ingested.
[329] Netcells (2012) "Adult stem cell banking: About Peripheral blood stem cells" online.
[330] A side effect to stem cell transplants utilising hematopoitic stem cells and peripheral blood stem cells is Engraftment syndrome. This causes the recipient of the stem cells to experience fever, erythrodermatous skin rashes and noncardiogenic pulmonary oedema. See also Spitzer TR (2001) "Engraftment syndrome following hematopoietic stem cell transplantation" *Bone Marrow Transplant* 27(9): 893-898.
[331] Cox (2008) 161.
[332] *Idem* 162. See also Pollack (2008) online and California Stem Cell Report (2010) "High cost of stem cell therapy: Will stem cell firms share more risk?" available online at http://californiastemcellreport.blogspot.com/2010/03/high-costs-of-stem-cell-therapy-will.html accessed 18/6/2012.

The necessary traceability of banked material opens the door to violations of privacy and access to information which some might prefer undisclosed. Material is subject to numerous tests which may lead to troubling discoveries regarding paternity in the case of umbilical cord blood, infectious diseases or the predisposition towards genetic illnesses.[333] Further issues surrounding cell banking pertain to the ethnicity and belief systems of donors and potential donors and in a hybrid country such as South Africa attention will necessarily have to be given to this aspect.[334]

Some controversy further exists surrounding private versus public stem cell banks.[335] Private banking enables preservation and storage of autologous cells and ensures access to the material.[336] Public banking offers material to persons in need of such material and thus a person is not guaranteed ready access.[337] In spite of this, persons may still prefer donating material to a public bank.[338] According to Professor Solly Benatar, some arguments may be made against private stem cell banks. What follows is a brief discussion of Professor Benatar's arguments against private stem cell banking and the rebuttal thereof:[339]

1. Stem cell banking is based on an overestimation of the benefits of stem cells. Although the current therapeutic application of stem cell technology is limited, this in itself is not a sufficient justification for the banning of private stem cell banks. This technology is new and, to a great extent, uncertain but it does hold a promise for great medical potential. It is suggested, given that the State may not possess the funds or "know-how" to establish a public bank at this time, private banks should, for the time being, be permitted to function as is. This would enable development and research opportunities in the interim;

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[333] Kharaboyan L, Knoppers BM, Avard D & Nisker J (2007) "Understanding umbilical cord blood banking: What women need to know before deciding" *Women's Health Issues*: 278. For a very insightful read on genetic testing for the purpose of early disease identification see Rochman B (2012) "The DNA dilemma: A test that could change your life" *TIME Magazine*, 24 December: 30.
[334] Kassah JE (2011) "Current state of stem cell research and its application in South Africa" *Stem Cell Research Around the World* available online at http://embrybros.wordpress.com/2011/04/06/current-state-of-stem-cell-research-and-its-application-in-south-africa/ accessed 28/6/2012.
[335] See in general, Jordaan DW, Woodrow C & Pepper M (2009) "Banning private stem cell banks: A human rights analysis" *South African Journal of Human Rights* 25: 128-132 and see also Warwick & Armitage (2004) 1002-1005.
[336] This is referred to as direct donations. See Warwick & Armitage (2004) 997.
[337] Donations may be made to a public bank due to altruistic reasons or ethical citizenship according to Warwick and Armitage. See Warwick & Armitage (2004) 999.
[338] Louw VJ & Heyns A (2010) "The role of the state in establishing a public cord blood stem cell bank" *South African Medical Journal* 100(5): 292.
[339] Jordaan D (2007) "Reality, ideology and stem cell banks" *Centre for International Political Studies: Electronic Briefing Paper No.52* available online at http://web.up.ac.za/sitefiles/File/46/3953/52-2007%20Reality%20ideology%20and%20stem%20cell%20banks%20by%20Adv%20Donrich%20Jordaan.pdf accessed 4/7/2012. Professor Benatar initially reacted against the pro-private banking arguments made by Jordaan in the *Cape Times* of 1 August 2007 in an article entitled "Stem cell ban is a first step to end all private healthcare." The original article however is Jordaan D (2007) "Stem cells and the equality of the graveyard: The Department of Health's efforts to level down access to stem cell banking" *Centre for International Political Studies: Electronic Briefing Paper No.40* available online at http://web.up.ac.za/sitefiles/File/Unit%20for%20Policy%20Studies/40-2007%20Stem%20Cells%20and%20the%20equality%20of%20the%20graveyard%20by%20Donrich%20Jordaan%20(revised).pdf accessed 4/7/2012.

2. The public may be vulnerable to exploitation due to the promises made regarding the wonder of stem cell therapy. This is a valid concern, yet it is not an unassailable obstacle which, in the absence of passing, renders cell banking an evil. According to Jordaan, the apparent solution would be the enforcement of a very high standard of informed consent.[340] Informed consent is aligned strongly with human dignity. It further essentially requires that a person is empowered with knowledge allowing them to make decisions and that the autonomy to make such decisions is respected. It is suggested that the *de facto* banning of stem cell banks at this time may even constitute a violation of autonomy;
3. Private stem cell banks are elitist. Professor Benatar is of the opinion that the South African and global private health care system is elitist, greedy and unresponsive to the needs of the majority of persons. This ethics of levelling down was described as "equality of the graveyard" by Judge Albie Sachs of the Constitutional Court.[341] Levelling down is the concept of equality which has in mind that unless everyone has access to a benefit, no one should have access to it. However, banning stem cell banks completely on these grounds is also not ethical, or constitutionally sound, and attention must rather be given to ways in which access may be increased; and
4. Private stem cell banks are profit-driven. In the South African context this argument may not hold water as private stem cells banks have continuously demonstrated their commitment to contribute their resources to the establishment of a public stem cells bank. As mentioned previously, the State may not possess the resources or technical skills to establish a public bank and for this reason the profits of a private bank may be the *sine qua non* for increasing public access to cell banking. If fact, the argument may be made that, in reality, the profit motive increases employment which increases wealth, which in turn increases the quality of life and health all round.

It is suggested that this issue be placed on the backburner for now. The State is nowhere near the establishment of a public bank and should private banks be banned, this science and technology will suffer a severe setback. Ideally, in the future, private and public stem cell banks may function together and in this manner serve more persons than just one would be capable of doing. In a free society, persons must have the right to make a choice regarding their biological material and this choice must be made without interference. Persons should thus be freely permitted to choose a private stem cell bank or a public bank or none at all. At that time, the consent process will be very important.

[340] This suggestion is in line with the consent format of dynamic consent which is introduced in the course of this thesis.
[341] Sachs A (2008) *Equality of the vineyard or equality of the graveyard?* presented at the Third Kuttan Menon Memorial Lecture, Old Council Chamber, Law Society, London, 22 January.

A final concern regarding banking of material relates to the process of consent. Mostly, cells are banked for a certain number of years which are paid for upfront and entail yearly costs. Usually cells are banked as a preventative measure to be used only in later therapeutic procedures. This suggests that a person making use of a banking facility may decide to discontinue such services. Questions may then be raised as to the fate of the material. Will such banked cells be discarded and destroyed? Should such cells not be donated to a research or educational facility? It is suggested that the dynamic consent format which is introduced in the course of this thesis offers a solution to this problem.[342] This allows for the banking person and the facility to conclude a preliminary agreement of sorts wherein the finality of the destiny of the material is subject to the change in preferences of the banking individual. When such time arrives, the banking individual may then decide to discard and destroy or donate the material. The appropriate consent protocols and procedures must then be employed.

The processes of stem cells storage have now been discussed to some extent and clarity has been provided on the manner in which cells may be obtained. It now remains necessary to examine the processes whereby stem cells become therapeutically applied. What is meant by "therapeutically applied" for purposes of this thesis is the manner or procedures wherein stem cells are transformed from loose cells, floating around in a culture medium into an actual medical implant or material object which may be utilised in a more standard medical procedure.[343] It is, in other words, the manner in which stem cells are taken out of the scientific arena into the medical one. This is where this science makes the leap from science-fiction to reality. The following section of this chapter will therefore deal with tissue and organ engineering.

5 TISSUE AND ORGAN ENGINEERING UTILISING STEM CELLS

The revolutionary field of tissue engineering, pioneered by Doctor Anthony Atala of Wake Forrest University Medical Centre,[344] may be described as a multidisciplinary field involving

[342] See chapter 9 *infra*.
[343] As previously mentioned peripheral blood (stem cells) is simply transfused by way of IV therapy or Intravenous therapy. Intravenous means "within a vein." The discussion on tissue and organ engineering thus focuses on scenarios where a new liver or ear or other such organ is required and a mere transfusion-like procedure is not adequate.
[344] See Hill DJ (2011) "Growing human organs-Dr. Anthony Atala blows the minds of a TED audience" *Singularity Hub* available online at http://singularityhub.com/2011/03/15/growing-human-organs-%E2%80%94-dr-anthony-atala-blows-the-minds-of-a-ted-audience/ accessed 7/7/2012. See also Ward L (2009) "Beyond transplants: Growing organs in the lab" *Popular Mechanics*, 17 December available online at http://www.popularmechanics.com/science/4212851 accessed 7/7/2012.

biology, medicine and engineering.[345] Langer and Vacanti define tissue engineering as "an interdisciplinary field that applies the principles of engineering and life sciences towards the development of biological substitutes that restore, maintain or improve tissue function or a whole organ."[346] In other words, tissue engineering may be described as making use of a three-dimensional combination of cells, engineering materials and biochemical factors in order to improve or replace biological functions. In practice, the term "tissue engineering" now represents the replacement or repair of structural tissues[347] which function by virtue of their mechanical properties.[348] In some instances it is referred to as "regenerative medicine" and this indicates emphasis on stem cell usage in the creation of tissue.[349] Tissue engineering is closely related to the older field of cell transplantation wherein cells with a certain biochemical function are transplanted into damaged organs and so health problems are solved by the use of living cells, and now, engineering materials.[350] Depending on the organ or tissue which is to be treated, a number of strategies may be used, namely substitution of one body part for another;[351] repair using non-vital, mostly synthetic materials and devices; transplantation from another human or nonhuman species; using an external device to augment or substitute the non-functioning organ or tissue; and utilising living cells in tissue engineering.[352] It is interesting to note that tissue engineering makes use of five dimensions to produce a three-dimensional product. The first dimension is length, the second is height, the third is breadth. In the tissue engineering arena, time forms the fourth dimension and force is the fifth.[353]

The amazing promise of this field lies in the potential of growing organs. In traditional organ transplantation, a high risk of rejection exists as HLA differs from person to person.[354] Where cells could be harvested from a person, grown into an organ or into tissue and re-implanted into the same person, this risk is eliminated. Organs may therefore be custom-engineered for a specific person.[355] Transplants are thus autologous and new tissue is grown making use of a person's own "old" tissue.[356]

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345 Tissue Engineering Pages (2012) "NIH definition of tissue engineering/Regenerative medicine" available online at http://www.tissue-engineering.net/index.php?seite=whatiste accessed 5/7/2012.
346 Langer R & Vacanti JP (1993) "Tissue engineering" *Science* 260(5110): 920-926.
347 For example: bone, cartilage, blood vessels, the bladder etc.
348 Science Daily (2012) "Tissue engineering" available online at http://www.sciencedaily.com/articles/t/tissue_engineering.htm accessed 12/11/2012.
349 See in general, Atala A & Lanza R (eds)(2001) *Methods of tissue engineering*.
350 Science Daily (2012) online.
351 This method has been employed since the time of Socrates. See Godbey AT & Atala A (2002) "*In vivo* and *in vitro* systems for tissue engineering" *Annals of the New York Academy of Sciences* 961: 1-26.
352 Side JD (2002) "Tissue engineering and reparative medicine" *Annals of the New York Academy of Sciences* 961: 1.
353 Godbey & Atala (2002) 4.
354 As previously explained in footnote 324 *supra*, HLA antigens are a major factor in histocompatibility.
355 Halley D (2009) "Growing organs in the lab" *Singularity Hub* available online at http://singularityhub.com/2009/06/08/growing-organs-in-the-lab/ accessed 7/7/2012. See also Andrews W (2009) "Grow your own replacement part" *CBS Evening News*, 6 February available online at

Engineering may have therapeutic applications, such as organ and tissue growth, as well as diagnostic applications. In therapeutic applications the tissue is grown either inside or outside of the body and transplanted into the patient. Diagnostically, the tissue is created *in vitro* and is then used for testing drug metabolism and uptake, toxicity and pathogenicity.[357] Tissue engineering research includes various fields, *inter alia* biomaterials,[358] cells[359] and stem cells.[360]

Tissue engineering consists of eight individually identifiable essential elements. These elements are listed and briefly discussed here:[361]

1. Cells. A number of different cell sources are being investigated for the purposes of tissue engineering including adult stem cells, adult differentiated cells, embryonic and fetal cells, cells generated by nuclear transfer and *ex vivo* manipulated cells;[362]
2. Signalling. Cells respond to their extracellular environment by sensing a chemical signal or physical stimulus which is transmitted to the cell's nucleus to trigger the expression or repression of certain genes. This in turn regulates cell division, migration, differentiation and apoptosis;[363]
3. Extracellular matrix. The extracellular matrix, abbreviated as ECM, is what confers physical, mechanical and functional properties to organs and tissues.[364] Insoluble signals and factors provided by the ECM interact with soluble signal and mechanical forces and this then promotes cell adhesion, division, migration and differentiation. An intimate link exists between cell signalling and adhesion. For this reason, the materials used in ECMs or bioscaffolds are of great importance;[365]

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http://www.cbsnews.com/stories/2008/02/06/eveningnews/main3799803.shtml?tag=;contentBody accessed 7/7/2012.
[356] CNN Health (2006) "Doctors grow organs from patient's own cells" available online at http://articles.cnn.com/2006-04-03/health/engineered.organs_1_bladder-cells-spina-bifida?_s=PM:HEALTH accessed 5/7/2012.
[357] Tissue Engineering Pages (2012) online.
[358] Biomaterials may be understood as including materials which provide physical and chemical cues which are designed to direct the organisation, differentiation and growth of cells during the process of forming functional tissue.
[359] This includes enabling methods for proliferation and differentiation of cells, the acquiring of the appropriate source of cells and immunological manipulation.
[360] Engineering in this regard uses stem cells from various sources and includes research wherein cells are isolated, derived or cultured.
[361] Side (2002) 2.
[362] These cells may be either autologous (self-donation); allogeneic (nonself, same species); xeogeneic (animal or other species).
[363] Apoptosis is cell death and may be defined as "a genetically determined process of cell self-destruction that is marked by the fragmentation of nuclear DNA, is activated either by the presence of a stimulus or by the removal of a stimulus or suppressing agent, is a normal physiological process eliminating DNA-damaged, superfluous, or unwanted cells (as immune cells targeted against the self in the development of self-tolerance or larval cells in amphibians undergoing metamorphosis), and when halted (as by genetic mutation) may result in uncontrolled cell growth and tumor formation-also referred to as programmed cell death." See Merriam Webster Online (2012) "Apotosis" available online at http://www.merriam-webster.com/medical/apoptosis accessed 23/1/2012.
[364] For example, strength of bone and elasticity of skin.
[365] Godbey & Atala (2002) 4.

4. Design principles. The needs of the patient who will undergo treatment are the first and foremost considerations regarding the design of engineered organs and tissues;
5. Vascular assembly.[366] This means that the engineered tissue or organ must be supplied with sufficient blood in order to provide necessities such as oxygen;[367]
6. Bioreactors. Prior to engineering, a decision must be made regarding whether tissue will be engineered inside or outside of the body. In some instances an extracorporeal assist or external device, such as a bioartificial liver or kidney, may be preferable;
7. Storage and translation. This relates to the changes cells may undergo when frozen. For this reason, vitrification[368] is preferred to preserve three-dimensional structures as it does not actually freeze the cells but rather makes them "glassy;"[369] and
8. Host remodelling and immune response. This is an inevitable and beneficial stage of the engineering process. Remodelling is a pivotal part of development during life and tissues or organs may change with age, disease and species. In other words, the natural changes which may occur in the human body must be taken into account in the process of engineering. Remodelling could also have an impact on the immune response of the body towards the engineered tissue or organ.[370]

Major advances in biomaterials, stem cells, growth and differentiation factors and biomimetic environments[371] have led to an opportunity to fabricate tissue by making use of a combination of extracellular matrices,[372] cells and other biologically active molecules. According to Doctor Atala, three developments are of importance: firstly, the creation and design of suitable biomaterials; secondly, the relative ease whereby organs may now be grown outside of the human body and the thirdly, the new fabrication techniques which mimic the vasculature of organs.[373] Tissue engineering is therefore likely to revolutionise health care as it enables restoration, maintenance and enhancement of tissues and organs. For the purposes of this thesis, tissue engineering in two forms is discussed. Firstly, extracellular matrixes or bioscaffolds and secondly tissue and organ printing.

[366] "Vascular" means that it is related to blood vessels.
[367] Suggested further reading, Hirschi KK, Skalak TC, Peirce SM & Little CD (2002) "Vascular assembly in natural and engineered tissues" *Annals of the New York Academy of Sciences* 961: 223-242 and Heinke J, Patterson C & Moser M (2012) "Life is a pattern: Vascular assembly within the embryo" *Frontiers in Bioscience (Elite Edition)*: 2269-2288.
[368] Vitrification is a procedure wherein a substance is transformed into glass by a process of rapid cooling. See Brockbank KGM, Walsh JR, Song YC & Taylor MJ (2003) "Vitrification: Preservation of cellular implants" in Ashammakhi N & Ferretti P (eds) *Topics in tissue engineering*: 1.
[369] Godbey & Atala (2002) 7.
[370] Side (2002) 7.
[371] Biomimetics is the study of the structures and functions of biological systems.
[372] This is more commonly referred to as a "scaffold."
[373] Hill (2011) online.

5.1 Bioscaffolds

Bioscaffolds, scaffolds or extracellular matrix (ECM) is "any substance produced by cells and excreted to the extracellular space within the tissues, serving as a scaffolding to hold tissues together and helping to determine their characteristics."[374] In other words, it is a three-dimensional (3D) mould, cast or base which lays the groundwork or structure on which or from which tissues and organs develop. This structure may be implanted into a human body in order to repair or replace damaged tissues and organs.[375] Cells are implanted, a process also referred to as "seeded," into this structure which is capable of 3D tissue formation. These scaffolds play an important role in mimicking the natural milieu of the tissue which is sought to be grown and allows cells to influence their own microenvironments. These scaffolds serve to fulfil the following purposes:

1. Allow for a surface on which the cells may attach and migrate;
2. They deliver and retain cells and biochemical factors;
3. They enable diffusion of vital nutrients and expressed products; and
4. They modify the behaviour of the cell phase by exerting certain mechanical or biological influences.

This branch of tissue engineering developed from 2D tissue growth. The 2D approach was found manually laborious and the eventual yield was about a tenth of what is possible using microcarriers. Researchers made use of microcarrier platforms to develop culturing HES cells on the surface of small, solid particles in 3D suspension systems. As research progressed, iPS cells were used along with cylindrical microcarriers in stirred vessels, referred to as spinner flasks, and twice-daily changes of the culture medium. This resulted in 20-fold expansion of the cells, as microcarrier-based cultures provided a larger surface area for cell growth.[376]

According to the father of tissue engineering, Dr Atala, tissue building may be broken down into four levels of complexity from the simplest to the most difficult.[377] Firstly, flat structures, for example skin, which is comprised of one cell type; secondly, tubes, such as blood vessels or urethras, consisting of two cell types; thirdly, hollow non-tubular organs, for example the bladder and stomach, both of which have more complex functions and structures; and lastly,

[374] The Free Medical Dictionary (2009) "Extracellular matrix" available online at http://medical-dictionary.thefreedictionary.com/extracellular+matrix accessed 11/12/2012.
[375] See in general, Ma PX (2004) "Scaffolds for tissue fabrication" *Materials Today* 7(5): 32.
[376] PhysOrg (2012) "Inducing stem cells to become different cell types efficiently now possible using a three-dimensional platform" available online at http://phys.org/news/2012-12-stem-cells-cell-efficiently-three-dimensional.html accessed 2/12/2012.
[377] Gallagher J (2012) "Will we ever grow replacement hands?" *BBC News*, 21 March available online at http://www.bbc.co.uk/news/health-16679010 accessed 3/12/2012.

solid organs such as the heart, kidneys or liver which all consist of various cell types and perform intricate and complex functions.

5.1.1 Method

Blood is extracted by apheresis,[378] or in the case of solid tissue, minced and digested with enzymes trypsin or collagnese which removes the extracellular matrix[379] which holds the cells. The cells are then free floating and may be extracted[380] by bulk method such as centrifuge.[381] The cells are then grown in culture for five to seven weeks[382] after which they are seeded onto the scaffold.[383] Scaffolds may be created in two ways: from natural or synthetic materials. Natural scaffolds are those which have been "created" by using an organ from an animal or a deceased person's donated organ.[384] This requires a process referred to as "decellularisation" and "recellularisation."[385] The donated or animal organ is chemically stripped of all cells as well as the muscular and vascular tissue, leaving only a semi-translucent decellularised scaffold behind. The decellularised scaffold is then recellularised by applying coats of stem cells layer by layer. The scaffold excretes chemical signals which allow the stem cells to specialise into the various necessary tissues of the organ.[386] For synthetic scaffolds, a natural substance such as collagen may be used.[387] Synthetic scaffolds may also, and more commonly, be created from certain polyesters such as PLA. PLA is a polyactic acid which degrades within the human body to form lactic acid which is then easily and naturally removed from the body. Such synthetic

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[378] Apheresis is "withdrawal of blood from a donor, with a portion (plasma, leukocytes, platelets, etc.) being separated and retained and the remainder retransfused into the donor." See The Free Medical Dictionary (2009) "Apheresis" available online at http://medical-dictionary.thefreedictionary.com/apheresis accessed 11/11/2012.
[379] The extracellular matrix or ECM is the part of tissue which provides structure thereto and it is the defining feature of connective tissue.
[380] Halley (2009) online.
[381] *Ibid*. A centrifuge is "a machine using centrifugal force for separating substances of different densities, for removing moisture, or for simulating gravitational effects" according to Merriam Webster Online (2012) "Centrifuge" available online at http://www.merriam-webster.com/dictionary/centrifuge accessed 11/11/2012.
[382] Halley (2009) online.
[383] Stem cells from the eventual recipient of the organ or tissue are then used to repopulate the scaffold and this creates a functioning, autologous organ. See Fight Aging (2003) "Stem cells, regenerative medicine and tissue engineering: Creating recellularised organs" available online at http://www.fightaging.org/archives/2003/11/stem-cells-regenerative-medicine-and-tissue-engineering.php accessed 7/7/2012.
[384] Fiore K (2010) "AASLD: Human cells grown on animal liver scaffolds" available online at http://www.medpagetoday.com/MeetingCoverage/AASLD/23073 accessed 7/7/2012.
[385] See in general, Rowel A (2011) "How to grow a new lung" *Discover Magazine*, 27 January available online at http://discovermagazine.com/2010/nov/13-how-to-grow-a-new-lung/#.UPF_IG8U-8A accessed 7/7/2012.
[386] Saenz A (2009) "Stem cells used to grow hearts" *Singularity Hub* available online at http://singularityhub.com/2009/06/23/stem-cells-used-to-grow-hearts-cool-new-pics-and-vid/ accessed 7/7/2012.
[387] Willerth SM & Sakiyama-Elbert SE (2008) "Combining stem cells and biomaterial scaffolds for constructing tissues and cell delivery" *StemBook* available online at http://www.stembook.org/node/450 accessed 7/7/2012. See also Pang Y & Greisler HP (2010) "Using a type 1 collagen-based system to understand cell-scaffold interactions and to deliver chimeric collagen-binding growth factors for vascular tissue engineering" *Journal of Investigative Medicine* 58(7): 845-484.

polyester scaffolds may be created by Particulate-leaching techniques, fibre bonding, solvent casting, gas foaming or phase separation or emulsification.[388] As with natural scaffolds, the synthetic scaffold is coated with stem cells, layer by layer. After the scaffold has been thoroughly coated and the cells placed in the correct positions, the "organ" is placed in a bioreactor, which mimics the conditions inside the human body, and allowed to "bake" for a period of two weeks. Eventually the scaffold will be implanted into a human recipient and as the scaffold is absorbed into the body and excreted by natural methods, the cells will remain in place.

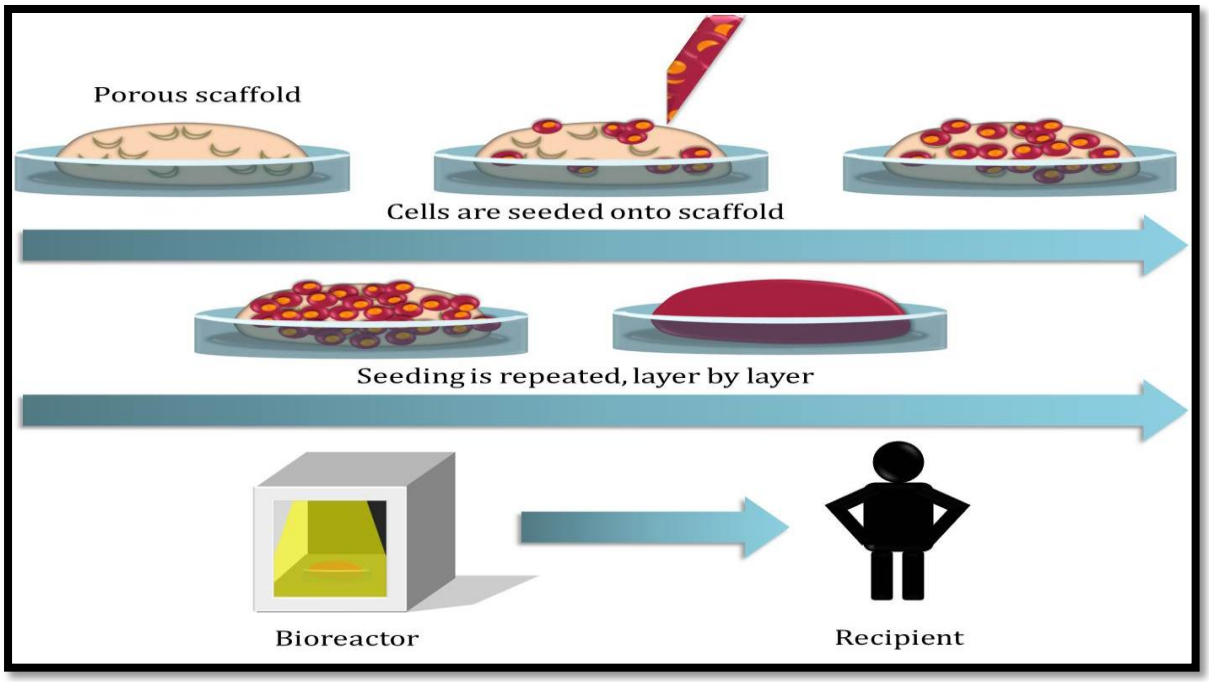

Figure F: Organ bioscaffolding

Scaffolds must, however, meet certain criteria to achieve the goal of tissue growth. Firstly, the scaffold must be highly porous and must possess the accurate pore size in order to facilitate seeding of the cells as well as diffusion of cells and nutrients throughout the entire structure.[389] Secondly, the scaffold must preferably be suitably biodegradable. This is important as it enables absorption by the surrounding tissue and eliminates the need for surgical removal at a later stage.[390] The rate of degradation must, however, coincide with the rate of tissue formation.

The materials from which scaffolds are created are crucial to the success of this technique. Not only the chemical properties of the material, but also the physical properties, such as the surface

[388] Ma (2004) 35. See in general, Mikos AG & Temenoff JS (2000) "Formation of highly porous biodegradable scaffolds for tissue engineering" *EJB Electronic Journal of Biotechnology* 3(2): 2-4 for an in-depth explanation of these techniques.
[389] Mikos & Temenoff (2000) 2. This is achieved by creating a highly porous foam which is large enough to encourage the cells to penetrate the pores. This further allows for nutrient and waste exchange between the cells.
[390] Scar tissue formation may play an important role in host remodelling and immune response. See Side (2002) 7.

area, are essential.[391] It has been found that in order to enable the cells to maintain tissue-specific functions after implantation, a substrate material is required which aids the cells in organisation. This means that biocompatibility is essential to the success of the procedure. Additional factors to be taken into account are the mechanical properties of the scaffold as it must not collapse and the material must be easily sterilisable.[392]

An issue still facing tissue engineering is the need for more complex functionality. Also engineered tissue lacks an initial blood supply which renders implantation very difficult as cells struggle to obtain the necessary oxygen and nutrients required to survive or properly function.[393] Scaffolding as the classic engineering approach involves the use of rigid, solid scaffolds made from polyglycoloic acid and isolated cells.[394] The founding premise is that seeding cells in a bioreactor, placed on a porous and biodegradable scaffold will be sufficient to generate organs. Scaffolding is an amazing development and is already being used in therapeutic settings,[395] but there are, however, problems with this method of engineering:[396]

1. Seeding and penetration of cells is not very effective;
2. Organs consist of various different cell types and the need to place different cells in specified positions may present a barrier to scaffold design;
3. Solid, rigid scaffolds made from PLA are not optimal for use in contractile tissues[397] such as vascular and heart tubes; and
4. The absence of vascularisation.[398]

Bioscaffolding is clearly still in its experimental phase and will be subject to a process of trial and error. Legally and in context of this thesis, the importance of a protective and flexible consent format is therefore once again brought to light as it becomes clear that in light of the great uncertainty and still unproven efficacy of much of biotechnology, informed consent is not

[391] Mikos & Temenoff (2000) 1.
[392] This means that the material must not cause an unresolved inflammatory response or demonstrate extreme immunogenicity or cytotocicity. See Mikos & Temenoff (2000) 1.
[393] See in general, Elisseeff J & Ma PX (2005) *Scaffolding in tissue engineering*.
[394] Langer & Vancanti (1993) 920-926.
[395] Doctors led by Retik, the chief of Urology at the Boston Children's Hospital, took bladder biopsies from patients. The urothlial cells of the inner layer were then separated from the cells of the outer layer of muscle and put through a process of culture. The cells were next plaited into a sponge like, biodegradable scaffold made of a synthetic polymer and collagen which is shaped like a bladder. The scaffold is then incubated for a seven week period after which surgeons graft the new bladder or sections thereof into the patient's damaged bladder. See Ward L (2009) online. Also, a synthetic trachea was grown using a scaffold built from porous polymer and tissue which was grown from the patient's own cells in a bioreactor. See Van Mensvoort K (2011) "First lab-grown organ transplant" *Next Nature* available online at http://www.nextnature.net/2011/07/first-lab-grown-organ-transplanted/ accessed 7/7/2012.
[396] Boland, Mironov *et al*. (2003) 498.
[397] This is tissue which has the ability of voluntarily or involuntarily contracting such as the heart muscle.
[398] Supplying blood and oxygen to the tissues and organs.

sufficient. Bioprinting may be able to offer a solution to the scientific problems however. For this reason, it is important now to discuss printing of tissues and organs.[399]

5.2 Bioprinting[400]

Bioprinting, also referred to as tissue or organ printing, may be defined as "the use of printing technology to deposit living cells, extracellular matrix (ECM) components, biochemical factors, proteins, drugs and biomaterials on a receiving solid or gel substrate or liquid reservoir."[401] Another description of tissue and organ printing which illustrates a further element thereof states that is may be defined as "layer-by-layer additive robotic biofabrication of three-dimensional functional living macrotissues and organ constructs using tissue spheroids as building blocks."[402] The benefits of tissue printing include the following:[403]

1. Simplicity of use;
2. Printing enables researchers to generate geometrically well-defined scaffolds in a rapid and inexpensive manner which makes use of ceramics and polymers as well as other cell stimulating factors which provide support and incubation for seeded cells;
3. It makes the generation of replicas of spatially and temporally well-controlled complex structures possible; and
4. 3D complexity may be achieved by multilayer printing.

The greatest benefits of organ and tissue printing are, however, the elimination of immune rejection, since the patient's own stem cells are used, and the fact that tissue and organs may be resized on a computer model prior to being printed in order to better suit the patient. This means that printed organs may be used for adult and child therapy.[404] For these reasons organ printing may be seen as the new emerging enabling technology paradigm which illustrates the tissue engineering approaches inspired by developmental biology[405] and solid scaffolding.[406]

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[399] See in general, Norotte C, Marga FS, Niklason LE & Forgacs G (2009) "Scaffold-free vascular tissue engineering using bioprinting" *Biomaterials* 30: 5910.
[400] See in general, Wilson WC & Boland T (2003) "Cell and organ printing 1: Protein and cell printers" *The Anatomical Record Part A* 272A: 491-496. See in general, Mironov V, Reis N & Derby B (2006) "Review: Bioprinting: A beginning" *Tissue Engineering* 12: 631.
[401] Tasoglu S & Demirci U (2013) "Bioprinting for stem cell research" *Trends in Biotechnology* 31(1): 10.
[402] Mironov, Visconti *et al*. (2009) 2164. See also Jakab K, Damon B, Neagu A, Kachurin A & Forgacs G (2006) "Three-dimensional tissue constructs built by bioprinting" *Biorheology* 43: 509.
[403] Tasoglu & Demirci (2013) 10.
[404] As mentioned above, organs grown on scaffolds cannot be used for children as the recipient must be grown to adult size.
[405] See in general, Marga F, Neagu A, Kosztin I & Forgacs G (2007) "Developmental biology and tissue engineering" *Birth Defects Research Part C: Embryo Today: Reviews* 81: 320.
[406] Mironov, Visconti *et al*. (2009) 2164-2174.

5.2.1 Methods

Operating in a manner similar to a 3D printer, live cells are capable of being layered to create the structure of an organ. These cells bond with one another naturally as well as spatially arrange themselves.[407] This process makes use of modified commercial inkjet printers where cell suspensions are placed in printer cartridges[408] and a computer controls[409] the printing pattern.[410] In the same manner as a normal printer is able to deposit different colour inks, organ printing allows researchers to specify where to place differing cell types.[411] As with normal printing ink, paper and a printer are required.[412] A printer was designed which is able to place cells in the position that mimics the cell's position in an organ.[413]

"Bioink" is comprised of spherical cell aggregates[414] and for this reason the spherical aggregate droplets are prepared with special compositions. If one were to think of ink in terms of normal printing and bioink in organ and tissue printing, the composition of the spherical aggregates may be explained in that "single-colour" printing makes use of one cell type while "multi-colour" printing makes use of various different types of cells and sometimes also includes ECMs.[415] Embryonic stem cells or embryoid bodies derived from HES cells are ideal for bioprinting due to the uniformity of the size and shape of the embryoid bodies.[416] Cells are referred to as bioink since liquid droplets fuse on contact in the course of the structure formation post printing.

"Biopaper" is made from biocompatible ECM-containing hydrogels[417] and mimic the normal environment of cells.[418] Cells are layered onto a "sheet" of hydrogel made from sugars and water which provide the structure with support and define any gaps and holes within the structure.

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[407] Thomas C (2012) *Organ printing* presented at the BME 281 Biomedical Engineering Seminar II, University of Rhode Island, Rhode Island, 19 September. Hereafter referred to as the BME seminar.
[408] Also referred to as "biocartridges." See Organ Printing (2012) "Process" available online at http://www.organprinting.missouri.edu/www/process.php accessed 10/11/2012.
[409] See in general, Neagu A, Kosztin I, Jakab K, Barz B, Neagu M, Jamison R & Forgacs G (2006) "Computational modeling of tissue self-assembly" *Modern Physics Letters* B 20: 1217.
[410] Tasoglu & Demirci (2013) 10.
[411] Halley (2009) online.
[412] Jakab K, Neagu A, Mironov V & Forgacs G (2004) "Organ printing: Fiction or science" *Biorheology* 41(3-4): 372. See also Mironov V, Kasyanov V, Drake C & Markwald RR (2008) "Organ printing: Promises and challenges" *Regenerative Medicine* 3(1): 93-103.
[413] Boland, Mironov *et al*. (2003) 498.
[414] Jakab, Neagu *et al*. (2004) 372. Speroidal cell aggregates are clusters of combined cells which are shaped like a sphere but are not perfectly round. Microtissues and tissue spheroids are living materials which possess certain measurable, evolving and potentially controllable compositions, biological properties and materials. See also Forgacs G & Kosztin I (2010) "Cellular aggregates under pressure" *Physics* 3: 43.
[415] Organ Printing (2012) "The bioink" available online at http://www.organprinting.missouri.edu/www/bioink.php accessed 10/11/2012.
[416] Tasoglu & Demirci (2013) 14.
[417] Jakab, Neagu *et al*. (2004) 372. See also Organ Printing (2012) "Understanding and employing multicellular self-assembly" available online at http://organprint.missouri.edu/www/ accessed 29/12/2012. Hydrogel may also be referred to as "smartgel." See Halley (2009) online.
[418] Organ Printing (2012) "The biopaper" available online at http://www.organprinting.missouri.edu/www/biopaper.php accessed 10/11/2012.

This is easily removed from the tissue or organ after it has cured and has reached maturation.[419] The gels used are nontoxic, biodegradable, thermo-reversible gels which are prepared as fluids at 20°C and within minutes become gel above 32°C[420] by a process of crosslinking.[421] These gels are used as the "paper" on which the tissue or organs structures are to be printed.

The cells, seen as the "ink," are placed in altered inkjet printer cartridges which have been cleaned out and filled with a mixture of live human cells.[422] After the first layer has been printed, further layers may be printed by simply dropping another layer of gel onto the already printed surface[423] and then dropping another layer of cells on top of the new gel layer. Layer by layer the cells are printed atop one another until a 3D organ is created.[424] Genes do not, however, create the shapes and forms of cells: they are created by physical mechanisms and processes.[425] Tissue spheroids placed closely together undergo tissue fusion as part of tissue self-assembly.[426] The self-organising properties of cells will then guarantee that the cells are correctly arranged in the final tissue or organ structure.[427] After the organ has been printed, it is placed in a bioreactor to be grown.

[419] Thomas (2012) BME seminar.
[420] Tissue liquidity is essential to constructing organ structures. Foty and co-workers measured the tension of a number of embryonic tissues. The tensions values of the tissues were consistent with the mutual engulfment behavior of the embryonic tissues. The more cohesive tissue with higher surface tension sorted out the less cohesive tissue with lower surface tension. See in this regard Jakab, Neagu *et al*. (2004) 372. This could be illustrated by making use of analogy. In the same manner as water and oil do not mix, cells and tissues with different surface tensions will remain separate. See also Norotte C, Marga F, Neagu A, Kosztin I & Forgacs G (2008) "Experimental evaluation of apparent tissue surface tension based on the exact solution of the Laplace equation" *Europhysics Letters* 81: 46003.
[421] Organ Printing (2012) "The biopaper" online.
[422] Halley (2009) online. See also Mironov V, Prestwich G & Forgacs G (2007) "Bioprinting living structures" *Journal of Materials Chemistry* 17: 2054.
[423] Boland, Mironov *et al*. (2003) 498.
[424] Halley (2009) online.
[425] Organ Printing (2012) "Understanding and employing multicellular self-assembly" online. See also Jakab K, Damon B, Marga F, Doaga O, Mironov V, Kosztin I, Markwald R & Forgacs G (2008) "Relating cell and tissue mechanics: Implications and applications" *Developmental Dynamics* 237: 2438 and Neagu A, Jakab K, Jamison R, & Forgacs G (2005) "Role of physical mechanisms in biological self-organization" *Physical Review Letters* 95: 178104.
[426] Mironov, Visconti *et al*. (2009) 2164-2174. See also Jakab K, Norotte C, Marga F, Murphy K, Vunjak-Novakovic G & Forgacs G (2010) "Tissue engineering by self-assembly and bio-printing of living cells" *Biofabrication* 2: 1.
[427] Jakab, Neagu *et al*. (2004) 372.

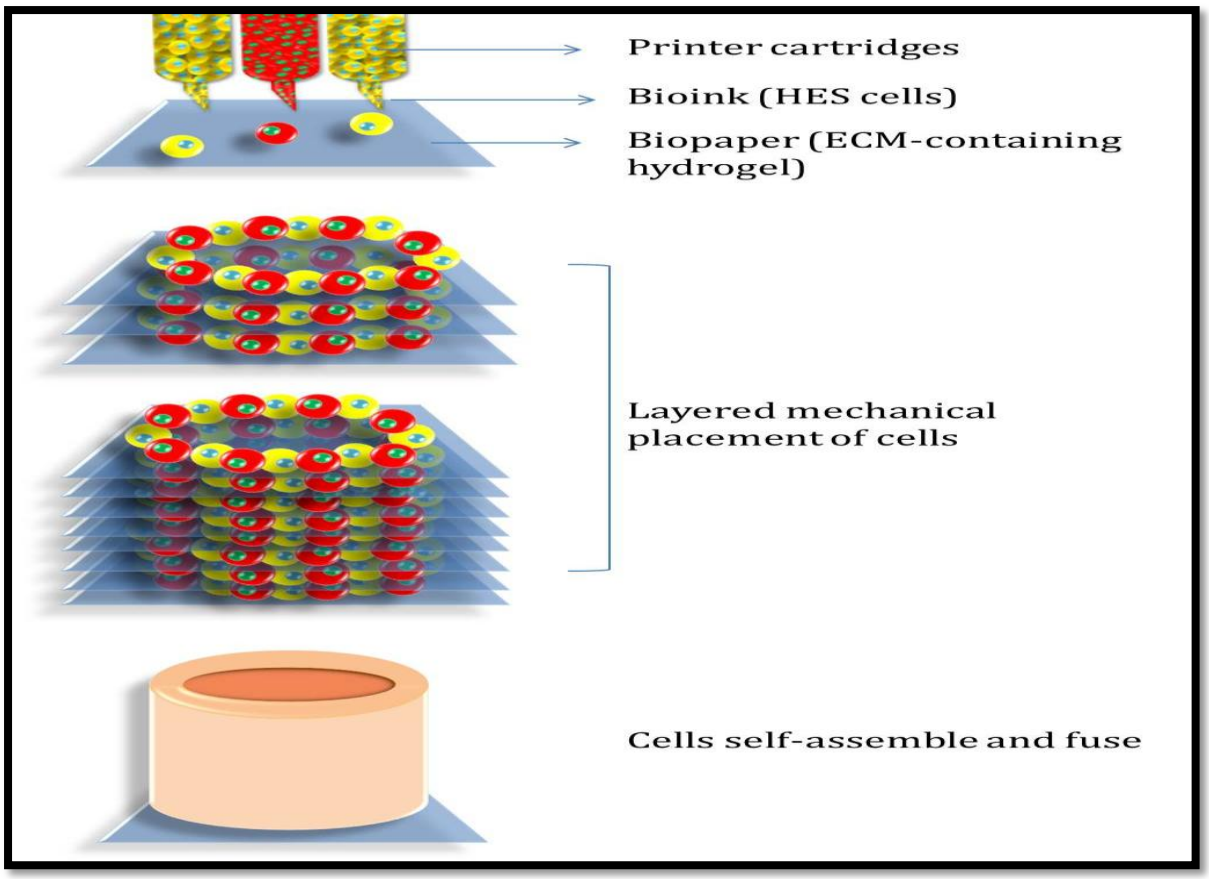

Figure G: Bioprinting

Bioreactors are "devices in which biological and/or biochemical processes develop under closely monitored and tightly controlled environmental and operating conditions."[428] This means that a bioreactor supports a biologically active environment. The functions of a bioreactor include the following:[429]

1. Maintaining 3D tissue construct viability;[430]
2. Serving as a tool for cell seeding and tissue construct assembly;
3. Dynamic tissue conditioning;[431]
4. Tissue maturation biomonitoring; and
5. Packaging, storage, tissue preservation and transportation.[432]

After the tissue or organ has been created in this manner, it may then be transplanted into a patient by surgical means. It must, however, be mentioned that although tissue and organ

[428] Martin I, Wendt D & Heberer M (2004) "The role of bioreactors in tissue engineering" *Trends in Biotechnology* 22(2): 80. See in general, Mironov V, Kasyanov V, Markwald RR & Prestwich GD (2008) "Bioreactor-free tissue engineering: Directed tissue assembly by centrifugal casting" *Expert Opinion on Biological Therapy* 8: 143.
[429] Organ Printing (2012) "Bioreactors" available online at http://www.organprinting.missouri.edu/www/biorector.php accessed 10/11/2012.
[430] See also Martin, Wendt *et al*. (2004) 80.
[431] See also *idem* 83.
[432] See also *idem* 81.

printing is a wondrous new development, it is not without problems. Challenges facing bioprinting are connected to cell viability and long-term functionality after the printing process such as any apoptotic effects.[433]

6 CONCLUSION

Stem cells, in short and despite the various question marks and challenges and taboos surrounding this science, provide hope of miracles. They have the potential to cure the currently incurable and to replace what has been damaged or that which is malfunctioning. In order to be able to fully pursue this wonder however, this technology must be knowledgably and strictly regulated in an informed manner. For this to be possible, the legislator and regulator must possess insight into a rapidly changing scientific and medical world. As was mentioned in the introduction to this chapter, the ignorance of knowledge will not solve the problems caused by such knowledge. A basic grasp of the science and applications thereof is therefore pertinent.

This chapter set out to explain the most essential concepts of stem cells and at the very least, illustrate the enormously uncertain, science-fictionesque, experimental nature of stem cells and related biotechnology. This is necessary in regard to the hypothesis of this thesis which argues that stem cell science and therapy are currently still so novel and unpredictably uncertain, that treatment interventions border or overlap with research studies. Working from this premise, it will become clear in the course of this thesis that neither informed nor broad consent will offer sufficient legal protection and should not be accepted as the format of obtaining consent.

In summary, it was explained that stem cells, be they embryonic or adult stem cells or cells derived from another source, are undifferentiated, unspecialised cells possessing the ability to renew and proliferate indefinitely and that this gives the cells the ability to develop into any and all cells in the human body. Due to this ability, stem cells may be divided into a hierarchy of totipotent, pluripotent, multipotent, bipotent and uni- or monopotent stem cells. In other words, as a cell becomes more specialised by way of differentiation, its plasticity decreases from totipotency to unipotency. Not all human cells, however, have the capacity to differentiate in any manner and so it was explained that differentiated adult cells, undifferentiated cells found in

[433] Tasoglu & Demirci (2013) 10. Another method of generating cell-encapsulated hydrogel droplets is called the valve-based droplet ejection method. This technique entails ejecting cell-encapsulating hydrogel droplets onto a surface drop-on-demand. The size and number of the cells in a single droplet and the number of these droplets are controlled by the valve opening and the duration and frequency of actuation. See in general, Demirci U & Montesano G (2007) "Cell encapsulation droplet vitrification" *Lab Chip* 7: 1428-1433; Song YS, Adler D, Xu F, Kayaalp E, Nureddin A, Anchan RM, Maas RL & Demirci U (2010) "Vitrification and levitation of a liquid droplet on liquid nitrogen" *Proceedings of the National Academy of Sciences of the United States of America* 107: 4596-4600 and Moon S, Kim Y, Dong L, Lombardi M, Haeggstrom E, Jensen RV, Hsiao L & Demirci U (2011) "Drop-on-Demand single cell isolation and total RNA analysis" *PLoS ONE* 6: e17455.

small numbers amongst differentiated cells and tissues, with decreased plasticity, are capable of being utilised by making use of processes such as SCNT and induced pluripotency. These cells are therefore effectively dedifferentiated to a potency state equal to that of an HES cell.

Following the explanation of what stem cells are, where they come from and how they are created, the issue of what happens after the cells have been found and withdrawn was addressed. To this end, banking practices and techniques were discussed as this is a branch of stem cell related science which will surely enjoy much attention and focus in future. This is where stem cell technology moves from outside the laboratory and scientific community into the public realm and where stem cells, to a great extent, become demystified and actual. Banking entails the storage and management of material removed from the human body and the keeping thereof in a frozen state until a stage where it might be used for therapeutic, research, training or educational purposes. In the course of this chapter, the banking of cord blood, adipose tissue and peripheral blood was discussed. Also tissue engineering in the form of bioscaffolding and bioprinting was explained. Bioscaffolding is the growing of tissues and even organs by combining biotechnology and engineering principles. Bioprinting is the method of three-dimensionally printing tissues. Tissue engineering makes stem cells even more concrete, in a very literal sense, and will therefore play a pertinent role in the development of stem cell related technology as it develops.

Stem cells are, as has been illustrated in this chapter, the holy grail of medical therapies and treatments in years to come. These cells are, however, complex in nature and have spawned various debates and arguments and questions in numerous different milieus. Not the least of which is the legal world which asks how this miraculous science will and could be regulated in an acceptable fashion. This then brings us back to the main subject of this thesis: the regulation of stem cells in general and more specifically how, in a litigious society and considering the fast development and still vast uncertainties surrounding stem cells, consent may be obtained for any research or treatment or a combination thereof. This thesis, after all, hypothesises that stem cell therapy is tantamount to research involving human subjects due to the unproven efficacy thereof. This means that a patient is more than a mere patient in a traditional medical treatment setting and broadens the regulatory environment which might be applicable to the matter at hand. In a bid to answer the questions which may arise in this context, it therefore becomes necessary to investigate the concept of consent in more detail. The following chapter will thus study the history and development of this concept in order to contribute to an understanding thereof in a wider sense. In the course of this thesis, this wide understanding of consent is then fine-tuned and ultimately refined to dynamic consent.

PART B
CONSENT IN SOUTH AFRICA

A certain amount of understanding of the science of stem cells was established in Part A of this thesis and Part B now focusses on the law and the focal inquiry of this thesis, namely consent. The purpose of Part B of this thesis is an inquiry into the status or understanding of consent in South Africa. Part B flows from understanding consent in abstraction to a concrete knowledge of the manifestation of consent in South Africa.

In order to gain insight into consent, Part B commences with an abstract, broad examination of discussing the history, rationale and development of consent. Following the winnowing methodology used throughout this thesis, a narrower discussion of consent will then be undertaken with reference to case law, the South African Constitution and law of obligation. Consent will become even more concrete as a *capita selecta* of relevant aspects is then discussed including consent in medical law, the requirements of valid consent and the traditional distinction between therapy and research and its relation to consent practices.

The hypothesis of this thesis argues that neither informed nor broad consent is sufficient where novel medical therapy borders on human subject research and this is elaborated on in Part B. This is achieved by analysing who may obtain and provide consent, when it may be obtained, what consent should include and in what format. A dynamic model of consent is introduced for the first time. Attention is further focussed and the quintessential aspects relevant to this thesis are investigated in the final section of Part B which offers a whittled examination of the South African regulatory environment pertaining to stem cells, both treatment and research aspects, and consent. The National Health Act of 2003 and the Regulations created under the Act are therefore dissected in the final chapter of Part B. It will also be argued that the Act and Regulations already permit or support a different format of consent such as dynamic consent.

Part B of this thesis consists of the following:

CHAPTER 3 - A BRIEF BACKGROUND OF AND INTRODUCTION TO CONSENT
CHAPTER 4 - SPECIFIC ASPECTS OF CONSENT
CHAPTER 5 - THE NATIONAL HEALTH ACT, ACT 61 OF 2003

CHAPTER 3
A BRIEF BACKGROUND OF AND INTRODUCTION TO CONSENT

1 INTRODUCTION

The previous chapter of this thesis served a dual purpose in that it entailed firstly, an explanation of the most essential concepts surrounding stem cells and secondly, illustrated the still greatly experimental nature of biotechnology in general. As a certain amount of understanding of this science has now been established, attention may be turned towards the law and the focal inquiry of this thesis, namely consent. In order to understand this concept, this chapter therefore seeks to provide an understanding and insight into the doctrine of informed consent. This chapter therefore entails a discussion of the history, rationale and development of consent in general as well as a narrower examination of some of these aspects as found in South African law by referencing South African case law, the Constitution of the Republic and the law of obligation.

Informed consent has a history that is diverse and difficult to reduce to a linear narration of events or practices.[1] It is, however, clear that it has developed in close relation to the physician-patient relationship. An examination of the history of consent may inform our understanding thereof and deepen our grasp of the current theory and practice.[2] It stretches from the fifth or sixth century to the fall of paternalism in the second half of the twentieth century in a medical context, while in research its history lies in the recent past as near as the Second World War. Some of the documents that best illustrate this recent history and novelty of the concept include the Nuremberg Code and the Declaration of Helsinki.[3]

Apart from the historical development of informed consent, it is also rooted in multiple disciplines, most prominently in moral philosophy and in law. While the legal concept of informed consent is pragmatic in nature, the philosophical principle lies in respect for autonomy and the individual concerned. In context of moral philosophy consent may be described as autonomous authorisation. On this subject a wide variety of literature was

[1] Ten Have HAMJ & Jean MS (eds)(2009) *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, principles and application*: 124.
[2] O'Shea T (2011) "Consent in history, theory and practice" *Essex Autonomy Project: Green Paper Technical Report*: 1.
[3] See chapter 6 *infra* for a discussion of these international instruments.

consulted which led to the identification of nine rationales underlying the concept of informed consent. These include protection, prevention of abusive conduct, trust, self-ownership, non-domination, personal integrity, justice, beneficence and autonomy. Autonomy is considered the most important of these rationales and is discussed in detail in the course of this chapter. It does, however, face certain challenges which are also discussed here.

Although philosophy provides a reasoned and systematic approach to informed consent, it is unable to provide mechanical solutions or definitive procedures for decision making and this is where the law steps in and makes itself heard. As a starting point for the discussion of consent as found in law, the focus of this chapter thus tapers from the broader examination of the concept as an abstract to the practical application thereof in South African case law. The reason for this is that more often than not, the true functioning of the law is observed by the courts. To this end the cases of *Stoffberg v Elliot*, *Lymbery v Jefferies*, *Rompel v Botha*, *Ex Parte Dixie*, *Esterhuizen v Administrator Transvaal*, *Dube v Administrator Transvaal*, *Verhoef v Meyer*, *Richter v Estate Hammann*, *Phillips v De Klerk*, *Castell v De Greef*, *Oldwage v Louwrens*, *Christian Lawyers' Association v National Minister of Health and Others* and the most recent case of *Sibisi NO v Maitin* are discussed in chronological order.

The National Health Act is discussed in great detail in the course of this thesis and is therefore not discussed here. The South African Constitution is, however, examined in context of consent with reference to stem cells. This is of great importance as the incorporation of a provision explicitly mandating informed consent is the ultimate recognition of the concept within South African law. It may be mentioned here that the National Health Act thus personifies the statutory mandate of consent created by but also giving substance to section 12(2)(c) of the Constitution.[4]

The Constitution is discussed against the background knowledge that it applies to all law and is binding on the legislature, judiciary and the Organs of State and in a vertical and horizontal manner. Also, the State has a progressive mandate to realise the rights as contained in the Bill of Rights. Section 12 is specifically discussed as it is relevant to this study due to the fact that it not only guarantees freedom and security of the person but it also provides for the right to bodily as well as psychological integrity.

Two questions are raised and answered in connection to section 12, namely whether the use of the word "their" renders proxy consent unconstitutional and to what extent the interests of

[4] Nienaber A (2013) "Consent to research by mentally ill children and adolescents: The implications of chapter 9 of the National Health Act" *South African Journal of Psychiatry* 19(1): 19.

society outweigh those of an individual if at all. In order to answer these questions, the section 36 limitation clause and principles of constitutional interpretation are used.

The Constitution however is a rather new development in South African law. The common law as a more established and older branch of law and legal source has long since contained the idea of consent as found in the law of obligation's law of contract and of delict. In closing, this chapter therefore gives some attention to consent as found in these branches of the law.

2 A BRIEF HISTORY OF INFORMED CONSENT

The history of informed consent is culturally diverse, manifold and somewhat controversial and can therefore not be reduced to a linear narration of social events or practices.[5] The evolution of informed consent, however, is clearly closely connected to the physician-patient relationship and developed as such throughout the centuries and reflects the changes in the manner in which this relationship has been regarded.[6]

The idea that a patient ought to have a say in medicine did not develop before the fifth or sixth century in ancient Greece. At this time, medicine was part of religion and it was believed that illness and disease were caused by evil spirits or as punishment for not conforming to the orders of the gods. Medicine therefore was practised by specially initiated persons and was considered a form of magic. This meant that the commands of the healer were unquestionable and complete obedience was a precondition of successful healing.[7]

The first explicit concept of medical ethics is found in parallel to the emergence of a more materialistic understanding of disease. This coincides with the time of Hippocrates and his secular and empirically-based approach to medicine. According to the Hippocratic Oath, physicians had the duty to act in a manner that benefitted patients and avoided doing harm.[8] This, however, did not include a duty to disclose and it was in fact at times considered harmful to be outspoken about an illness, treatment or prognosis. Physicians were considered as knowing best and this way of thinking, referred to as paternalism, prevailed in Western

[5] Ten Have & Jean (eds)(2009) 124. See also Osman H (2001) "History and developments of the doctrine of informed consent" *The International Electronic Journal of Health Education* 4: 41-47. See in general, O'Shea (2011) 1-35.
[6] See in general, Kettle NM (2002) *Informed consent: Its origins, purpose, problems and limits* (Graduate School thesis unpublished, University of South Florida). See also Waddington I (1975) "The development of medical ethics-A sociological analysis" *Medical History* 19: 36-51 and Bennett M (2000) "A history of informed consent" *Ventana Centre for Psychotherapy* available online at http://www.ventanacenter.com/articlesbackground_007.htm accessed 30/9/2013.
[7] Ten Have & Jean (eds)(2009) 124.
[8] See chapter 6 paragraph 3.3.1.1 *infra* for a detailed discussion of the Hippocratic Oath.

countries until the second half of the twentieth century.[9] The social emancipation movements of the 1960's and 1970's slowly changed this as physicians began to recognise that a patient is responsible for the final authorisation of matters related to their bodies and individualism and autonomy became more relevant.[10] Obtaining informed consent for treatment is, however, only one part of the history of consent.

The other, more controversial and recent part of this history relates to systematic medical research involving human volunteers. This type of research became important with the introduction of scientific and experimental methodology in clinical medicine and the establishment of hospitals during the second half of the nineteenth century. Research was often done without the consent of the subject in the service of medical progress and science. After it came to light that some subjects had suffered injury, the ethics of human experimentation became a political and public issue and this led to the first set of regulations regarding non-therapeutic research and consent in Germany in 1900.[11]

It was not until the terrifying acts committed by Nazi doctors became known and the subsequent publication of the Nuremberg Code in 1947, that it became widely recognised that physicians and researchers have a moral duty to obtain consent. This was emphasised by the Declaration of Helsinki in 1964[12] and since then the scientific community has continually revised ethical principles in order to ensure the proper treatment of patients and research participants.[13] Today, the doctrine of informed consent is widely accepted in clinical practice and biomedical research and is a central tenet of ethical and legal regulations regarding human subject research.[14] The acceptance and development of this doctrine in South African law is well documented in case law and is discussed in the course of this chapter. At this juncture, however, the thinking behind consent must be discussed and as such the following section of this chapter examines the rationales underlying informed consent.

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[9] Ten Have & Jean (eds)(2009) 125.
[10] Fox RC (1990) "The evolution of American bioethics: A sociological perspective" in Weisz G (ed) *Social science perspectives on medical ethics*: 201-217.
[11] Vollmann J & Winau R (1996) "Informed consent in human experimentation before the Nuremberg Code" *British Medical Journal* 313(7070): 1445-1449.
[12] See chapter 6 *infra* for a discussion of these international instruments.
[13] Escobende C, Guerrero J, Lujan G, Ramirez A & Serrano D (2007) "Ethical issues with informed consent" *Elizabeth Zubiate* 8: 1.
[14] Nijhawan LP, Janodia MD, Muddukrishna BS, Bhat KM, Bairy KL, Udupa N & Musmade PB (2013) "Informed consent: Issues and challenges" *Journal of Advanced Pharmaceutical Technology & Research* 4(3): Table 1. For a detailed discussion of the history and development of informed consent see Faden RR & Beauchamp TL (1986) *A history of informed consent*: 23-101. Suggested further reading, Brody BA (2001) "A historical introduction to the requirement of obtaining informed consent from research participants" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 7-14.

3 PHILOSOPHY OF INFORMED CONSENT

The history of informed consent is rooted in multiple social and disciplinary contexts which include inter alia the health profession, the law, moral philosophy and social and behavioural sciences.[15] Law and moral philosophy have become the most prominent of these fields but differ since the law's approach to informed consent springs from pragmatic theory whereas moral philosophy springs from the principle of respect for autonomy and focuses on the patient or subject.[16] In terms of the law, a physician has a duty to inform patients and a duty to obtain their consent and thus focuses almost exclusively on clinical and research contexts. Moral philosophy on the other hand, examines rather the autonomous choices of patients and subjects. Morally speaking, informed consent may therefore be defined as "an autonomous authorisation by a patient or subject."[17]

In the course of this section of this thesis, attention is given to the philosophy underlying informed consent. Faden and Beauchamp[18] identified three primary moral concepts which are used to justify informed consent, namely justice, beneficence and autonomy. However, upon reading broader literature, six other rationales may be identified. The nine arguments listed below may be made to substantiate the existence of informed consent and will be discussed in greater detail:[19]

1. Protection;
2. Prevention of abusive conduct;
3. Trust;
4. Self-ownership;
5. Non-domination;
6. Personal integrity;
7. Justice;
8. Beneficence; and
9. Autonomy.

Each individual rational or philosophy will be discussed. Attention is given firstly to the lesser known rationales of protection, abuse prevention, trust, self-ownership, non-domination and

[15] Faden & Beauchamp (1986) 3.
[16] *Idem* 4. See in general, Foster C, Herring J, Melham K & Hope T (2013) "Intention and foresight-From ethics to law and back again" *Cambridge Quarterly of Healthcare Ethics* 22(2): 86-91.
[17] Faden & Beauchamp (1986) 3.
[18] *Idem* 5-16.
[19] Stanford Encyclopaedia of Philosophy (2011) "Informed consent" available online at http://plato.stanford.edu/entries/informed-consent/#IdeCon accessed 13/10/2015. Suggested further reading, Doyal L (2001) "The moral importance of informed consent in medical research: Concluding reflections" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 309-317.

personal integrity after which justice and beneficence are discussed. This builds to autonomy which is then discussed in the most detail.

3.1 PROTECTION

Protection of health and welfare, may perhaps be the simplest rationale behind the requirement of informed consent. This requirement protects patients and research subjects from the overzealous attempts of physicians and scientists to promote their own agendas and often incorrect notions of what is best for the patient or research subject. Although such a pragmatic and instrumental rationale seems utilitarian,[20] various moral doctrines endorse the duty to protect patients and research participants. According to John Stuart Mill and advocates of his utilitarian philosophy, patients and research participants are the best judges of their own good and are far more conscious of its protection than physicians and scientists.[21] This argument cannot, however, substantiate why informed consent must be honoured as various questions remain unanswered. For example, why should consent stand in the following instances?

1. Where the patient or participant are not experts and are biased and ignorant in their decision making;
2. Where patients or participants knowingly jeopardise their own protection and health based on moral or religious grounds such as a Jehovah's Witness who refuses a life-saving blood transfusion;
3. Where health is not at stake such as in proposed research on stored human material; and
4. Where public health may be benefitted by certain experiments and research.

3.2 PREVENTION OF ABUSIVE CONDUCT

A second rationale is that informed consent forms a wall against deontological[22] offences such as assault, deceit, exploitation and coercion.[23] This rationale renders informed consent instrumentally valuable in preventing certain acts, but not in preventing the outcomes, such as

[20] Utilitarianism is the theory found in normative ethics which holds that the moral action is the one which maximizes utility. In other words, it is the belief that a morally good action is the one which would offer help to the greatest number of people.
[21] Mill JS (1990) "On liberty" in Warnock M (ed) *Utilitarianism/On Liberty/Essay on Bentham*: 215.
[22] Deontology is an approach to ethics which centres on the "rightness" or "wrongness" of actions rather than the "rightness" or "wrongness" of the consequences thereof. In other words, the means do not have to be justified by the ends. Consequentialism on the other hand holds that the consequences of certain actions are the only measure of its "rightness" or "wrongness." In other words, the ends must justify the means.
[23] Manson NC & O'Neill O (2007) *Rethinking informed consent in bioethics*: 75. See also Jackson E (2010) *Medical law: text, cases and materials*: 169.

health setbacks. The abuse prevention argument also faces specific challenges. The first is that this rationale does not account for the full extent of the physician or researcher's duties in context of informed consent. In other words, it does not account for instances where a clinician has fully explained a proposed course of action to a patient yet the patient misunderstands.[24] The second challenge is that the abuse prevention rationale is not fully founded in deontology or in consequentialism.[25]

3.3 TRUST

In recent years, various philosophers have opined that informed consent may be important in general as it may be able to restore the element of trust.[26] This rationale looks towards the future and points out the importance of ongoing public trust in caretakers and medical institutions. As any violation of informed consent endangers this trust, such violations are to be avoided. This argument may perhaps justify the requirement of informed consent even in low-risk and low-impact scenarios. It also underscores the honesty required by physicians and researchers. Furthermore, this rationale justifies the necessity of consent even where it would never become known that this requirement may have been violated. However, this argument may be faulted by taking into consideration that an infringement of a person's informed consent is an infringement on the person themselves and not only some potential future person or society. It is the consenting individual who must have trust in informed consent.

A second version of the trust rationale is backward-looking and defends informed consent as a manifestation of honouring the trust which a patient has placed in a physician as part of the fiduciary relationship between them. This version, however, accounts only for pre-existing relationships.[27]

[24] Beauchamp TL, Faden R & Childress JF (2008) *Principles of Biomedical Ethics*: 118. See also Stanford Encyclopaedia of Philosophy (2011) "Informed consent" online.
[25] See footnote 22 *supra*. Suggested further reading, Lidz CW, Meisel A, Zerubavel E, Carter M, Sestak RM & Roth LH (1985) *Informed consent: A study of decisionmaking in psychiatry*: 3-9.
[26] O'Neill O (2002) *Autonomy and trust in bioethics*: 145. See also Bok S (1995) "Shading the truth in seeking informed consent for research purposes" *Kennedy Institute of Ethics Journal* 5(1): 1-17.
[27] Joffe S & Truog RD (2010) "Consent to medical care: The importance of fiduciary context" in Miller FG & Wertheimer A (eds)(2010) *The ethics of consent*: 352. See in general, Pellegrino ED & Thomasma DC (1993) *The virtues in medicine*: 65-78.

3.4 SELF-OWNERSHIP

The rationale of self-ownership holds that individuals have certain property rights in themselves and their bodies. This argument is in line with the consent theory of John Locke that individuals are free agents and every man has property in his person.[28] In terms of this rationale, individuals as owners of property may therefore make decisions regarding the use of such property.

This argument, however, does not explain why, even where the human body is the possession of the individual concerned, physicians are obliged to disclose information and ensure understanding on the part of the patient or research participant prior to an intervention. There are no property rights to information after all. The notion of self-ownership may therefore be used against coercing physicians and researchers to provide patients and subjects with information as such coercion may violate their self-ownership right to interact as they please.

3.5 NON-DOMINATION

The non-domination rationale is normally associated with sexual ethics and political philosophy and is seldom relied upon in bioethics. The basis of this argument is that no person may be under the arbitrary control of another and that informed consent provides protection from such control. Medical procedures have the potential of becoming hierarchical due to the dependency of patients on the physician as well as the inherent knowledge gap between them.[29] This rationale may therefore be useful regarding consent to research participation as the knowledge gap between the participant and researcher is even greater and specific measures apply regarding the withdrawal of informed consent. This rationale however offers not explanation as to why physicians or scientists who are closely monitored in order to prevent abusive practices are still obliged to allow the patient or subject to make decisions.

3.6 PERSONAL INTEGRITY

The second to last rationale behind informed consent relates to the need to protect the patient's sense of personal integrity. Gerald Dworkin attempted to explain the importance of personal integrity by stating that a person's body is irreplaceable and inescapable.[30] Ronald Dworkin also

[28] Locke J (1988) "Second treatise on civil government" in Laslett P (ed) *Locke: Two treatises of government*: 305.
[29] Levine RJ (1988) *Ethics and regulation of clinical research*: 121-122.
[30] Dworkin G (1988) *The theory and practice of autonomy*: 113.

weighed in on the subject and stated that a precautionary line is required which makes the body inviolable.[31] It should, however, be guarded against that this rationale is extended to the extreme. Such normative continuum might for example be where it constitutes a violation of personal integrity both to touch a person in a sensitive area and to touch their shoes.[32] It is suggested that although integrity does play an important role in autonomy, the law has a better grasp of the concept and may better protect it.[33]

3.7 JUSTICE

In terms of the justice framework, every civilised society is a venture of cooperation which is structured by moral, legal and cultural principles which define the terms of such cooperation. It holds that a person has been treated in accordance to justice where such person has been treated according to what is fair, owed and due.[34]

"Just," in terms of this rationale, may be understood in a broad and nonspecific sense and refers to that which is generally justified or morally right. Literature relating to the subject of informed consent often refers to justice where it is believed that a person's legal or moral rights have been violated in some way. Justice is then also related to social justice concerns of research and medical treatment and often the justice rationale is utilised in the analysis of using vulnerable groups and whether or not autonomous consent is sufficient in order to override issues based on approaching such persons to participate in the first place.[35]

Justice, however, does not share the prominence of beneficence and autonomy as the primary moral and conceptual issues arising from the concept of informed consent are not justice-based and do not confront the issues of social justice head on.

3.8 BENEFICENCE

Patient welfare is the goal of health care and therapeutic research, in that clinical therapies are aimed at the promotion of health by curing or preventing disease. This value of benefit is

[31] Dworkin R (1983) "Comment on Narveson: In defence of equality" *Social Philosophy and Policy* 1: 24-40.
[32] Thomson JJ (1990) *The realm of rights*: 207-208.
[33] See in general, Pieterse M (2008) "The interdependence of rights to health and autonomy in South Africa" *South African Law Journal* 125(3): 553-572.
[34] Faden & Beauchamp (1986) 14.
[35] See in general, Prinsen L (2010) *An analysis of the proposed regulatory framework for the procurement and distribution of stem cells* (LLM thesis unpublished, University of Pretoria): 127-128 for a discussion of justice concerns in stem cell research. See also Assiter A (2005) "Informed consent: Is it sacrosanct?" *Research Ethics Review* 1(3): 77-83.

therefore often viewed as the core foundation in medical and now also, in bioethical thinking. Welfare then also connects the four elements of beneficence namely:[36]

1. Evil or harm must not be inflicted;
2. Evil or harm must be prevented;
3. Evil or harm must be removed; and
4. Good must be done or promoted.

It is interesting to note that these elements may be divided into passive non-maleficence as expressed in the first element, which provides a negative duty to avoid doing harm and active beneficence as expressed in elements two to four, which provide for a positive duty to offer help.[37]

However, beneficence is not firmly sanctioned by either moral or ethical theory and in concrete cases these elements of beneficence break down. In general, the principle of beneficence requires that intentionally doing harm must be avoided and must further the interests of others by preventing or removing harm. This leads to two concerns regarding this rationale for informed consent. The first holds that the principle of beneficence must not be restricted to a single party, even in the context of the patient-physician or subject-researcher relationship. This then begs the question to whom beneficence is owed. The second issue concerns the extent to which this principle generates duties and it has been argued that beneficence creates ideals and not duties.[38]

As is evident from the above discussions, no clearly sufficient rationale for informed consent which holds water has been provided. The last rationale to be discussed is that of autonomy and it is suggested that this is the superior argument and philosophy underlying informed consent. For this reason, it will be discussed in rather more detail than the previous rationales and will be discussed in various contexts throughout the course of the thesis.

4 AUTONOMY

Informed consent as a primary precondition to an intervention is based on the recognition that all persons have unconditional worth. This in turn is founded on the principle of respect for autonomy.[39] Autonomy therefore needs to be discussed in greater detail.

[36] See in general, Frankena WK (1973) *Ethics*: 47.
[37] Faden & Beauchamp (1986) 10.
[38] *Idem* 11.
[39] Nienaber (2013) 19.

Discussions regarding the relationship between the physician and patient, or then the subject and scientist, have changed in the last few decades and focus has shifted from the duty of discloser to the quality of understanding. Autonomy as the predominant justification of informed consent saw its ascent during the 1970's through influential work by Ruth Faden, Tom Beauchamp and James Childress.[40]

According to philosophers of action,[41] autonomy is the governance over one's own agency which means acting in accordance to the law that one sets for oneself. In terms of this, the autonomous individual therefore acts freely and according to their self-chosen plan. Although autonomy initially seems like a promising ground for the requirement of informed consent, fully informed consent involves various elements of autonomy. Beauchamp and Childress opine that personal autonomy encompasses, minimally at least, self-rule free from controlling interferences from others and from limitations such as an inadequate understanding which hampers making meaningful choices.[42] Further limits may include deceit and other threats to voluntariness. An autonomy-based justification of informed consent therefore offers an explanation as to why personal autonomy matters and why it is given such a high status.

Instrumentally speaking, there seems to be a concordance between the care of an individual and his values which is the key to continued satisfaction and cooperation with medical personnel. Philosophically speaking, autonomy is inherently good for individuals. Firstly, self-rule is central to a good life as it makes individuals less self-alienated and more worthy of praise for virtuous decision making. Secondly, autonomous decisions promote an individual's ultimate goals which define how well their lives are led.[43] This argument however is not without its weaknesses. It may be said that fully autonomous decisions are at times bad for the individual such as when it leads to torturous deliberation, embarrassing mistakes and pressure to make a certain decision. In fact, it would seem that neither informed consent nor autonomous choices make the life of the individual better in any theory of well-being[44] and if they did indeed, it might be absurd to claim that informed consent and autonomy are distinct or supersede the principle of beneficence.[45]

[40] Stanford Encyclopaedia of Philosophy (2011) "Informed consent" online.
[41] Action refers to agency.
[42] Beauchamp, Faden *et al*. (2008) 100-101.
[43] Dworkin (1988) 113.
[44] Desire satisfaction, hedonic state and objectives list theory. Suggested further reading, Heathwood C (2006) "Desire satisfaction and hedonism" *Philosophical Studies* 128: 539-563 as well as Dolan P & White MP (2007) "How can measures of subjective well-being be used to inform public policy?" *Perspectives on Psychological Science* 2(1): 71-85. See also Selingman MPE & Royzman E (2003) "Happiness: The three traditional theories" available online at https://www.authentichappiness.sas.upenn.edu/newsletters/authentichappiness/happiness accessed 16/5/2016.
[45] Stanford Encyclopaedia of Philosophy (2011) "Informed consent" online.

Differently viewed from a Kantian perspective, autonomy commands awe and reverence, whether it is good for individuals or not. Numerous literary sources cite Kant's *Formula of Humanity*[46] as establishing the duty of physicians to respect autonomy. An example of the Kantian approach is also evidenced in the work of Alan Donagan who states that recognition of every human being as possessing a unique human dignity and thus being an end in moral relation to others, means that no human being may be interfered with in pursuing their conception of happiness in the manner they deem best.[47]

O'Neil disagrees with the idea of autonomy as understood by bioethicists, which resemble Kant's autonomy theory, and opines that it bears an affinity rather to the work of Mill regarding individuality and spontaneity.[48] Mill was a utilitarian and associated with well-being so closely that he concluded that an individual is sovereign over himself, his body and mind.

However, it seems that grounding informed consent in autonomy is not as simple as hoped, regardless of whether bioethicists relate to Kant or Mill or whether autonomy is good for an individual. Four difficulties arise and are discussed shortly.[49] The first issue is that not all acts which seemingly violate informed consent are in conflict with autonomous decision making. An example might be where a patient makes a certain decision due to a misunderstanding on his behalf of the medical information. In other words, informed consent practices might be sound but rest on a different justification than autonomy. Secondly, in context of informed consent, some acts are deemed to be more reprehensible than other. For example, an unconsented-to breast examination is deemed more reprehensible than scrutinising a mole on a person's face. The difference and therefore the degree of reprehensibility thus seem to be related to the sensitivity of the area of the body. The principle of autonomy, however, would make no distinction and view either scenario as interference into the person's autonomy in equal measure. The third argument which might be made is that violating personal autonomy may have a positive impact on autonomy. Where one option falls away due to the violation of informed consent, other freedoms become available such as freedom from pressure to make use of a certain medical option.[50] Lastly, in considering a patient who has received fair treatment and a simple explanation of the proposed treatment and alternatives which they were able to comprehend but do not comprehend, presents a challenge to rooting informed consent in

[46] See in general, Korsgaard CM (1986) "Kant's formula of humanity" *Kant-Studien* 77(1-4): 183-202.
[47] See in general, Donagan A (1977) "Informed consent in therapy and experimentation" *Journal of Medicine and Philosophy* 2(4): 307-329.
[48] O'Neill O (2003) "Autonomy: The emperor's new clothes" *Aristotelian Society Supplementary Volumes* 77(1): 15. See also Mill (1990) in Warnock (ed) 135.
[49] Stanford Encyclopaedia of Philosophy (2011) "Informed consent" online.
[50] An example of this is euthanasia. See in general, Velleman JD (1992) "Against the right to die" *Journal of Medicine and Philosophy* 17(6): 665-681.

autonomy. The patient autonomously makes a decision and a lack of informed consent may therefore not be blamed for the consequences of said decision.[51]

Regardless of the above challenges, autonomy is still regarded as the foundation of the informed consent requirement. It is suggested that it is not the quality of the choice or the measure of autonomy which is relevant, but rather that a person was able to make such choice which is important.

Autonomy and the respect thereof is the most frequently mentioned moral rationale in informed consent literature as it is considered a principle rooted in liberal Western tradition regarding the importance of freedom and choices.[52] Historically speaking, autonomy comes from the Greek *autos*, meaning self and *nomos*, meaning rule of law. The terms "autonomy" and "respect for autonomy" are loosely associated with several other ideas such as privacy, self-mastery, voluntariness, free choice and accepting responsibility for those choices. In moral philosophy, autonomy has come to be understood as ruling of the self while remaining free from limitations imposed by others.

Patients and participants capable of deliberating their personal choices must be treated with respect and given the opportunity to make informed decisions regarding their treatment and participation in the research. This is in concordance with the *voluntas aegroti suprema lex* maxim, a supreme agreement, which refers to voluntary acceptance of treatment for illness and is indicative of the intrinsic worth and dignity of all people. This means that not only the autonomy of the patient or participant must be respected but also that of the physician or researcher. Due to this, a physician may refuse to administer a certain treatment should it conflict with the physician's conscience and the same applies to scientists in context of research.[53] A health care provider or researcher may, however, not misuse their freedom of conscience to exploit a patient or research participant, even where they do not personally agree with the choices of the patient or participant[54] and must still act in a courteous positive manner with patience and tolerance. Also, the autonomy of persons with diminished or impaired capacity must be respected and afforded special protection. [55]

[51] Miller & Wertheimer (eds)(2010) 85 & 95.
[52] Faden & Beauchamp (1986) 7. Some ethicists regard autonomy as the most important ethical principle, while others consider it one of many important principles. See in general, Foster C (2009) *Choosing life, choosing death: The tyranny of autonomy in medical ethics and law*: 57-112.
[53] Section 15 of the Constitution of the Republic of South Africa, 1996 also protects freedom of conscience.
[54] See in general, Department of Health's National Patients' Rights Charter 2007.
[55] Health Professions Council of South Africa (2008) "General ethical guidelines for health researchers" *Guidelines for good practice in the health care professions: Booklet 6*: 1.

The principle of respect for autonomy is the justificatory basis for the right to make autonomous decisions and this in turn makes provisions for specific autonomy related rights,[56] such as section 12(2)(c) of the South African Constitution as discussed below.[57] Although philosophy is able to provide a reasoned and systematic approach to informed consent, it is not able to provide mechanical solutions or definitive procedures for decision making. This is where the law becomes relevant and as such, will be discussed below in context of the history and development of informed consent. Due to factors such as constitutional development as well as civil and consumer rights movements,[58] the need for patients and research subjects to become involved in decision making became more apparent and slowly the move was made from paternalism[59] to autonomy and as such it was ultimately recognised in law either by incorporation into legislation or by way of case law.[60] The development of the concept of consent in case law must thus be discussed.

5 DEVELOPMENT OF CONSENT IN CASE LAW

As was mentioned at the onset of this chapter, consent has both moral philosophical and legal origins. The philosophical origins of consent have now been discussed and at this juncture we turn to the legal development of informed consent. Currently, there are a number of South African laws regulating aspects of consent such as the Mental Health Care Act,[61] the Children's Act[62] and the National Health Act.[63] Each of these Acts distinguishes between broad categories of persons and the relevant provisions in context of these persons will be discussed in the course of this thesis.[64] The National Health Act is also discussed in great detail in the course of this thesis and as such these Acts are not discussed in greater detail here.[65] The law, however, is not merely a collection of Acts and is more often than not shaped and created by the legal precedents set by courts. The development of informed consent in case law is thus an important

[56] Faden & Beauchamp (1986) 9.
[57] See in general, Pieterse (2008) 553-572.
[58] Carstens P & Pearmain D (2007) *Foundational principles of South African medical law*: 875.
[59] Paternalism is "a conflict between beneficence and autonomy, such as when a practitioner ignores the choice that a patient makes because he or she feels that more good can be done by the practitioner's judgment." See The Free Dictionary (2010) "Paternalism" available online at http://medical-dictionary.thefreedictionary.com/paternalism accessed 16/8/2010. See in general, Stanford Encyclopaedia of Philosophy (2010) "Paternalism" available online at http://plato.stanford.edu/entries/paternalism/ accessed 16/8/2010 and McKinstry B (1992) "Paternalism and the doctor-patient relationship in general practice" *The British Journal of General Practice* 42(361): 340-342. Suggested further reading, Bailey-Harris R (2000) "Patient autonomy-A turn in the tide?" in Freeman M & Lewis ADE (eds) *Law and medicine: Current legal issues*: 127-140.
[60] See in general, Oosthuizen H & Verschoor T (2008) "Ethical principles becoming statutory requirements" *South African Family Practice* 50(5): 36-40.
[61] Mental Health Care Act, Act 17 of 2002.
[62] Children's Act, Act 38 of 2005.
[63] National Health Act, Act 61 of 2003.
[64] See chapter 4 paragraph 5.1.2 *infra*.
[65] See chapter 5 *infra*.

aspect of examination in defining and understanding the doctrine of informed consent.[66] In the following section of this chapter, South African case law pertaining to consent will be discussed to illuminate the development of this doctrine in law. This discussion takes place in a chronological manner in order to best indicate the rising and evolving nature and understanding of the concept.

5.1 STOFFBERG V ELLIOT (1923)[67]

The concept of autonomy, specifically in relation to failing to obtain consent, was considered in the case of *Stoffberg v Elliot*.[68] Mr Stoffberg, a patient of Dr Elliot, had been diagnosed with cancer of the penis and was scheduled to undergo treatment therefore. He was admitted to hospital for an operation but during said operation it was discovered that the cancer was much more advanced than Dr Elliot had expected. Upon regaining consciousness Mr Stoffberg discovered that his penis had been amputated. Since this was a clear departure from the consent given by Mr Stoffberg prior to the operation, an action for damages due to assault was instituted.

Watermeyer J held that in terms of the law, every person has certain absolute rights and these rights include the right of absolute security of the person. He further held that by entering a hospital a person does not waive this absolute right nor does he submit himself to whatever surgical treatment the attending physician thinks necessary. A person remains a human being and retains his rights of control and disposal of his own body. As a result of this, any operation in the absence of expressly obtained consent is an unlawful interference in a person's right of security and control of their body.[69]

5.2 LYMBERY V JEFFERIES (1925)[70]

The patient *in casu* suffered from fibrosis[71] of the uterus for which her doctor recommended X-ray treatment. She, however, sustained severe burns and as a result thereof suffered a great deal of pain and discomfort. In an action for damages the patient contended that the doctor had been negligent in that he had failed to warn her that the treatment was dangerous and might cause

[66] See in general, Van Oosten FFW (1991) *The doctrine of informed consent in medical law*: 33-48.
[67] *Stoffberg v Elliot* 1923 CPD 148.
[68] *Stoffberg v Elliot supra*.
[69] See in general, Naidoo P (2003) "Informed consent in South Africa" *South African Radiographer* 41(2): 8-10. See also Oosthuizen H (2010) "The use of stem cells in therapeutic procedures: Legal and ethical aspects" *Obiter* 31(3): 594-605.
[70] *Lymbery v Jefferies* 1925 AD 236.
[71] This is a thickening and scarring of connective tissue.

pain and suffering and that her ovaries would be damaged to such an extent that she would be rendered sterile. The doctor had, however, informed that patient that she would no longer have menstrual periods. Wessels JA reasoned that as a middle-aged woman, she must have understood that this would mean that she would no longer be able to bear children.

On the other hand, the learned judge accepted that the physician has a duty to inform a patient that an intervention is dangerous and may result in death or that it may cause pain and that the physician must then obtain the consent of the patient.[72] The *Stoffberg* case[73] also stated that a physician has a duty to inform.

Regarding the scope of information to be disclosed, Wessels JA remarked that a physician is called upon to give some general idea of the consequences but need not meticulously point out all the complications which may arise.[74]

5.3 ROMPEL V BOTHA (1953)[75]

Support for the view that a medical practitioner is obliged to disclose the nature and consequences of a treatment to a patient may be found in *Rompel v Botha*.[76] In brief, the facts of the case are that Rompel received shock treatment for a neurotic condition but was not informed of the possible dangers or serious results thereof. The Court held that a physician has at least the duty to inform patients of the serious risks involved in a proposed treatment.

The *Rompel* case is unreported but was largely discussed in the *Esterhuizen* case.[77] Neser J comprehensively discussed the scope of information which a physician must disclose to a patient. It was held that there was no doubt that a physician who intends to operate on a patient must obtain the patient's consent. The patient must be informed of the serious risks involved. Where these dangers are not pointed out to the patient, consent to the treatment is not consent

[72] *In casu* there was evidence to suggest that as a rule the recommended treatment was not dangerous and that the burns suffered by the patient were a rare occurrence and often due to an idiosyncrasy of the patient themselves. It was thus held that a duty to disclose such information could not be imposed on the doctor.
[73] *Stoffberg v Elliot supra*.
[74] See in general, Slabbert MN (2004) "Parental access to minors' health records in the South African health care context: Concerns and recommendations" *Potchefstroom Elektroniese Regsblad/Potchefstroom Electronic Law Journal* 2: 1-21.
[75] *Rompel v Botha* 1953 (T) (unreported).
[76] *Romple v Botha supra.*
[77] *Esterhuizen v Administrator Transvaal* 1957 (3) SA 710 (T).

in reality, as it is consent without knowledge of the possible injuries. This case therefore elaborated on the scope of the information to be provided in comparison to *Lymbery*.[78]

5.4 EX PARTE DIXIE (1950)[79]

Mr Dixie was detained in a mental hospital under section 18(1) of the 1916 Mental Disorders Act.[80] *In casu* and in reference to surgery, Millin J held that an operation cannot be lawfully performed without consent of the patient and where the patient is not competent to give such consent, it should be given by a person who has authority over the incompetent person. The mere presence of the incapacitated person in a hospital does not warrant performing a major operation in the absence of consent. An intervention without consent will only be justified where it is urgently necessary and cannot be delayed, having due regard to the patient's interests.[81]

5.5 ESTERHUIZEN V ADMINISTRATOR TRANSVAAL (1957)[82]

Once again the failure to obtain consent formed the basis of the decision in the *Esterhuizen* case.[83] *In casu*, the patient was a ten year old girl who had developed a small nodule below her right ankle which she had injured and was causing her discomfort. Her father had consulted a doctor who treated the injury, excised the nodule and had it sent away for analysis. The analysis identified the nodule as a manifestation of Kaposi's Haemangiosarcoma.[84] The patient's mother was advised to take her for X-ray treatment to which both parents consented. She was subjected to superficial X-ray treatment after which her wound completely healed. However, three months later, new nodules appeared on both her feet as well as her right hand. Once again, she received X-ray treatment at the same hospital as before.

Four years later, she once again developed nodules on all her extremities. In the years that passed, her father had passed away and as her mother had remarried and moved away, she was living with her grandmother. Her mother instructed that she be taken to the same hospital to

[78] *Lymbery v Jefferies supra*. See in general, Swanepoel M (2011) "A selection of constitutional aspects that impact on the mentally disordered patient in South Africa" *Obiter* 32(2): 282-303. See also Naidoo P (2004) "Esterhuizen v Administrator, Transvaal: Case review" *South African Radiographer* 42(1): 7-8.
[79] *Ex Parte Dixie* 1950 (4) SA 748 (W).
[80] Mental Disorders Act, Act 38 of 1916. This section provided for the powers of a judge on consideration of reception orders and documents.
[81] See in general, Unknown (1950) "Law of persons" *Annual Survey of South African Law*: 67.
[82] *Esterhuizen v Administrator Transvaal supra*. See in general, Naidoo (2004) 7-8.
[83] *Esterhuizen v Administrator Transvaal supra*.
[84] This is a highly invasive, rapidly growing form of cancer.

receive treatment. At this point, a different physician took charge of the patient who concluded that the patient had a life expectancy of a year as the disease was rapidly progressing. He therefore administered radical X-ray treatment while fully aware of the consequences of such a course of action.[85] The patient and her mother, however, had no knowledge of these consequences, and in spite of having ample time to obtain consent, it was not considered necessary by the physician. Due to the radical treatment the patient's legs as well as right hand were amputated, as well as two fingers on her left hand which was also at risk of being removed in its entirety.

An action for damages on the grounds of assault was brought before the court. Bekker J stated that the later radical treatment was vastly different from the previous treatments and that consent was not constituted by the instruction to bring the patient to the hospital. This together with the absence of knowledge and appreciation on the part of the patient's mother meant that in no way was the necessary consent obtained in order to subject the patient to the treatment.[86]

5.6 DUBE V ADMINISTRATOR TRANSVAAL (1963)[87]

In *Dube*[88] the court showed that liability may be incurred where a patient is not provided with sufficiently clear and unambiguous information. *In casu*, the patient had contracted Volkmann's ischemia[89] after receiving treatment for a fractured arm which had been too tightly set in plaster of Paris. The hospital failed to warn the patient to return immediately should any abnormal symptoms appear. The patient reasonably believed or assumed that the persistent pain and swelling occurred in the ordinary course of healing and not that it was a sign of danger. Due to this, the court refused to accept the failure of the patient to return to hospital as contributory negligence.[90]

[85] These included that the patient would suffer severe irradiation of the tissue as well as ulceration; become disfigured or deformed as the growing bone would be permanently harmed in the treated areas and that the treated limbs would possibly have to be amputated.
[86] See in general, Slabbert (2004) 1-21. See also Naidoo (2004) 7-8.
[87] *Dube v Administrator Transvaal* 1963 (4) SA 260 (W).
[88] *Dube v Administrator Transvaal supra.*
[89] This is also known as Volmann's contracture and is a permanent flexion contraction of the hand and wrist which causes a claw-like disfiguration of the hand and fingers.
[90] See in general, McQuoid-Mason D (2008) "An introduction to aspects of health law: Bioethical principles, human rights and the law" *South African Journal of Bioethics and Law* 1(1): 7-10. See also McQuoid-Mason D (2010) "What constitutes medical negligence?" *SA Heart* 7(4): 248-251 and Otto SF (2004) "Medical negligence" *SA Journal of Radiology* 8(2): 19-22.

5.7 VERHOEF V MEYER (1975)[91]

Verhoef[92] was the first case to make use of the phrase "informed consent." This case is unreported and therefore the facts of the matter are only briefly relayed here. The patient underwent an eye operation. It was alleged by the patient that they had only consented to an operation on the right eye but that the left eye was also operated on, without consent. The plaintiff was, however, not able to prove their case on a preponderance of probabilities.[93] This matter was heard by the Appellate Division regarding a therapeutic operation and for this reason the word "eksperiment" or experiment must be understood as meaning "operasie" or operation.[94]

In defining "informed consent" Wessels JA with whom Trollip, Muller, De Villiers and Miller JJA concurred, stated as follows:[95]

> "Onder 'ingeligte toestemming' word eenvoudig verstaan dat die persoon wat die toestemming gee, weet waartoe hy toestem. Hy moet dus ten volle besef wat die eksperiment behels waartoe hy toestem. Hy moet in staat wees om die moontlike voordele daarvan te kan opweeg teen die moontlike nadele daarvan en hy moet ook in 'n posisie verkeer om die voor- en/of nadele van die normale gebruiklike behandeling of middel te kan opweeg teen die moontlike voor- en/of nadele van die onbekende middel of behandeling. Daar word eenvoudig maar net vereis dat die betrokke persoon wat sy toestemming verleen het in 'n posisie moes verkeer het om na 'n opweging en oorweging van alle moontlike faktore 'n besluit in hierdie verband te kon maak. Dit is nie nodig dat die pasiënt geskool moet word in alle fasette van die behandeling of middel nie of elke moontlike bekende gevaar hoe nietig en onwaarskynlik ook al nie. Dit is egter belangrik om daarop te let dat mens nie kan sê dat ons met 'ingeligte toestemming' te doen het waar die persoon wat die toestemming verleen het nie met alle basiese feite met betrekking tot die aangeleentheid vertroud was nie. As 'n pasiënt dus sy toestemming verleen het tot 'n eksperiment terwyl hy bv. nie ingelig is oor moontlike nadelige newe-effekte daarvan nie of nie verstaan waaroor die hele aangeleentheid gaan nie, sal sy toestemming nie beskou word as 'n regverdigingsgrond as dit bv. kom by 'n vervolging weens aanranding nie. 'n Pasiënt wat sy toestemming verleen het tot 'n eksperiment en wat in die duister verkeer het ten tyde van toestemming aangaande die wesentlike feite daarvan is in presies dieselfde posisie, in die oë van die reg, as die pasiënt wat geen toestemming hoegenaamd verleen het tot sodanige eksperiment nie."[96]

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[91] *Verhoef v Meyer* 1975 (T) and 1976 (A) (unreported).
[92] *Verhoef v Meyer supra*.
[93] Carstens & Pearmain (2007) 911 footnote and 914 footnote 273.
[94] Burchell JM (1978) "Non-therapeutic medical research on children" *South African Law Journal* 95: 205.
[95] *Verhoef v Meyer supra* as discussed in Burchell (1978) 205. The use of these words should not be confused with the clarification of the term "experimentation" as provided for in chapter 1 *supra*.
[96] This may be translated as: "Under 'informed consent' it is simply understood that the person giving consent knows what he is agreeing to. He must fully realize what the experiment involves to which he is giving consent. He should be able to weigh the potential benefits against the possible disadvantages and should be in a position to be able to weigh up the advantages and/or disadvantages of the normal customary treatment or cure against the advantages and/or disadvantages of the unknown drug or treatment. It simply requires that the person who gave his consent had been in a position to be able to undertake a weighing and considering of all possible factors and to come to a decision in this regard. It is not necessary that the patient should be trained in all aspects of the treatment or is aware of every known danger how insignificant and unlikely whatsoever. It is important to note that one cannot say that informed consent was present where the person who gave the consent was not familiar with all the basic facts relating to the matter. If a patient consented to an experiment while not informed of the possible adverse side effects for example or did not understand what the entire matter entailed, his consent shall not be regarded as a justification in the event of prosecution for assault. A patient who gave permission to an experiment and who was in utter darkness at such time regarding the material facts thereof, is in the same position, in the eyes of the law, as the patient who did not whatsoever consent to such experiment."

In other words, consent is only informed consent where a person understands what they are consenting to, have been fully informed of what the procedure entails and have been able to weigh up the possible benefits and risks which may normally occur in the course of the procedure and the decision to give consent is based hereon. It is absurd to argue that where a person has not been given the basic facts, informed consent has been obtained. According to Wessels JA, in the eyes of the law, a person who consents without the required information having been given to him is in the same position as a person who gave no consent whatsoever.

Burchell commented on this case and stated that in light of the decision reached, a patient must be informed of the likely risks involved in an operation which is a therapeutic procedure. He further opined that where a person, however, is subject to non-therapeutic procedures, they must be informed of all the known risks, be they likely or remote. Burchell motivates this by stating that it is only on this basis that consent serves as justification of a procedure from which the subject has not directly benefitted.[97] Where a procedure is experimental, Burchell continues, it may then also involve unknown risks and in such instances the subject must also be alerted of this possibility.[98]

5.8 RICHTER V ESTATE HAMMANN (1976)[99]

In *Richter*,[100] the patient, who was a young married woman, had fallen on the sharp edge of a chair which resulted in an injury to her coccyx. She first sought help from her family doctor who prescribed treatment which did not help. She then consulted with a second doctor who prescribed pain medication. Still unsatisfied she asked to be referred to Dr Hammann who was an experienced neuro-surgeon. He first recommended an epidural block containing saline and anaesthetic which was administered on the 7th of April 1972. The first round of treatment did not relieve her pain and Dr Hammann suggested a bilateral phenol block of the lower sacral nerves on an outpatient basis. On the 12th of April the first of the injections was administered to Richter's right side. The desired pain relief was achieved but the patient suffered the unfortunate consequences of loss of control over her bladder and bowel, loss of sexual feeling and loss of power in her right leg and foot.

Watermeyer J held in relation to the duty of a doctor to inform a patient of the possible dangers that a failure to disclose information may render the doctor liable for assault, but disclosing

[97] See chapter 4 paragraph 4 *infra* for more on the difference between therapeutic and non-therapeutic.
[98] Burchell (1978) 205.
[99] *Richter v Estate Hammann* 1976 (3) SA 226 (C).
[100] *Richter v Estate Hammann supra*.

information may also frighten the patient out of continuing with the procedure where the doctor knows that it is in the interest of the patient to be treated. In order to determine whether or not the doctor must incur liability, the test of the reasonable doctor in the same situation must be applied.[101]

The evidence in the case at hand indicated that the likelihood of the complications was very unusual and extremely rare and so the court held that the possibility of the complications was too remote to establish negligence.[102]

5.9 PHILLIPS V DE KLERK (1983)[103]

Mr Phillips, an electrical engineer, was injured in a collision while travelling. He was admitted to hospital where it was clear that he had sustained numerous fractures. He also contracted a lung infection and was kept in the intensive care unit of the hospital. Dr De Klerk approached the court with an urgent *ex parte* application authorising a blood transfusion to Mr Phillips as his wife was refusing such transfusion on religious grounds. She contended that as Jehovah's Witnesses they could not receive blood transfusions. The application was granted. Seven months later Mr Phillips brought an application to have the previous order set aside. He claimed that he had explicitly refused a blood transfusion after the collision and had instructed the hospital staff under no circumstances to administer a transfusion. This case thus dealt with a person's right to die and therefore the recognition of a person's autonomy to decide whether or not to submit to treatment.[104] As it turned out, no transfusion was administered and Mr Phillips thus felt vindicated.

In this case the court confirmed the principle of the patient's entitlement to self-determination and autonomy by recognising the right of a patient to refuse medical treatment.[105]

[101] See in general, Carstens & Pearmain (2007) 302-308 & 621-623. See also *Mitchell v Dixon* 1914 AD 519 and *Van Wyk v Lewis* 1924 AD 438.
[102] See in general, McQuoid-Mason (2008) 7-10.
[103] *Phillips v De Klerk* 1983 (T) (unreported). See Carstens & Pearmain (2007) 921.
[104] See Strauss SA (1991) *Doctor, patient and the law*: 5-7.
[105] Swanepoel (2011) 282-303.

5.10 CASTELL V DE GREEF (1994)[106]

The requirements of informed consent were introduced and imported into South African law in *Castell v De Greef*[107]and as such it is commonly regarded as the *locus classicus* in this regard.[108] For this reason much attention must be given to this case.

On the 7th of August 1989 the plaintiff[109] underwent a subcutaneous mastectomy.[110] The operation was performed by the defendant, a plastic surgeon, but was unsuccessful causing the plaintiff to sue for damages[111] as the plaintiff had suffered pain, embarrassment and trauma. The defendant had recommended a surgical procedure whereby as much breast tissue as possible would be removed while simultaneously reconstructing the plaintiff's breasts with silicone implants. After the plaintiff and her husband discussed the proposed procedure with the defendant, she decided to undergo the operation. During the operation tissue was removed and the areolas were repositioned by the process of transposition[112] as this method does not require the complete removal of the areola and therefore reduces the risk of necrosis.[113] The operation is high risk by nature since the removal of tissue results in a decrease in blood supply to the skin, areola and nipple. The more tissue a surgeon removes the less the risk of necrosis but the less effective the procedure is as a preventative measure against cancer.

Initially the operation was considered a success in that all seemed well. However, 36 hours after the procedure the defendant noticed that the left nipple had become discoloured which aroused concern regarding the blood supply. He expressed this concern to the plaintiff. The plaintiff further had a wedge-shaped area below the right areola which was pale in colour. There were also incision marks around both areolas. The defendant was called upon by the plaintiff's husband and accused of removing the areolas but he explained that he had only moved them. Upon the plaintiff's discharge from hospital on the 13th of August, the condition of her left areola and nipple had worsened and had turned black in colour while the area below her right areola

[106] *Castell v De Greef* 1994 (4) SA 408 (C). The Castell case confirms the influence of English law on the South African medical law as it heavily relied on the *Sidaway v Bethlem Royal Hospital Governors* [1985] 1 All ER 643 case. See chapter 7 paragraph 6.2 *infra*.
[107] *Castell v De Greef supra*.
[108] Labuschagne D & Carstens PA (2014) "The constitutional influence on organ transplants with specific reference to organ procurement" *Potchefstroom Elektroniese Regsblad/Potchefstroom Electronic Law Journal* 17(1): 232/612.
[109] The plaintiff had a family history of breast cancer. She had had lumps in the breast removed previously in 1982 and also in June 1989. In light of her family and own history, she was referred to the defendant in the matter to receive a prophylactic mastectomy.
[110] This is a skin-sparing mastectomy method whereby tissue is removed from an incision beneath the breast and leaves the skin, areola and nipple intact.
[111] The claim was instituted for R94 952.12.
[112] This entails that skin surrounding the areola is removed while creating two pedicles to bear the nipple-areola complex. The nipple-areola complex is then moved to the proposed new position and a purse-string suture is used to close the surrounding circular edge of the skin.
[113] Necrosis is premature cell death caused by injury to the cells in living tissue by autolysis. Autolysis is self-digestion of destruction of a cell by its own enzymes.

had also become more discoloured. The defendant advised the plaintiff that she might require further surgery, depending on the extent of the necrosis.

While changing the dressing on the 14th of August, the plaintiff and a friend noticed a discharge coming from both areolas as well as an offensive smell. The plaintiff consulted with the defendant on the 16th of August during which he explained that the discharge was a consequence of the necrosis and that she would have to wait a while longer before they could remove the dead tissue. The plaintiff later testified that at this time the discharge and odour became worse and she also started experiencing pain and fever. The plaintiff again consulted with the defendant on the 21st of August at which time he prescribed antibiotics. The plaintiff also started laser treatment of her scars on this date. During a consultation on the 23rd of August the defendant informed the plaintiff that he would be away over the weekend and that if she had any problems, to see his colleague Dr Lückhoff. The plaintiff did indeed suffer from pain and was admitted to hospital by Dr Lückhoff. The defendant returned and on the 28th took swab samples to be analysed and on the 30th of August a debridement of the dead tissue was performed. The plaintiff had, however, lost the entire areola and nipple on her left breast as well as a portion of skin on her right breast. A skin graft was performed on these areas using skin removed from the upper thigh and left arm. The results of the swabs taken on the 28th became available and indicated *Staphylococcus aureus*.[114] According to the report of the pathologist, this strain was resistant to both the antibiotics the plaintiff had been prescribed. The plaintiff underwent numerous further surgeries in 1990 and 1991 in order to correct her scars as well as to have her left nipple recreated. These procedures were not performed by the defendant.

The parties agreed that the defendant was under a duty of care towards the plaintiff to perform the subcutaneous mastectomy with the professional skill and making use of procedures and materials as would be reasonably required of a specialist plastic surgeon and that a further duty of care existed to take reasonable steps to ensure that the plaintiff suffered no harm or damages other than those normally associated with the surgery concerned. The complaints against the defendant were numerous.[115] In context of this thesis the complaint of most relevance is that the defendant had failed to warn the plaintiff of the risks involved in the surgery and of the possible complications which could arise. The defendant denied breach of his duties, wrongfulness, unlawfulness and negligence. He admitted to the scarring of the breasts but averred that it was an unavoidable consequence of the surgery and also that the need for further surgeries was a normal and expected result of the complications which arose.

[114] This is a type of coccal bacterium.
[115] See Carstens & Pearmain (2007) 713 for a complete list of complaints.

Scott J of the court *a quo* observed that both in performing surgery and in the post-operative care of the patient, a doctor is obliged to exercise no more than reasonable diligence, care and skill and that the highest possible degree of professional skill is not expected. In other words, the general level of skill and diligence possessed and exercised by the members of the same branch of medicine must be observed. As the defendant had spent a great amount of time discussing the operation with the plaintiff, answering her questions and even drawing explanatory sketches, the court held that there was no basis for assuming that any misunderstanding on the part of the plaintiff was due to the fault of the defendant. The plaintiff's complaint thus failed. The matter was brought on appeal to the full bench of the Cape Provincial Division during which Ackerman J held that Scott J was correct in finding that the plaintiff was aware of the risks involved in the operation. Some negligence was, however, shown and therefore the appeal succeeded with costs.

The impact of the *Castell* case[116] is wide and substantial. In order to illustrate this, the principles established in this case are listed below:[117]

1. The duty to disclose is seen as contractual in nature;
2. The test for disclosure of information by a physician was developed. A doctor has the duty to warn a patient of the inherent and material risks and complications attached to a proposed procedure.[118] A risk or danger is material where a reasonable patient, if warned of the risk or danger, would attach significance thereto or the doctor is or should reasonably be aware that the patient, if warned, is likely to attach significance to the risk;[119]
3. Expert evidence must be used in determining what risks are inherent in a particular procedure;
4. Since the court established the reasonable-patient yardstick and rejected the reasonable-doctor approach in favour of the doctrine of informed consent, a move away from medical paternalism towards patient autonomy was established;[120]
5. The lack of consent is a matter of assault and not of negligence;[121]
6. In order to establish whether or not consent is informed, Ackermann J formulated the following requirements. The consenting party must have:

[116] *Castell v De Greef supra*.
[117] See in general, Thomas R (2007) "Where to from Castell v De Greef? Lessons from recent developments in South Africa and abroad regarding consent to treatment and the standard of disclosure" *South African Law Journal* 124(1): 188-215.
[118] Norton Rose Fulbright (2010) "Contract and consent" available online at http://www.nortonrosefulbright.com/knowledge/publications/44147/contractandconsent accessed 23/10/2015.
[119] Carstens & Pearmain (2007) 885.
[120] Labuschagne & Carstens (2014) 232/612.
[121] Carstens & Pearmain (2007) 892.

a. Had knowledge and been aware of the nature of the harm or risk involved;
b. Appreciated and understood the nature and extent of the harm and risks involved;
c. Consented to the harm and the assumed risks involved; and
d. Given consent which is comprehensive, meaning that it extends to the entire transaction which includes the consequences; and

7. Most importantly in context of this thesis and the current discussion of the development of informed consent by way of case law, the doctrine of informed consent was imported and accepted into South African medical law by this decision.[122]

5.11 OLDWAGE V LOUWRENS (2004)[123]

The defendant Dr Louwrens, a surgeon, performed vascular surgery on Mr Oldwage, the plaintiff, following complaints that he suffered excruciating pain in his right leg. The plaintiff suffered from claudication[124] in the left leg after the surgery which prevented him from enjoying the lifestyle he was accustomed to. The plaintiff argued that he had not been warned of the risk of claudication, thus resulting in inadequate consent, rendering the operation assault.

The court *a quo* stated that in considering whether or not a patient had consented to a procedure, it had to be shown that a patient not only consented to the medical procedure and injury but also to the risks and consequences of such intervention. Consent is therefore only valid as a defence where it is based on essential knowledge regarding the nature and the effect of the proposed treatment. This means that consent must be informed. Furthermore, consent will only be informed where it is based on a substantial knowledge of the nature and effect of the act consented to. The court applied the *Castell v De Greef*[125] formulation as discussed above[126] and found in favour of the plaintiff.

However, on appeal[127] Mpati DP, Streicher JA, Lewis JA and Ponnan JA concurring with Mthiyane JA opted to rather quote, with approval, the *Richter* case[128] as "in reaching a conclusion a court should be guided by medical opinion as to what a reasonable doctor, having regard to all the

[122] *Ibid*. The Supreme Court of Appeal by implication gave recognition, albeit with some technical revision, to the doctrine of informed consent in the case of *Broude v McIntosh* 1998 (3) SA 60 (SCA) by not overturning the *Castell* decision. See in general, Thomas (2007) 188-215. See also McQuoid-Mason (2008) 7-10.
[123] *Oldwage v Louwrens* [2004] 1 All SA 532 (C).
[124] Claudication is a condition which entails cramping pains or weak and tired feeling in the leg induced by exercise as a result of too little blood flow.
[125] *Castell v De Greef supra*.
[126] See paragraph 5.10 *supra* for the formulation of the duty to disclose test.
[127] On 21 September 2005 the Supreme Court of Appeal delivered judgement in the appeal of *Oldwage v Louwrens* (case 181/2004 unreported).
[128] *Richter v Estate Hammann supra*.

circumstances of the particular case, should or should not do."[129] The Court of Appeal set the trial court's decision aside and found in favour of the appellant Louwrens.[130]

5.12 CHRISTIAN LAWYERS' ASSOCIATION V NATIONAL MINISTER OF HEALTH AND OTHERS (2004)[131]

The *Christian Lawyers' Association* case was decided in the same year as *Oldwage v Louwrens*.[132] The Association challenged the constitutionality and sought a declaratory order striking down the relevant provisions of the Choice on Termination of Pregnancy Act[133] which allows a pregnant minor of whatever age to consent independently to the termination of pregnancy.

Of importance to the current discussion is the consideration given to the judicial meaning of "informed consent." The court stated that although the term was not defined in the concerned Act, informed consent had been accepted at common law as entailing the elements of knowledge, appreciation and consent.[134] "Knowledge" means that the consenting person must have full knowledge of the nature and extent of the harm or risks. "Appreciation" implies more than mere knowledge and so the consenting person must comprehend and understand the nature and extent of the harm or risks involved. Lastly, "consent" means that the consenting person must in fact subjectively consent to the harm or risks associated with the proposed intervention and this consent must be comprehensive and extend to the entire transaction, including the risks and consequences.[135]

The court continued by discussing the capacity to consent. Accordingly, only a person with the intellectual and emotional capacity for the required knowledge, appreciation and consent is truly able to give consent. The reasoning behind this is that consent is a manifestation of will and so capacity to consent depends on the ability of a person to form an intelligent will based on the appreciation of the nature and consequences of a consented-to action.[136]

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[129] *Richter v Estate Hammann supra* at 232GH.
[130] See in general, Britz R & Le Roux-Kemp A (2012) "Voluntary informed consent and good practice for clinical practice for clinical research in South Africa: Ethical and legal perspectives" *South African Medical Journal* 102(9): 746-748.
[131] *Christian Lawyers' Association v National Minister of Health and Others* [2004] 4 All SA 31 (T).
[132] *Oldwage v Louwrens supra*.
[133] Choice on Termination of Pregnancy Act, Act 92 of 1996.
[134] This means that in terms of the Choice on Termination of Pregnancy Act 1996, informed consent rather than age is the key to regulating access to abortion.
[135] *Christian Lawyers' Association v National Minister of Health and Others supra*.
[136] See in general, Savage-Oyekunle OA & Nienaber A (2015) "Adolescent girls' access to contraceptive information and services: An analysis of legislation and policies and their realisation in Nigeria and South Africa" *African Human Rights Law Journal* 15(2): 433-448. See also chapter 5 paragraph 3.3 *infra*.

5.13 SIBISI NO V MAITIN (2015)[137]

Most recently, the Supreme Court of Appeal heard the matter of *Sibisi*[138] wherein the court once again considered the issues of medical negligence. The facts of this case are as follows. The plaintiff instituted a claim on behalf of her minor daughter due to bodily injuries suffered during natural birth. The injuries and the *sequela* thereof include damage to the brachial plexus[139] of the infant resulting in Erb's palsy[140] caused by traction in the birthing process. The claim against the defendant was instituted on the grounds of medical negligence and in the alternative, the absence of informed consent. Medical negligence was alleged on the grounds of the attending physician's failure to inform the plaintiff of the risks involved in natural birth and the option of undergoing a Caesarean. Informed consent, it was argued, was absent as there was no knowledge of the inherent risks involved in the procedure. The plaintiff further asked the court to develop the common law concept of consent in line with the Constitution, section 12 to be particular. The common law holds that consent may act as a defence which excludes the wrongfulness of an action, or *volenti non fit injuria*.[141]

The matter was first heard in the KwaZulu-Natal High Court from where it was taken on appeal. The appeal was dismissed. In making the decision of the court, Lewis JA, Ponnan and Pillay JJA and Mathopo AJJA concurring, found that where medical negligence is not proven, informed consent is no longer an issue which needs to be addressed and as such the doctrine was not further discussed *in casu*. This case is somewhat unsatisfactory and confusing as it seems that the court erred in recognising the distinction between the elements of wrongfulness, for which consent may act as a defence, and fault, the *culpa* form being present in instances of medical negligence.

Although the law and principles related to informed consent were not developed in this matter, the court made reference to the test for the duty of disclosure as formulated in *Castell*,[142] once again confirming this watershed case as the primary case law in unpacking informed consent.[143]

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[137] *Sibisi NO v Maitin* 2014 (6) SA 533 (SCA).
[138] *Sibisi NO v Maitin supra*.
[139] This is a fibrous nerve network which runs down the length of the spine, through the shoulder and into the arm and hand.
[140] This manifests as a paralysis of the arm.
[141] The five elements of a delict which must be proven in order to establish delictual liability in terms of the common law are conduct, causality, wrongfulness, capacity and fault as either *dolus* or *culpa*. See paragraph 7.1 *infra*.
[142] *Castell v De Greef supra.*
[143] See in general, Zwart L (2015) "Sibisi NO v Maitin: Dual burden of proof?" *De Rebus* 553: 33.

5.14 SUMMARY OF CASE LAW

The idea of requiring consent in order to lawfully undertake a medical procedure on a person was first verbalised in *Stoffberg v Elliot*.[144] Two years later the case of *Lymbery v Jefferies*,[145] the first pertinent case dealing with the duty of disclosure, stated that a patient must be provided with information in order to make a decision whether to consent or not. The court, however, held that this need only be general information. *Rompel v Botha*[146] broadened the scope of disclosure to include the nature and consequences of a procedure. The court held that a patient must be informed of the serious risks involved in a procedure since without such knowledge the given consent cannot constitute real consent.

Instances of incapacity to give consent were addressed in the case of *Ex Parte Dixie*[147] wherein the court held that for an operation to be lawful, consent must have been given and where the patient lacks the capacity to consent, consent must be given by a person who has authority over the person of the incapacitated individual. *Esterhuizen v Administrator Transvaal*[148] once again confirmed that consent is a *condictio sine qua non* for a lawful medical intervention.

An unlawful intervention may lead to liability on behalf of the physician or hospital according to *Dube v Administrator Transvaal*[149] where a patient is not provided with sufficiently clear and unambiguous information. The provision of information was further dealt with in *Verhoef v Meyer*,[150] the first case to make use of the term "informed consent." The court held, in defining informed consent, that consent is only informed where a person understands what they are consenting to, they have been informed of what the procedure entails and where the consenting person has been given ample opportunity to consider the benefits and risks normally associated with the proposed procedure. *Richter v Estate Hammann*[151] once again addressed the duty of disclosure.

Phillips v De Klerk[152] confirmed the principle of self-determination and autonomy by recognising that a patient has the right to refuse medical treatment. The watershed case of *Castell v De Greef*[153] incorporated informed consent into South African law and greatly developed the concept thereof. The test for duty of disclosure was formulated; medical paternalism was ousted in favour patient autonomy and requirements for valid consent were established.

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144 *Stoffberg v Elliot supra*.
145 *Lymbery v Jefferies supra*.
146 *Rompel v Botha supra*.
147 *Ex Parte Dixie supra*.
148 *Esterhuizen v Administrator Transvaal supra*.
149 *Dube v Administrator Transvaal supra*.
150 *Verhoef v Meyer supra*.
151 *Richter v Estate Hammann supra*.
152 *Phillips v De Klerk supra*.
153 *Castell v De Greef supra*.

Oldwage v Louwrens[154] held that consent is only valid where it is based on essential knowledge of the nature and effect of an intervention. Consent must therefore be informed and it will only be informed where it is based on a substantial knowledge of the nature, effect and consequences of a procedure.

For consent to be valid, knowledge, appreciation and consent must exist and these terms were explained in the case of *Christian Lawyers' Association v National Minister of Health and Others*.[155] "Knowledge" means knowledge of the nature and extent of the harm or risks. "Appreciation" means the consenting person must have comprehension and understanding of the nature and extent of the harm or risks. "Consent" means the consenting person must subjectively consent to the harm or risks and that this consent must be comprehensive and extend to the entire transaction which includes the risks and consequences. The capacity to consent was also discussed in the *Christian Lawyers'* case and it was held that only a person with the intellectual and emotional capacity to have knowledge, appreciation and then consent is truly able to give consent.

The most recent case addressing consent namely *Sibisi NO v Maitin*[156] did not develop informed consent but the use of the *Castell* principles confirms its importance and status in South African law. It is striking to note how frequently it was emphasised in the above cases that a consenting person must have full knowledge and information. This is in concordance with the hypothesis of this thesis which questions the legitimacy of informed consent in context of the still greatly unknown and experimental scope of biotechnology with specific regard to stem cell therapy and research.

As the development of consent in case law has now been discussed, attention must be given to the ultimate recognition of the concept of consent as found in South African law, namely section 12 of the Constitution of the Republic of South Africa.

6 CONSENT AND THE CONSTITUTION

Before examining individual rights in the Bill of Rights, it is necessary to have an understanding of the application of the Bill of Rights. Section 8 states that the Bill of Rights is applicable to all law and binding on the legislature, the executive, the judiciary and all the State Organs,[157]

[154] *Oldwage v Louwrens supra*.
[155] *Christian Lawyers' Association v National Minister of Health and Others supra*.
[156] *Sibisi NO v Maitin supra*.
[157] Section 8(1) of the Constitution.

natural and juristic persons.[158] The rights in the Bill of Rights enjoy a wide application and may be applied directly or indirectly as well as vertically or horizontally.[159] Section 8 further states that the common law must be applied and developed to the extent that it does not give effect to the provisions of the Bill of Rights.[160] It must also be kept in mind that the State has a progressive duty to realise the rights in the Bill of Rights.[161] Courts therefore have a duty to develop the common law and legislation must be promulgated in order to enable persons to fully experience their fundamental rights.

The wide application of the Bill of Rights has two important implications in context of this thesis. Firstly, all Organs of State are bound by the Bill of Rights and this includes the Department of Health and public hospitals.[162] This means that the organs as well as the legislature are influenced by medical law. Secondly, since the legislator is bound by the Bill of Rights, any legislation not in compliance with the Bill of Rights must be declared invalid.[163] Legislation may therefore be tested against the Bill of Rights and declared invalid to the extent that it is inconsistent with the Constitution. This means that any attempt at regulating consent, and specifically with regard to stem cells, will have to be in line with the Constitution and adhered to by the Department of Health as well as public hospitals. It will also apply between individuals.[164]

As some background to the application of the Bill of Rights has now been provided, the specific provisions, sections 12 and 36 of the Bill of Rights, relevant to this thesis must be examined. As the primary focus of this thesis falls on informed consent, section 12 which enshrines this right will now be discussed.

6.1 SECTION 12: FREEDOM AND SECURITY OF THE PERSON

Section 12 of the Constitution is relevant in context of this thesis for two reasons. It not only guarantees the right to freedom and security of the person[165] but it furthermore provides for the

[158] Section 8(2) of the Constitution.
[159] Vertical application is used to indicate that the rights conferred on persons by the Bill of Rights are only intended to protect individuals from legislative and executive state powers. Horizontal application indicates that the rights in the Bill of Rights also govern the relationships between individuals and may be invoked in private law disputes. See *Du Plessis v De Klerk* 1996 3 SA 850 (CC).
[160] Section 8(2) of the Constitution.
[161] Section 27(2) of the Constitution.
[162] Section 213 of the Constitution.
[163] Section 172(1) of the Constitution.
[164] Suggested further reading, Swanepoel M (2007) "Constitutional, legal and ethical issues regarding the regulation of cloning in South Africa" *SA Publiekreg/SA Public Law* 22(2): 336-365.
[165] Section 12(1) of the Constitution.

right to bodily and psychological integrity.[166] This section therefore protects two different but combined rights. In the case of *Ferreira v Levin*,[167] Chaskalson P held that the aim of section 12 is to protect the integrity of the individual and as such it may be said that this combination of rights functions in relation to one another. It may be noted that at the time of this decision, only the Interim Constitution was in force and this statement was made referring to section 11 of the Interim Constitution which stated that "every person shall have the right to freedom and security of the person, which shall include the right not to be detained without trial." Although section 11 only mentioned physical liberty and security, Chaskalson P further held that it must not be limited to physical integrity only. Section 12 of the Final Constitution extended the protection of integrity and specifically made provision for psychological integrity. In context of this thesis, section 12(2) is of relevance due to this expansion of the freedom protected in section 12(1) by protecting aspects of self-determination and autonomy which include the right to informed consent.

Section 12(2) creates a protective provision whereby the autonomy of a person to make a decision to participate in biomedical treatment and research may be embodied. Should a person therefore choose to undergo an experimental treatment or to participate in research, such as stem cell treatment or research, section 12 may be invoked in order to protect the individual's choices. *Castell v De Greef*[168] confirms this as it was held that an individual has the right to make decisions regarding the type of medical treatment or intervention to which they will submit, similar to the manner whereby an individual may refuse treatment on the grounds of their integrity. This section reads as follows:

> "Section 12: **Freedom and security of the person**
> (1) …
> (2) Everyone has the right to bodily and psychological integrity, which includes the right
> (a) to make decisions concerning reproduction;
> (b) to security in and control over their body; and
> (c) not to be subjected to medical or scientific experiments without their informed consent."

From the above, three important rights included under bodily and physiological integrity are identifiable namely, the right to make decisions regarding reproduction; the right to security in and control over the body and the right to give informed consent to any medical or scientific experimentation. Subsections (a) and (b) are discussed only briefly as they do not fall under the main ambit of this thesis.[169] Both sections 12(2)(a) and (b) however embody and personify

[166] Section 12(2) of the Constitution.
[167] *Ferreira v Levin NO* 1996 (1) SA 984 (CC).
[168] *Castell v De Greef supra*.
[169] For an in-depth discussion of section12(2)(a) and (b) see Prinsen (2010) 69-73. See also Van Wyk C (2001) "Guidelines on medical research ethics, medical 'experimentation' and the Constitution" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 64: 4-22.

autonomy which is the *raison d'être* of informed consent and which is therefore indirectly enshrined in these sections. Section 12(2)(c) on the other hand, explicitly protects informed consent and will be discussed in more detail below.

Section 12(2)(a) which provides for decisions regarding reproduction, guarantees the right of a person to make reproductive decisions which include the rights to birth control and termination of pregnancy. In other words, an aspect of bodily integrity, namely autonomy and autonomous decision making is constitutionally protected. Section 12(2)(b) provides for security in and control over the body. It may be said that the essence of the right to freedom and security of the persons is the right of a person to be left alone. An individual may therefore be seen as inviolable on a certain level. Section 12(2)(b) contains two elements. The first is that of "security in" which indicates that a person's bodily integrity must be protected from any outside interference. In other words, "security in" may be regarded as the right to not be harassed by others and to be left in peace. The second is that of "control over" which illustrates the protection of self-determination and autonomy. "Control over" may therefore be regarded as being able to live the life of ones choosing.[170] In fact, this right to live the life one chooses is so important that it was held in *Phillips v De Klerk*[171] that the right of a competent person to control their destiny according to their own values is of higher value than his health or life.[172]

6.1.1 Section 12(2)(c)

Morally speaking, informed consent is the realisation of the patient or research participant's optimal decision making regarding if and how they are willing to partake in certain processes.[173] Thus, informed consent may have originated as a moral term but since section 12(2)(c) expressly and directly protects informed consent it now finds concrete form and is a constitutionally enshrined legal term and requirement.

At this juncture the meaning of "experiments" as found in section 12(2)(c) must be briefly clarified as this will ease any ambiguity on this front in the remainder of this thesis. According to van Wyk, "experimentation" means medical or scientific research.[174] As these phrases are used interchangeably in numerous international instruments, ethical documents and the

[170]Currie I & De Waal J (2016) *The Bill of Human Rights handbook*: 287.
[171] *Phillips v De Klerk supra* as quoted by Strauss SA (1991) "Voluntary sterilization for convenience: The case of the unwanted child" *Consult* 3(2): 93-97.
[172] See in general, McQuoid-Mason (2008) 7-10.
[173] Van Loon K & Lindegger G (2009) "Informed consent in clinical trials: Perceptions and experiences of a sample of South African researchers" *Health SA Gesondheid* 14(1): 1.
[174] See in general, Van Wyk C (2005) "HIV preventative vaccine research on children: Is this possible in terms of South African law and research guidelines?" *Journal for Contemporary Roman Dutch Law* 68: 35-38.

National Health Act, it is suggested that this interpretation is correct. Nienaber, however, opines that the inclusion of the word "or" indicates that "scientific" and "medical" are different concepts and that "scientific" connotes a wider concept than "medical."[175] It is suggested that this interpretation is also correct. In context of this thesis, "experiments" therefore suggest experiments or investigative processes of a medical or scientific nature but with a wider understanding of the concept than a mere medical one so as to include the greater field of biotechnology.[176]

The subject of medical experimentation on human subjects in general and stem cells regulation specifically, is highly contentious and controversial and raises numerous ethical and legal questions. One such question forms the object of this thesis, namely the manner wherein consent should be obtained or could most validly be obtained. Section 12(2)(c) of the Constitution explicitly states that "no person may be subjected to medical or scientific experimentation without their informed consent" and in so doing creates an absolute condition which must be adhered to.

As a legal norm it carries the force of law and therefore not only provides protection but also imposes obligations on persons. Since consent may be described as the moral, ethical and legal expression of an individual's right to respect for autonomy and self-determination, any failure in obtaining consent may result in legal liability.[177] Consent is thus a prerequisite in any medical or scientific procedure. The case of *Stoffberg v Elliott*[178] confirmed this as Watermeyer J held that any intervention without the consent of the person concerned constitutes "an unlawful interference with his right to security and control of [the] body." Clearly, consent is a requirement of lawful medical or scientific intervention and any such intervention, meaning scientific or medical procedure or research, in the absence of informed consent is an infringement of a person's right to physical integrity. In context of this thesis, it is important to keep in mind that it is argued that stem cell therapy is equal to stem cell research and therefore, bringing it in line with section 12(2)(c), it is medical and scientific experimentation. Constitutionally speaking, consent must therefore be obtained in order to lawfully involve a person in biotechnology.

[175] In other words, most medical experiments may be deemed scientific in nature but not all scientific experiments are medical in nature. See Nienaber A (2010) "The regulation of informed consent to participation in clinical research by mentally ill persons in South Africa: An overview" *South African Journal of Psychiatry* 16(4): 121.
[176] This may therefore also include social and legal aspects of an experimental intervention wherein human subjects are involved.
[177] Van Oosten FFW (1989) *The Doctrine of informed consent in medical law* (LLD thesis unpublished, University of South Africa): 31.
[178] *Stoffberg v Elliot supra*.

Two issues arise in context of section 12(2)(c). The first is in relation to the use of "their"[179] as it may denote that only the patient or participant may give consent to a proposed intervention.[180] This would then render proxy consent invalid and unconstitutional.[181] The second issue relates to the circumstances under and the extent to which the benefits to society which may result from medical and scientific research outweigh the dignity and autonomy of the individual. In addressing these issues constitutional interpretation becomes relevant as well as the limitation clause.

6.2 SECTION 36: THE LIMITATION CLAUSE

At the onset of this discussion it must be mentioned that a distinction must be drawn between the interpretation and limitation of rights as enshrined in the Constitution's Bill or Rights. Where a claim is made that a right has been infringed upon, the court is required to determine whether or not the right has truly has been infringed upon. This is done by way of interpretation.[182] On the other hand, where a right may be limited it must first be interpreted and so these two concepts interact with one another.

A discussion of section 36 is necessary at this juncture due to the possibility of restricting certain rights in the course of research and the application of the mechanisms of this section during interpretation. The fundamental rights contained in the Bill of Rights are not absolute and may therefore be limited in terms of section 36 of the Constitution. Section 36 reads as follows:

> "Section 36: **Limitation of rights**
> (1) The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including
> (a) the nature of the right;
> (b) the importance of the purpose of the limitation;
> (c) the nature and extent of the limitation;
> (d) the relation between the limitation and its purpose; and
> (e) less restrictive means to achieve the purpose.
> (2) Except as provided in subsection (1) or in any other provision of the Constitution, no law may limit any right entrenched in the Bill of Rights."

The limitation clause sets specific criteria for the lawful limitation of fundamental rights resulting therein that such rights may only be limited under restricted and compelling

[179] Section 12(2)(c): "not to be subjected to medical or scientific experiments without ***their*** informed consent" [own emphasis added].
[180] See in general, Van Oosten (1989) 23.
[181] See in general, Van Wyk (2005) 35-38.
[182] Swanepoel M (2006) *Embryonic stem cell research and cloning: A proposed legal framework in context of legal status and personhood* (LLM thesis unpublished, University of Pretoria): 71 footnote 231.

circumstances.[183] A limitation will thus only be constitutionally valid where it is possible to justify such limitation in an open and democratic society based on human dignity, equality and freedom.

In limiting certain fundamental rights, it is important to be conscious that having a right comes with an innate corresponding duty. In general, the limitation clause may thus be described as the inherent restriction of rights and liberties by the duty to respect the rights of others.[184] The State is not excluded from this as the Bill of Rights intends to protect the individual against the abuse of State power since the relationship between the State and the individual is of a vertical and unequal nature.[185] An example of this duty on the State is the duty to enact legislation which gives effect to the rights contained in the Bill of Rights.

According to section 36, the rights in the Bill of Rights may only be limited in terms of a law of general application. This is referred to as the "rule of law"[186] and here "law" includes legislation as well as common and customary law.[187] In the case of *President of the Republic of South Africa v Hugo*,[188] Mokgoro J held that in order for a law to qualify as a law of general application, it must be accessible, precise and generally applicable. Any limitation must then furthermore be "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom." This translates into the required balance between the purpose of the limitation on the one hand and the limitation itself on the other. In other words, a limitation must be legitimate. The legitimacy of a limitation was addressed in *S v Makwanyane and Another*[189] and it was held that the limitation of rights for a reasonable and necessary[190] purpose involves the weighing of competing values and the ultimate assessment thereof based on proportionality. Since different rights have different implications there is no absolute standard in determining reasonableness and necessity. Certain principles may be established but their application in a particular circumstance will have to be done on a case by case basis as it is inherent to the requirement of proportionality which calls for the balancing of different interests. During this balancing process, the requirements as established by section 36 will therefore have to be

[183] Currie & De Waal (2016) 155. See in general, Woolman S & Botha H (2002) "Limitations: Chapter 34" in Woolman S & Roux T (eds) *Constitutional law of South Africa*. See also Devenish GE (2005) *The Constitution of South Africa*: 179-184.
[184] Devenish GE (1998) *A commentary on the South African Constitution*, mentioned in Swanepoel (2006) 72.
[185] Section 8 of the Constitution specifically provides that the Bill of Rights has horizontal and vertical application. Section 38 which may be read with section 8, further states that anyone may approach a competent court and be granted relief where a fundamental right has been threatened or infringed upon. This relief may include a declaration of rights.
[186] Currie & De Waal (2016) 168. See in general, Woolman S (2002) "Application: Chapter 31" in Woolman S & Roux T (eds) *Constitutional law of South Africa*.
[187] *Khala v Minister of Safety and Security* (1994) 2 BCLR 89 (W).
[188] *President of the Republic of South Africa v Hugo* 1997 (4) SA 1 (CC).
[189] *S v Makwanyane and Another* 1995 (3) SA 391 (CC).
[190] This case was heard under the Interim Constitution and refers to section 33 thereof, which later became section 36 in the Final Constitution which is why the term "necessary" is used.

considered. This means that the purpose, importance and effect of legislation as well as the nature and effect of a limitation must be balanced. The more substantial a limitation, the more substantial the justification required to render it constitutional.[191]

An aspect which requires some clarification at this juncture relates to the importance of the right. This phrasing first appeared in the *Makwanyane* judgement[192] and later in *National Coalition for Gay and Lesbian Equality v Minster of Justice*[193] and although it is not expressly worded as such, it may be understood as the importance of a right in the context of an open and democratic society based on human dignity, equality and freedom.[194] The importance of a right is therefore taken into consideration as a necessary implied factor.

This discussion then lastly turns to the actual limitation process as it is applied. South African courts follow a two-stage approach. The first stage is an interpretive stage and the second a limitation stage.[195] Section 36 commences by stating that the extent to which a limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom is a relevant factor to be considered. It then elaborates by providing for five factors to be considered when determining whether a limitation is in fact reasonable and justifiable.[196] The first factor relates to the nature of the right, meaning that an infringement must be weighed against the protections offered by the right itself.[197] Secondly, the importance of the purpose of any limitation must be considered.[198] The limiting purpose must thus be valid and necessary in a constitutional democracy wherein a minimum reasonableness is required. Thirdly, section 36 requires that the nature and extent of the limitation be taken into consideration. This means that an assessment of the manner in which the concerned right will be affected by the limitation must be undertaken.[199] Fourthly, the relationship between the limitation and the purpose of the limitation must be examined.[200] The limitation must be reasonable and justifiable meaning that a good reason exists for the infringement and lastly, the possible existence of a less restrictive means to achieve the purpose must be determined.[201] The limitation must attain goals proportionate to the costs of the limitation in order to be legitimate. Where any other means are

[191] *S v Bhulwana* 1996 (1) SA 388 (CC).
[192] *S v Makwanyane supra*.
[193] *National Coalition for Gay and Lesbian Equality v Minster of Justice* 1999 (1) SA 6 (CC). Ackerman J held that although the importance of the right is not expressly mentioned in section 36(1), it must be taken into account in any enquiry into proportionality on the grounds of necessity.
[194] Iles K (2007) "A fresh look at limitations: Unpacking section 36" *South African Journal on Human Rights* 23: 78.
[195] Iles K (2004) "Limiting socio-economic rights: Beyond the internal limitation clauses" *South African Journal on Human Rights* 20: 453.
[196] Currie & De Waal (2016) 155-164.
[197] Section 36(1)(a) of the Constitution.
[198] Section 36(1)(b) of the Constitution.
[199] Section 36(1)(c) of the Constitution. See also Iles (2007) 80-83.
[200] Section (1)(d) of the Constitution.
[201] Section 36(1)(e) of the Constitution.

available by which the same ends may be achieved but in a manner which is less restrictive, this alternative method must be employed.

Broadly speaking, any attempt at regulating research will be measured against the Constitution and in order to do so section 36 will be utilised. This section therefore has the umbrella task of qualifying the constitutional validity of any right which relates to stem cells[202] and in context of this thesis, particularly the right to give consent to any medical or scientific research procedure and participation.[203]

As was mentioned previously, the limitation of rights and the interpretation thereof are separate but interacting processes and for this reason the process of interpretation must be discussed here.

6.3 THE INTERPRETATION OF SECTION 12(2)(C)

Interpretation follows a two-stage procedure. The first entails an examination of the content of the right being interpreted and the second is an investigation of the limitation thereof. Each of these stages will now be discussed in context of section 12(2)(c).

6.3.1 The First Stage of Constitutional Interpretation

During the first stage of constitutional interpretation, the content of the right which may be infringed on is examined. In terms of section 12(2)(c) the values entrenched in the right, the interests the section attempts to protect and the purpose of the constitutional guarantee must therefore be examined. Differently stated, the content, ambit and boundaries of the right to not be subjected to medical or scientific experimentation without informed consent are analysed.[204]

The value-based approach to interpretation requires that effect must be given to the values inherent in the Constitution. The language in which the right is expressed, the historical origins of the concept and the meaning as well as the purpose of the right must be considered. In determining the purpose of a right, the character and larger objects of the Constitution must be

[202] These rights include equality (section 9); human dignity (section 10); life (section 11); privacy (section 14); freedom of religion, belief and opinion (section 15); freedom of expression (section 16); health care, food, water and social security (section 27); children (section 28) and in the context of stem cell banking, freedom of trade, occupation and profession (section 22). See in this regard Prinsen (2010) 54-101 & 105-107. Suggested further reading, Sommerville A (2001) "Informed consent and human rights in medical research" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 249-256.
[203] Prinsen (2010) 54.
[204] Van Wyk (2001) 13.

used as guidelines.[205] Care must, however, be taken not to overshoot the true purpose of the right in question.

Although the Constitution does not define "experimentation" or "research," language plays an important role in the interpretation process. Language is an indispensable interpretive tool. Kentridge AJ best described this in the *Zuma* case[206] where he held that while being conscious of the values underlying the Constitution, it is still a written instrument. Language does not have a single objective meaning and at times it may be difficult to avoid the influence of an individual's personal and intellectual preconceptions. The Constitution may not be interpreted to mean what a person wishes it to mean. Traditional rules of statutory interpretation may therefore be used such as the plain language approach utilising the dictionary meaning of words.[207] In terms of the plain language movement, the most common understanding must be ascribed to the terms "their," "experiment" as well as "research." In relation to "their" the argument may be made that it alludes to the person who is concerned and must not be over-extended and manifested into a far-off entity. It is the patient or participant who must consent. By the general working of the law, however,[208] a substituted "their" may be used where a person is not able to make certain decisions due to mental incapacity or minority.[209] The meaning of "experiment" and "research" may best be determined by ethical guidelines as medical dictionaries are of little help. Since no distinction is drawn between these terms, it is recommended that these concepts are interlinked and interchangeable and thus research may include various experiments.[210]

6.3.2 The Second Stage of Constitutional Interpretation

During the second stage of interpretation, an inquiry is made into the limitation of the right and where the right does in fact seem to be limited, whether or not it is reasonable and justifiable as envisioned in section 36 of the Constitution. Section 36 allows the limitation of rights to serve a public interest even though it may *prima facie* seem unconstitutional and the limitation of a right may thus be viewed as the process of striking a balance between the importance of the

[205] *S v Zuma* 1995 2 SA 642 (CC) as cited in the Canadian case *R v Big M Drug Mart Ltd* [1985] 1 SCR 295.
[206] *S v Zuma supra.*
[207] Botha C (2005) *Wetsuitleg: 'n Inleiding vir studente*: 28 & 88-89. See in general, Cornelius E (2015) "Defining 'plain language' in contemporary South Africa" *Stellenbosch Electronic Law Journal* 16(5): 514-553.
[208] See in general, Bodill A & Daniel R (2015) "Advanced health directives-A constitutional right" *Without Prejudice* 15(10): 48-49.
[209] A strict, literal interpretation of the word "their" would imply that proxy consent is not permissible and that only the consent of the research participant himself is valid. According to Van Oosten such interpretation is unrealistic and not "up-to-date" with national and international trends. See Van Oosten FFW (2000) "The law and ethics of information and consent in medical research" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 63: 17. See also chapter 5, paragraph 5.1.1 *infra* in this regard.
[210] Van Wyk (2001) 17. See also Christakis N (1992) "Ethics are local: Engaging cross-cultural variation in the ethics of clinical research" *Social Science and Medicine* (35): 1079-1091.

right and the social objectives of the infringement thereon. In terms of section 36, a court will be required to weigh the purpose, effect and importance of any infringement against the importance and nature of the infringed-upon right. At all times during this process it must be kept in mind that South Africa is an open and democratic society based on human dignity, equality and freedom.[211] As section 12(2)(c) protects not only autonomy and freedom and security of the person but also human dignity which is a core principle of the Constitution, any limitation of this right may only be allowed in exceptional circumstances. *In casu*, it may perhaps be limited by the promise of new knowledge which may be beneficial to science and humankind.[212] However, even where sufficient reason exists whereby a limitation may be justified, it must still be determined whether or not less invasive measures may be taken to achieve the same objective of the proposed limitation. Competing rights must be balanced, including the rights of others.[213]

The balancing of constitutional rights is a complex process as the rights are diverse and incommensurable and often a choice must be made as to how society must be ordered and in what version of the world.[214] In the broad context of human research as well as the more specific context of stem cell research, a primary guarantee by the Constitution such as section 12(2)(c) protection, may have to be sacrificed for a lesser guarantee in order to promote scientific progress.[215] Such progress may then come at the cost of the right to human dignity and autonomy of the research subject.[216]

6.4 ADDRESSING THE ISSUES IN TERMS OF SECTION 12(2)(C)

Previously, two issues were identified as arising in context of section 12(2)(c). The first was related to the use of the word "their" and whether or not this means that the patient or research participant only may consent to a procedure. The second questioned the extent to and circumstances under which medical and scientific progress trump the individual's dignity and autonomy.

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[211] Section 36(1) of the Constitution.
[212] See in general, Burchell (1987) 193-216.
[213] In context of the right not to be subjected to medical or scientific experimentation without consent, the rights of others may include: the right to life, human dignity and the right to access to health care services as persons who suffer from the same condition as the research subject may be benefitted by such research.
[214] Chaskalson M (1999) *Constitutional law of South Africa*: 12.61-12.63.
[215] See section 16 of the Constitution which provides for academic freedom and freedom of scientific research.
[216] It must be shortly noted that when a right is limited, it is done by way of a law of general application as mandated in section 36 of the Constitution. It is submitted that directives and guidelines issues by government agencies or statutory bodies such as the MRC would then be included as law of general application. The court will rarely find that a physician has acted in an unlawful manner where such physician has adhered to ethical guidelines. See Van Wyk (2001) 20-21.

In order to address these issues, the limitation clause and principles of constitutional interpretation were discussed. The first issue is best addressed by making use of interpretive measures while the second is directly related to the limitation of rights.

The issue arising from the use of the term "their" is addressed firstly. The first stage of constitutional interpretation entails an examination of the content as well as ambit and boundaries of the right in question. The content of section 12(2)(c) is that a person must not be subjected to medical or scientific experimentation without informed consent. The ambit, or purpose, of the right is to protect an individual's autonomy which is their right to make decisions regarding their person. The boundaries of the right should not be over-extended in a manner which forces the content and purpose to become absurd and for this reason the language used to express the right becomes relevant. The traditional statutory interpretation instruments are helpful in this regard and from the plain language approach it is clear that ordinary dictionary meanings may be ascribed to words in the process of interpretation. "Their" may therefore be seen as suggesting that it is the person who is the patient or research subject who must give consent in medical and scientific experimentation.

The general working of the law, however, allows for substituted consent where persons are not able to give such consent. This may suggest that if the person concerned is not able to give consent they should be excluded from the medical procedure or scientific research. This interpretation however is an infringement in itself as such persons are then denied the exercise of their autonomy. It must then be established whether or not such a limitation would be permissible, which leads to the second stage of constitutional interpretation.

The second stage of interpretation then enquires as to the reasonableness and justifiability of a limitation of the right in question. Although section 36 allows for the limitation of a right it is premised thereon that this may only be done in exceptional circumstances. It is true that, in context of the history of not only South Africa but of medical research, the protection of vulnerable persons such as the mentally incapacitated and minors is exceptionally important, but this must be weighed against the greater interest that the public have in health and the promise of new knowledge which may be beneficial to all of mankind. It is suggested that societal benefit weighs heavier than individual protection especially since less restrictive measures do exist whereby autonomy may be protected other than the blunt exclusion of certain groups. These less restrictive measures relate to the additional protective measures which may be taken such as proxy consent by certain defined persons and ethics committee

reviews.[217] It is therefore suggested that although the consent of the person concerned is preferable, the use of the word "their" in section 12(2)(c) must not act as a limitation and that the person concerned or a person authorised by law in some way, may consent to medical and scientific experimentation.

The second issue which arose was whether and to what extent a person's right to autonomy as manifested in the requirement of consent could be limited. This section may be read as having two interpretations and a distinction may be drawn between, on the one hand, instances where an individual may use the protection of section 12(2)(c) against being forced to undergo medical and scientific experimentation. An example of this would be quarantine situations or even government-run experimental projects on human subjects.[218] On the other hand, instances where a person is excluded from partaking in medical and scientific experimentation due to some additional factor may be identified. For example, where a person belongs to a vulnerable group and is not able to make certain decisions. In both instances, however, the essence of the infringement is the barring of their autonomous decision making.

Section 36 commences by stating that any limitation of a fundamental right may only be done in terms of a law of general application. As was mentioned previously, a law includes legislation, the common law and customary law and therefore it is suggested that in the event of any proposed limitation of autonomy, such limitation may only be done by legislation or other equally authoritative legal document. The National Health Act[219] for example contains certain prohibitions which apply to all persons within the jurisdiction of South Africa. Furthermore, a right may only be limited to an extent which is reasonable and justifiable in an open and democratic society. Public interests are therefore an important factor to be taken into consideration. The public have an interest in health and protection of individuals against exploitation and of their right to make decisions but also in the inviolability of fundamental constitutional rights. Public health scholars have opined that individual rights should be limited only in the interest of public health and societal benefit where such limitation is the least invasive cause of action available.[220] Where a limitation of a right attempts to contribute to

[217] See chapter 4 paragraph 5.1 *infra* for more on the protection of vulnerable groups in medical and scientific research by way of proxy consent.
[218] See in general, Nienaber A (2009) "The involuntary isolation of patients with XDR-TB: Is the term 'health service' in section 7 of Act 61 of 2003 interpreted too broadly? Minister of Health, Western Cape v Goliath and Others 2009 (2) SA 248 (C)" *SA Publiekreg/SA Public Law: States of Statelessness: Politicide and Constitution in the African Post-colony* 24(2): 659-667. Pieterse M & Hassim A (2009) "Placing human rights at the centre of public health: A critique of Minister of Health, Western Cape v Goliath" *South African Law Journal* 126(2): 231-245.
[219] The National Health Act 2003. See chapter 5 *infra* for a discussion of this Act.
[220] Mann JM, Gruskin S, Gordin MA & Annas GJ (eds)(1999) *Health and human rights: A reader*: 54-71.

public health, the measures to be taken must be clearly conceptualised, effective, well-targeted, linked to realistic risk assessments and administered in a transparent and fair manner.[221]

The further factors established by section 36 must then also be taken into consideration, namely the nature of the right to be limited, *in casu* the right to autonomy. The importance and purpose as well as the nature and extent of the limitation are further factors to be considered. It must be noted that a limitation need not be a complete barring of the exercise of the right and may be partial and conditional. Lastly, the relationship between the limitation and its purpose as well as the possibility of less restrictive measures must be considered.

Therefore, with regard to the above discussion, it is submitted that autonomy as embodied in section 12(2)(c) may indeed be limited but the validity of such limitation will have to be examined on a case by case basis. Section 36 must be employed in finding a balance between the competing rights and interests of autonomy and societal benefits. In context of this thesis, it is further submitted that in certain instances the partial limitation of the right will occur. The autonomy of mentally incapacitated persons and minors will be limited to the extent in which no other person is permitted or able to give consent to medical or scientific experiments on their behalf.[222] Also, they must only be permitted to partake in such experimentation where stringent protective measures are in place and no alternative to research on such vulnerable persons exists.

Although the Constitution is the supreme law of South Africa, it does not exist in a vacuum and it is a part of the greater legal framework. Another part of this framework is the common law. In fact, the Constitution is a relatively new addition to the greater body of South African law. Specifically, in context of this thesis, the law of obligation is relevant as the concept of consent has long since existed therein.

7 CONSENT AND THE LAW OF OBLIGATION

The patient-physician or subject-scientist relationship is a complex issue and the basis of this relationship has been widely debated and examined. The most popular opinions state that it is based on the law of obligations which consists of the laws of contract and of delict.[223] More often

[221] Pieterse & Hassim (2009) 232. See also Carstens P (2009) "Involuntary detention and isolation of patients suffering from XDR-TB: Minister of Health v Goliath and others" *Obiter* 30(2): 420-429.
[222] See chapter 5 paragraph 5.1.2.3 *infra* for an example of where even the Minister of Health may not consent to certain procedures.
[223] Contracts are agreements entered into by two or more parties and have the effect of creating reciprocal rights and duties. Contracts must meet the requirements discussed here in order to be valid. In some instances, where these requirements are not met, contracts may be either void or invalid from the outset or they may simply be voidable. A

than not, a single act or omission may give rise to liability both under the contract entered into between a physician or hospital and patient and under delict in the form of a breach of the duty owed to the patient.[224] The nature of the relationship is also further complicated by the changing legal environment[225] and the status of the Constitution.[226] In context of this thesis, the primary basis for the establishment of a relationship is contract as the initiation of the interventions conceived of in this thesis commence based on an agreement. As consent falls under the greater sphere of the patient-physician or subject-scientist relationship, some attention must be given to contracts in a medical setting. Consent is, however, also found in the law of delict and as such, some attention must also be given thereto. For the sake of completeness, what follows is therefore a discussion of consent in the law of delict and then a discussion of the law of contract and consent.[227]

7.1 CONSENT AND THE LAW OF DELICT

The law of delict finds it origins in the common law of South Africa[228] and is a part of the law of obligations. In South Africa, the law of delict rests on three pillars, namely the *actio legis Aquiliae*, the *actio iniuriarum* and the action for pain and suffering.[229] All delicts contain five elements which characterise them as such. These elements are briefly discussed here.[230]

The first element of a delict is that of harm or damage suffered by the plaintiff.[231] Harm has been described as the cornerstone of the law of delict and serves as the fundamental point of departure in matters of delictual liability. Once the nature of the damage is established it becomes possible to identify which other elements of a delict must be proven as there is an interaction between the elements of a delict. In context of medicine and research, harm may take the form of an injury or an infringement of a person's integrity.[232]

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delict on the other hand is an "act of a person that in a wrongful and culpable way causes harm to another." In other words, no prior agreement exists. See Neethling J & Potgieter JM (2015) *Law of Delict*: 3. See in general, Smit PC (1975) "Enkele opmerkings aangaande eksperimentering op menslike wesens deur medici" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 38: 254-267.

[224] Liability may be incurred from various actions or omissions, be they contractual, delictual, statutory or *sui generis*. The remedies available to plaintiffs in each instance may, however, differ. See in general, Neethling & Potgieter (2015) 267-378.

[225] For example, the move away from paternalism towards a more patient-orientated approach.

[226] See in this regard section 27 of the Constitution.

[227] Suggested further reading, Naidoo (2003) 8-10.

[228] South African common law is based on Roman-Dutch law.

[229] Neethling & Potgieter (2015) 8-16.

[230] See in general, Loubser M & Midgley R (eds)(2012) *Law of delict in South Africa*.

[231] Neethling & Potgieter (2015) 221-266.

[232] See in general, Nienaber (2010) 120-124.

The second element is conduct on the part of the defendant.[233] This conduct must be voluntary in order to result in liability and it must be done by a person who has the capacity to act. Conduct may, however take the form of a positive act, *commissio*, or an omission to act, *ommissio*. In other words, both where a physician or researcher acts wrongfully and neglects to act properly he may incur liability.

The third element is wrongfulness.[234] This denotes conduct which is *contra boni mores* and not acceptable by the norms and standards set by society and the Constitution.[235] The fourth element is the causal connection between the conduct and the harm suffered.[236] Causation may be either factual or legal. In order to demonstrate that conduct was factually the cause of the harm the "but for" test[237] is used whereby it must be shown to be a *condictio sine qua non* of the suffered harm.[238] It must then further be shown that the wrongful conduct is closely enough linked to the harm that it results in legal liability.[239] This is where legal causality comes into play and this depends on a juridical determination which takes policy, fairness and reasonableness into account. The South African courts have adopted a flexible approach in this regard and therefore harm which is considered too remote will not be seen as having been caused by the conduct in question.[240]

The fifth element of a delictual act is fault or blameworthiness in the form of *dolus* or *culpa*.[241] Fault, however, presupposes accountability meaning that the wrongdoer must be able to differentiate between what is right and what is wrong and to act according to this knowledge. Fault is established by overt behaviour. Intention or *dolus* is subjectively tested and consists of the direction of a person's will[242] and consciousness of the wrongfulness thereof. Where both of these components of intention are present *animus iniuriani* arises.[243] Negligence is tested objectively by establishing how a reasonable person would have acted[244] and entails an enquiry firstly into foreseeability and secondly into preventability. When determining foreseeability, the

[233] Neethling & Potgieter (2015) 25-32.
[234] *Idem* 33-128.
[235] Suggested further reading, Strode AE, Toohey J, Singh P & Slack CM (2015) "Boni mores and consent for child research in South Africa" *South African Journal of Bioethics and Law* 8(1): 22-15.
[236] Neethling & Potgieter (2015) 183-220.
[237] See in general, Botha MFT (2013) "Private defence in the South African law of delict: Rethinking the rethinker" *South African Law Journal* 130(1): 154-186.
[238] This means that it is a condition without which the harm would not have been suffered.
[239] See in general, Botha (2013) 154-186.
[240] See *Fourway Haulage SA v South African National Roads Agency* 2009 2 SA 150 (SCA) in this regard. See also Neethling J & Potgieter JM (2014) "Wrongfulness and legal causation as separate elements of a delict: Confusion reigns" *Tydskrif vir die Suid-Afrikaanse Reg* 4: 889-900.
[241] Neethling & Potgieter (2015) 129-182.
[242] This is either direct intent or *dolus directus*, indirect intent or *dolus indirectus* or where there is intent with a reconciliation with the eventual consequences or *dolus eventualis*.
[243] This is the intention to injure.
[244] The reasonable person or the *bonus paterfamilias*.

likelihood of the harm and the possible consequences are examined and when determining preventability, factors such as utility and burden are considered.

In context of the law of delict, consent is a defence and where successful, no delictual liability may be incurred.[245] The defence of consent to injury or *volenti non fit injuria* manifests as consent to a specific harm or the assumption of risk of harm.[246] In order to invoke this defence the following requirements must, however, be met:

1. Capacity to consent;
2. Knowledge and appreciation of the harm;
3. Consent must have been freely and voluntarily given;
4. Consent may not be against public morals; and
5. Consent must not have been revoked.

7.2 CONSENT AND THE LAW OF CONTRACT

Normally, the relationship between a doctor and patient or a researcher and a research participant is based on a contract as entered into by the mentioned parties. In order to understand the role of consent as essential to the contract on which the relationship is based, the requirements of a valid contract must be discussed.

The first requirement for a valid contract is consensus which denotes an agreement or a subjective meeting of the minds of the parties to the contract. Usually consensus may be evidenced by one party's offer and the acceptance thereof by the other party.[247] Where there is no consensus, there can be no contract and this requirement is often referred to as the basis of a contact. The consensus requirement is closely related to the necessity of certainty in contracting. Contracting parties must therefore be certain of the rights and obligations created by the agreement between them. Where the subject of the contract cannot be ascertained, it will not result in the creation of obligations or rights. In context of the health sector, it is therefore preferable that particular consideration is given to the manner wherein parties express themselves in terms of the scope of the agreement. This requirement is then also important when examining the problem which this thesis attempts to address.[248] The second requirement

[245] See in general, Van der Walt JC (1970) "A few thoughts on the basis of delictual liability" *Comparative and International Law Journal of South Africa* 3(1): 1-17.
[246] See in general, Neethling & Potgieter (2015) 8-16.
[247] Christie RH & Bradfield GB (2011) *Christie's the law of contract in South Africa*: 60-74.
[248] It would seem as though it would not be possible to conclude contracts in context of stem cells as the uncertain nature of stem cells would render any consensus insufficient to establish a valid contract. This enquiry, however, falls outside the scope of this thesis and may form the basis of a separate study.

is that of possibility of performance. This means that the performance as agreed upon by the parties must be objectively possible at the time of concluding the contract. Objective impossibility of performance would render a contract null and void. This should, however, not be confused with subjective impossibility which does not nullify the agreement.[249]

The third requirement is that an agreement must be legal.[250] Legality as a requirement is based on the notion that agreements between parties must be in line with public interest and the norms and convictions of society as a whole. Contracts which are deemed to be *contra boni mores* are generally not enforceable. The fourth requirement is that the contracting persons should possess contractual capacity meaning that the contracting party must not be a minor or mentally unfit to conclude a contract.[251] The last requirement relates to formalities.[252] Although not all contracts have to be reduced to writing and signed by the parties thereto, the law may at times provide for specific formalities to be complied with. In context of health and research it is preferable to have a written agreement between the parties as this allows for a detailed record of the agreed-upon procedure.[253] This might be problematic in context of stem cell treatment and research as the full extent of the possible applications is as yet still greatly uncertain and even experimental in nature.

It is important to note that the concept of freedom of contract remains a fundamental principle in South African law of contract, even in a medical or research context. Writers have opined that a standard view of freedom of contract should not be applied in medical situations as patients are not conventional consumers due to their vulnerability. Freedom of contract therefore must be informed by and founded on public policy, and it is now greatly governed by the values provided for by the Constitution, meaning that autonomy to contract must fall in line with fairness and reasonableness as determined by the Constitution.[254]

In bringing the principles of the law of contract and the doctrine of informed consent together, it may be noted that in both, the scope or nature of the action, be that concluding a contract or giving consent, must be understood. From the cases discussed in the course of this chapter, this requires knowledge, appreciation and acquiescence on the part of the concerned person.[255] As

[249] An example of subjective impossibility is where a patient has agreed on a specific procedure to be performed by a physician (Dr A). On the day of the procedure however, the physician (Dr A) takes ill and arranges for another physician (Dr B) to perform the procedure in his stead. See in general, Christie & Bradfield (2011) 419-450.
[250] *Idem* 351-358.
[251] *Idem* 235.
[252] See in general, *idem* 109-136.
[253] Payment is not a requirement for a valid contract.
[254] See in general, Miller PB & Johnston J (2009) "Consent and private liability in clinical research" in Corrigan O, McMillan J, Liddell K, Ricjards M & Weijer C (eds) *The limits of informed consent: A socio-ethical approach to human research in medicine*: 54.
[255] See paragraph 5 *supra*.

these concepts will be mentioned again in the course of this thesis an understanding thereof is important to this study.

Knowledge refers to the information with which the person concerned should be furnished. This includes *inter alia* the nature and scope, consequences, dangers, complications, benefits, advantages and disadvantages of the consenting-to or contracting action.[256] Appreciation entails understanding of the information on the part of the consenting or contracting person. The level of a person's understanding determines their capacity and this will differ in instances where a person is mentally ill or a minor.[257] Appreciation also influences acquiescence in that consenting or contracting must be free and voluntary. Acquiescence means that consenting or contracting is done without any undue influence and that it is clear, unequivocal and comprehensive to render the entirety of the agreement or consent valid. Clearly, the law of contract and the doctrine of informed consent are intertwined.

8 CONCLUSION

This chapter sought to explain and give insight into the doctrine and concept of consent. To this end it therefore contained a discussion of the history, rationale and development of consent in general as a broad abstract idea and narrower examination of this doctrine as found in South African law by analysing South African case law, the Constitution the South African law of obligation.

It was shown that informed consent has a diverse history which has both an ancient facet in context of medicine which stretches from the earliest centuries where the doctor was akin to a deity, to the second half of the twentieth century and the departure from paternalism. In context of research, it was shown that consent is a rather new development which originated after the Second World War.

The philosophical rationales underlying consent were next discussed and it became clear that consent is multidisciplinary and has strong roots in moral philosophy and the law. The initial legal conception of consent was centred on pragmatisms to an extent while morally the idea of respect for autonomy reigned supreme. To illustrate the superiority of autonomy as the rationale underlying consent, several other approaches were discussed such as protection, prevention of abusive conduct, trust, self-ownership, non-domination, personal integrity, justice

[256] See chapter 4 paragraph 5.3 *infra* for a discussion of how detailed the consent procedure should be.
[257] See chapter 4 paragraph 5.1 *infra* for a discussion of who may consent. See in general, Christie & Bradfield (2011) 240.

and beneficence, but they were found lacking and as such the focus of this chapter turned to autonomy.

Autonomy, as the most important rationale of consent was described and analysed in detail. It was stated that it is the governance over a person's own agency which means acting in accordance to the law that a person creates for himself. The autonomous individual thus acts freely and in accordance to his own self-chosen plan. At a minimum, autonomy entails self-rule free from controlling interferences from outsiders and from limitations which hamper the making of meaningful decisions. It would appear that there is a concordance between the care of an individual and his values and therein lies the key to continued satisfaction and cooperation with the medical and even scientific community. Philosophically, autonomy is deemed inherently good for individuals and the individual is considered sovereign over himself, his body and mind. Autonomy was challenged in the course of this chapter yet it is still regarded as the foundation of informed consent. It was also suggested that it is not the quality of the decision or the measure of autonomy which is relevant, but the fact that an individual was able to make such decision.

Philosophical thinking is able to provide a systematic and reasoned approach to informed consent but does not provide actual real-life mechanisms or procedures whereby decisions may be made and as such the law and the origins and development of consent therein was discussed. This discussion commenced with an in-depth and chronological analysis of the development of informed consent in South African case law which examined the cases of *Stoffberg v Elliot, Lymbery v Jefferies, Rompel v Botha, Ex Parte Dixie, Esterhuizen v Administrator Transvaal, Dube v Administrator Transvaal, Verhoef v Meyer, Richter v Estate Hammann, Phillips v De Klerk, Castell v De Greef, Oldwage v Louwrens, Christian Lawyers' Association v National Minister of Health and Others* and the most recent case of *Sibisi NO v Maitin* was discussed. Although it is suggested that the *Castell* case is of most importance, the study of the case law resulted in numerous insights into the development of this doctrine.

The requirement of consent in order to undertake lawful medical action involving a person was first pronounced in *Stoffberg v Elliot* and a mere two years later *Lymbery v Jefferies* was the first pertinent case to address the duty of disclosure wherein it was stated that a patient must be provided with general information in order to make a decision. *Rompel v Botha* expanded the scope of disclosure to include the nature and consequences of a proposed procedure and held further that a patient must be informed of the serious risks involved in a procedure as without this knowledge, the consent given cannot constitute real consent. *Ex Parte Dixie* addressed instances of incapacity to consent and held that consent was necessary for a lawful operation

and where the patient lacks the capacity to consent, consent must be given by a person who has authority over such an incapacitated person. *Esterhuizen v Administrator Transvaal* also confirmed that consent is a *condictio sine qua non* for a lawful medical treatment. In the absence of consent, the doctor or hospital may thus incur liability as decided in *Dube v Administrator Transvaal*. It was also held *in casu* that a patient must be provided with sufficiently clear and unambiguous information.

Verhoef v Meyer further addressed the provision of information and was the first case to use the term "informed consent." The court defined the term as something which only occurs when a person understands what they are consenting to, where they have been informed of what the procedure entails and where such person has been given enough opportunity to consider the benefits and risks associated with the procedure. Once again the duty of disclosure was also addressed in *Richter v Estate Hammann*.

The principle of self-determination and autonomy was confirmed in *Phillips v De Klerk* by recognising a patient's right to refuse medical treatment. The all-important watershed case of *Castell v De Greef* incorporated informed consent into South African law and developed the concept thereof in much detail which included formulating the test for duty of disclosure, ousting medical paternalism in favour of patient autonomy and establishing the requirements for valid consent. *Oldwage v Louwrens* elaborated on these requirements by holding that consent is only valid where it is based on essential knowledge of the nature and effect of an intervention. It must thus be informed and will only qualify as such where it is based on a substantial knowledge of the nature, effect and consequences of an intervention. The case of *Christian Lawyers' Association v National Minister of Health and Others* clarified the meaning of "knowledge," "appreciation" and "consent" by determining that knowledge indicates knowledge of the nature and extent of the risks or harm; appreciation denotes that consenting person must have comprehension and understanding of the nature and extent of the risks or harm and consent means such person subjectively consents to the risks or harm and it must be comprehensive and extend to the entire transaction, including the risks and consequences. *Christian Lawyers'* also addressed the capacity to consent and held that only a person with the intellectual and emotional capacity to have knowledge, appreciation and then consent is truly able to consent to an intervention. The most recent case of *Sibisi NO v Maitin* confirmed the importance and place of the *Castell* case in South African law.

Although case law provided insight into the development of the doctrine of informed consent, the ultimate recognition thereof is found in the Constitution and is embodied in section 12(2)(c) thereof. This was shown to be of immense importance as the Constitution and the Bill of Rights

are applicable to all law and binds all relevant role players which include the judiciary and the executive as well as natural and legal persons. The binding nature of the Constitution functions both horizontally and vertically and a progressive obligation to develop the common law and realise the rights in the Bill of Rights is provided for. The legislature must take cognisance of principles of medical law and is bound by the Constitution as well and any conduct in conflict with the Constitution may be declared invalid. This means that legislation may be tested against the Bill of Rights and that any attempted regulation of stem cells and consent will have to pass any constitutional scrutiny in order to be valid and generally accepted.

In the specific context of this thesis, section 12(2) as discussed is important. This is due to the dual protection of both freedom and security of the persons as well as bodily and psychological integrity. It was stated that section 12(2) therefore establishes protective measures for a person who makes decisions of a biomedical nature. Informed consent is the realisation of a person's autonomous decision to participate or to refuse participation in a proposed intervention and this principle finds concrete form in section 12(2)(c) of the Constitution which expresses this right directly. The impact hereof is that a concept with moral and ethical roots now finds concrete expression as a legal term in context of the South African legal system.

Two questions were raised in relation to section 12(2)(c). The first questioned the validity of proxy consent due to the use of the word "their" while the second questioned the possibility and extent of limiting an individual's rights in favour of the interests of society. In addressing these questions, the limitation clause as found in section 36 of the Constitution and principles of constitutional interpretation were discussed and ultimately applied to the issues at hand.

The first issue was examined by utilising principles of interpretation and it was found that although the consent of the concerned person is preferable, the use of "their" in section 12(2)(c) does not act as a limitation and that such person or a person authorised by the usual working of the law may consent to medical and scientific experimentation involving such concerned person. By following the procedure as set forth in section 36, the second issue was addressed and it was found that autonomy is not absolute and will be limited in prescribed and compelling circumstances. *In casu*, the autonomy of a person who lacks capacity due to minority or mental illness may be limited as it is in the interests of the community to protect such persons against exploitation. Their autonomy may be limited to the extent to which no other person may give consent to medical or scientific experiments on their behalf and their participation in research should be limited only to studies which adhere to stringent protective measures and where no alternative to their participation exists.

Due to the novelty of the Constitution in relation to other branches of law, the law of obligation was also examined, as the principle of consent has long been present in both the law of contract and the law of delict. A delict is a wrongful act which causes harm or damage to another and to which some form of fault may be ascribed. Consent as a defence must then adhere to certain requirements in order to be valid. These requirements were found to be the capacity to consent, knowledge and appreciation of what is being consented to, the consent must be free and voluntary, it may not be contrary to the *boni mores* of society and it must not have been revoked.

A contract comes into being where there is consensus, possibility of performance, legality, capacity to contract and adherence to any prescribed formalities. Contractual freedom is also an important concept, even in the context of medicine or research. It must be informed by public policy and the Constitution and as such it must be fair and reasonable. It was found that, in merging the law of contract and informed consent that in both the scope and nature of the relevant activity must be fully understood. In other words, both the conclusion of a contract and granting informed consent rely upon knowledge, appreciation and acquiescence on the part of the concerned person or persons.

Knowledge relates to the information which the person concerned must be furnished with such as the nature and scope, consequences, dangers, complications, benefits, advantages and disadvantages of the consented or contracted-to action. Appreciation involves an understanding of the information by the relevant person and must be determined against the individual's capacity. Appreciation will also influence acquiescence and the relevant activity must be free and voluntary. Acquiescence suggests that the consenting or contracting activity is done without any undue influence, that it is clear, unequivocally given and comprehensive. The law of contract and the doctrine of informed consent were thus shown to be closely intertwined. This chapter therefore offered a general introduction to consent. The next chapter narrows the focus of this part of this thesis and will examine specific aspects of informed consent.

CHAPTER 4
SPECIFIC ASPECTS OF CONSENT

1 INTRODUCTION

The previous chapter provided for background and a broad introduction to the concept of consent. During the course of that chapter, the abstract concept was systematically narrowed into a more concrete form as found in case law, the Constitution and the law of obligation. This chapter focuses its attention to some extent and especially on the concept of informed consent and thus addresses a *capita selecta* of aspects of consent relevant to this study. In the course of this chapter attention will be given to consent in medical law, the requirements of valid consent and the traditional distinction between therapy and research and the impact thereof on consent practices. This is then followed by an in-depth discussion of specific aspects of importance in relation to informed consent, namely who must obtain and provide consent, when must consent be obtained, what should the consent process cover and in what format should consent be given? As mentioned in the problem statement of this thesis, the most appropriate model of consent in circumstances where medicine borders on research due to the uncertain nature and scope of an intervention is highly contested and this argument is strengthened and elaborated on in the course of this chapter. At the onset of this chapter, however, it must be mentioned that in context of South African law, consent to participation to research is regulated under the wider concept of consent to a medical intervention. Common law and case law do therefore not provide for these concepts separately.[1] This extrapolation of principles fits well into the greater spirit of the hypothesis as posited throughout the course of this thesis, namely that medical interventions pertaining to stem cells are akin to research studies. Lastly, a model of dynamic consent is discussed in brief as it is more eloquently examined at a later stage in the course of this thesis.

The doctrine of informed consent serves various functions within the South African legal system which include ensuring autonomy, encouraging rational decision making, establishing a proper doctor-patient relationship and acting as a legal defence. It therefore has a special status in the minds of ethics, medicine, research and the law.

[1] Nienaber A (2010) "The regulation of informed consent to participation in clinical research by mentally ill persons in South Africa: An overview" *South African Journal of Psychiatry* 16(4): 118.

Informed consent basically means that a consenting person shows knowledge, appreciation and acquiescence. However, as may be expected from such an important medical and legal principle, informed consent is not without controversy and the suggested reasons for this are discussed in more detail in the course of this chapter.

The duty of disclosure entails that a patient or research participant must be provided with information regarding the scope, nature, benefits, risks, consequences and prognosis of an intervention and as such is inextricably bound to the concept of informed consent. In context of stem cell technology and the infinite possibilities thereof this is a complex issue by nature. The duty of disclosure, however, hinges on the materiality of risk and the case of *Castell v De Greef* is once again mentioned as it was therein that the court formulated the determination of materiality of risk and thus the subsequent scope of the duty of disclosure. In context of research however, full disclosure must be made. The duty of disclosure and the concept of therapeutic privilege must, however, not be confused with instances where consent is absent. In such instances liability may be incurred. Some attention is thus given to the consequences of the absence of consent. This chapter also examines the requirements for valid consent as it is important to understand such requirements in order to exclude the possibility of infringing the above-mentioned rights.

Traditionally, medical therapy and scientific research have been regarded as separate disciplines and therefore different consent models seemed more applicable to the one than to the other. For example, whereas simple or informed consent may be preferable in medical procedures and treatment, broad or blanket consent is viewed as the popular option for research participation. Therapy and treatment are used interchangeably in the course of this thesis and usually denote a medical context where the objective of the intervention is the direct benefit of the patient as well as the promotion of their health. Research is an investigation into knowledge and may be either therapeutic or non-therapeutic in nature. Here, the objective of the intervention is broader and may benefit the participant and the community as a whole. The argument that stem cell treatment is actually research is also substantiated in this section of this chapter as well as the need to develop a new model of consent.

The examination of consent as contained in this chapter then becomes even more focussed and specific aspects of consent are given attention. An examination is made into the issue of who bears the responsibility of obtaining consent and from whom. Specific attention is given to adults, the mentally ill and minors. The next issue to be addressed is the timing of obtaining consent. The scope of consent is then addressed and lastly specific attention is given to the format of consent. Here, various forms of consent are discussed including express, implied,

simple, specific, generic, blanket and broad consent. Criticism against each model is also provided. At the closing of this chapter the issue with consent as expressed in the problem statement is discussed in reference to other forms of consent and dynamic consent and Ensuring Consent and Revocation (EnCoRe) is briefly introduced as an alternative and perhaps the most appropriate form of consent for treatment bordering on research on human subjects.

2 CONSENT IN MEDICAL LAW

Consent to lawful interventions is based on the *volenti non fit iniuria* maxim which means that no harm can be done to a person who consents thereto. The doctrine of informed consent as manifested in medical law entails numerous notable aspects which it is necessary to note. In the following section of this chapter, these aspects are investigated and as such the nature and scope of informed consent, the controversial nature of the doctrine and the duty of disclosure will be discussed.

2.1 NATURE AND SCOPE OF INFORMED CONSENT

In context of the South African medical law, the doctrine of informed consent has various purposes which illustrate its nature. Firstly, it ensures a patient or research participant's right to self-determination and autonomy. Secondly, it encourages rational decision making on the part of the patient by allowing the patient or research participant to come to a decision after being able to consider and weigh the benefits and risks.[2] Thirdly, it establishes a proper relationship between a doctor and a patient and lastly, it acts as a legal defence. The doctrine is given special status due to ethics, the respect thereof by medical practitioners and researchers and its position in law.[3] It should, however, be noted that although consent is a prerequisite to a lawful intervention involving a human person, certain situations do arise wherein consent need not be obtained. Van Oosten states the following as such circumstances:[4]

[2] Van Oosten FFW (1989) *The doctrine of informed consent in medical law* (LLD thesis unpublished, University of South Africa): 446. See also Van Oosten FFW (2006) "Medical law-South Africa" in Blanpain R & Nys H (eds) *International encyclopaedia of laws*: paragraph 121 and Strauss SA (2006) "Medical law-South Africa" in Blanpain & Nys (eds) *International encyclopaedia of laws*: paragraph 126. See also section 11 of the National Health Act, Act 61 of 2003 as discussed in paragraph 4.1.5 i*nfra*.
[3] Van Oosten (1989) 438.
[4] Van Oosten (2006) in Blanpain & Nys (eds) paragraph 76-78.

1. Deviations or extensions. This is where during a consented-to operation, a doctor discovers an undiagnosed condition and treatment thereof qualifies as an extension of the agreed-upon intervention;[5]
2. Emergency interventions;
3. Statutory authority. This is where legislation provides for circumstances wherein consent need not be obtained; and
4. Court authorised instances.

The scope of informed consent is a somewhat more complicated issue which will be discussed in the course of this chapter. At this juncture, informed consent means that a consenting person is appreciative of what they are consenting to.[6] This means that knowledge as well as appreciation is regarded by scholars and in case law, as being of primary importance in the process of consent and at least two of its essential elements establishing real consent. A third element is that of acquiescence, meaning submission to a proposed treatment or research study.

2.2 THE CONTROVERSIAL NATURE OF THE INFORMED CONSENT DOCTRINE

Although, as stated above, the doctrine is granted special status and is awed, it is not without controversy and numerous opinions exist regarding the complex nature thereof. Carstens and Pearmain are amongst the voices in the debate regarding the reasons for the controversial nature of consent and propose that the reasons therefore are the following:[7]

1. Informed consent is undoubtedly the foundation or core of the patient-physician relationship which originates in the law of obligation[8] and is underscored by ethics;
2. The introduction of the doctrine into South African law resulted in a shift from paternalism to patient autonomy, a shift which was legitimised by the Bill of Rights,[9] but health care professionals are not always comfortable with endorsing this autonomy;
3. In a health care institutional setting, obtaining consent may be difficult and the question as to who has the responsibility of obtaining such consent is often raised;[10]
4. The application of the doctrine may be unclear in context of a multi-layered approach which includes the governance of the Constitution, the common law, legislation, policy guidelines and case law;[11]

[5] See again *Verhoef v Meyer* (1976) AD 33 as discussed in chapter 3 paragraph 5.7 *supra*.
[6] Strauss SA (1991) *Doctor, patient and the law:* 14-15.
[7] Carstens P & Pearmain D (2007) *Foundational principles of South African medical law*: 877-878.
[8] The Law of Obligations consists of the Law of Contract and the Law of Delict. See chapter 3 paragraph 7 *supra*.
[9] See chapter 3 paragraph 6 *supra*.
[10] See paragraph 5.1.1 *infra* in this regard.

5. The doctrine exposes the delicate balance in and tension between power and respect found in the patient-physician relationship and due to this, points ultimately towards shared decision-making;[12]
6. Informed consent challenges physicians to "rise to the occasion" which means they must establish a rapport with their patients and improve their "bedside manner;"
7. The format of informed consent may have to be procedure specific;[13]
8. In a developing country such as South Africa, a discrepancy may exist between the private and public health sectors;
9. Related to the above is that physicians feel that it is an impossible task to obtain informed consent at times as many patients are illiterate and/or ignorant;[14]
10. Issues surrounding liability exist such as the interpretation of material risk and the reasonable patient;[15]
11. Court decisions regarding the interpretation of the doctrine have been greatly unsatisfactory; and
12. Courts rarely and hesitantly find that the medical practitioner failed to properly inform a patient.[16]

2.3 THE DUTY OF DISCLOSURE

A patient or a research participant as a layperson must be given a broad and general idea of the nature, scope, benefits, risks, consequences and prognosis of an intervention.[17] Additionally, such concerned person must be informed of any alternative courses of action, their right to refuse the proposed treatment or research procedure and even the relevant costs involved.[18] At this juncture and taking into consideration the discussion of the infinite potential and great uncertainty regarding stem cells, it should already become clear that this aspect of the consent process is problematic. Differently stated, fully informing a patient or research participant becomes an act of somewhat educated guessing or conjecture.

In the context of treatment and medicine, the duty of disclosure is somewhat restricted in that a physician need not disclose risks deemed to be remote or unusual. Where the risk is so unusual

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[11] This may be illustrated by the methodology followed in the course of writing this thesis. See chapter 1 paragraph 4 *supra*.
[12] Strauss SA (1987) "Geneesheer pasiënt en reg: 'n Delikate driehoek" *Tydskrif vir die Suid-Afrikaanse Reg*: 1.
[13] This relates directly to the problem identified in the hypothesis and problem statement of this thesis. See chapter 1 paragraph 2 *supra*.
[14] This issue is addressed by section 6 of the National Health Act.
[15] See paragraph 2.4 *infra* regarding liability in the absence of consent.
[16] This may be ascribed to the long held suggestion that a fraternity exists between the legal and medical professions.
[17] See section 6 of the National Health Act discussed in chapter 5 paragraph 4.1.1 *infra*.
[18] Carstens & Pearmain (2007) 885.

that no stretch of the imagination might have expected it, the risk is deemed remote and immaterial.[19] This is partly due thereto that although a physician has a duty to disclose relevant facts to a patient, the physician must take care not to cause the patient anxiety or distress. Only material information need be disclosed.[20] For example, in context of stem cells the formation of cancerous cells will be considered material and must therefore be disclosed. Restrictions of the duty to disclose may be viewed as justifiable limitations of the freedom of choice and self-determination of the patient. The right to informed consent is not an absolute one and as such a physician need not disclose information to a patient in certain circumstances. This is known as therapeutic privilege.[21]

The *Castell* case[22] formulated the manner whereby the materiality of risk may be determined and it was held that inherent risk[23] is material where a reasonable patient if warned of the risk or danger would attach significance thereto[24] and where a physician is or should reasonably be aware that the patient, if warned of the risk or danger, is likely to attach significance thereto.[25]

Information which a careful and reasonable physician might disclose should be determined on an *ad hoc* basis depending on the specific circumstances and may include *inter alia* the nature of the information and the intervention, the desire of a patient to be informed, the medical history of the patient as well as their intelligence, maturity, mental health status,[26] temperament and understanding of the proposed procedure.[27]

As was mentioned above, the duty of disclosure may be restricted but it may also be extended. For example, where a patient has questions or refuses treatment which has been medically indicated, the duty is extended in that the physician must give full information to the patient and press upon them the necessity of the therapy.[28]

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[19] See *Richter v Estate Hammann* and *Oldwage v Louwrens* in chapter 3 paragraphs 5.8 and 5.11 *supra*.
[20] Carstens & Pearmain (2007) 886. See also Strauss (1991) 19 and Van Oosten (1989) 199-200.
[21] See in general, Carstens & Pearmain (2007) 887-890. See also Coetzee LC (2003) "A critical evaluation of the therapeutic privilege in medical law: Some comparative perspectives" *Comparative and International Law Journal of South Africa* 36(3): 268-288. See also Waltz JR & Scheuneman TW (1970) "Informed consent to therapy" *Northwestern University Law* Review 64(5): 641-643. Suggested further reading, Gillon R (2001) "'Fully' informed consent, clinical trials and the boundaries of therapeutic discretion" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 257-265.
[22] *Castell v De Greef* 1994 (4) SA 408 (C). See chapter 3 paragraph 5.10 *supra* for a discussion of this case. See also Wilson M (2006) "When is a risk of medical treatment material?" *De Rebus* March: 22.
[23] Inherency or risk is determined by expert evidence. See in general, Carstens & Pearmain (2007) 599-867 and Carstens P (2002) "Setting the boundaries for expert evidence in support of defense of medical negligence" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 65: 430.
[24] This is known as objective disclosure. See Strauss (2006) in Blanpain & Nys (eds) paragraph 128 footnote 14.
[25] This is known to as subjective disclosure. See Strauss (2006) in Blanpain & Nys (eds) paragraph 128 footnote 15.
[26] It is submitted that the mental health status of a person in this instance includes their strength of character, resilience and general attitude or personality and should not be limited to a mental capacity only.
[27] Van Oosten (1989) 450 footnote 68. Suggested further reading, Stiffler HL (2003) "Guidelines for obtaining informed consent for clinical research" *Applied Clinical Trials Supplement*: 6-8 & 13.
[28] *Ibid*. See also Strauss (2006) in Blanpain & Nys (eds) paragraph 131.

2.3.1 Medical Research and the Standard of Disclosure

As was discussed previously,[29] the Constitution in section 12(2)(c) explicitly entrenches informed consent in context of medical and scientific experimentation involving human subjects and as such it should be articulated, interpreted and applied in medical research.[30] Scholars have opined that full disclosure should be the minimum standard of disclosure in context of medical research. The patient must therefore be informed that the procedure being proposed entails research and that the patient must be provided with detailed and comprehensive information relating to the following:[31]

1. The precise scope, nature, duration and purpose of the research;[32]
2. The scope, nature and consequences of the proposed research intervention;
3. The hoped for benefits and advantages of the research for the patient themselves as well as for society at large and a comparison of these benefits and advantages to available alternative treatments; and
4. The foreseeable risks, dangers, complications and prognosis of the experimental therapy.

A participant must furthermore be informed that they are under no obligation to participate and that their participation is voluntary. Sufficient time should be allowed to permit the potential subject to consider the information.[33]

2.4 THE CONSEQUENCES OF THE ABSENCE OF CONSENT

The duty of disclosure as discussed above, where some information may at times be omitted in the process of obtaining consent, must however not be confused with the complete absence of consent. Where consent is absent from a medical or scientific intervention the physician, researcher or the institution where the intervention was performed may incur legal liability. Such liability may be based on breach of contract,[34] civil or criminal assault as a violation of bodily integrity, civil or criminal *inuiria* as a violation of dignity and/or privacy or on the basis

[29] See chapter 3 paragraph 6.1.1 *supra*.
[30] Carstens & Pearmain (2007) 893. See also Van Wyk C (2001) "Guidelines on medical research ethics, medical 'experimentation' and the Constitution" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 64: 3-22.
[31] *Idem* 894.
[32] Such as whether the research is therapeutic or non-therapeutic in nature.
[33] Van Oosten FFW (2000) "The law and ethics of information and consent in medical research" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 63: 5. See also Van Wyk (2001) 3 and Van Wyk C (2004) "Clinical trials, medical research and cloning in South Africa" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 67: 1-21.
[34] See chapter 3 paragraph 7.2 *supra* for aspects of consent and contract.

of medical negligence. An institution or the liable person may also be barred from recovering their fee.[35]

Any procedure performed in the absence of consent constitutes a violation of a person's integrity, dignity or privacy and as such an ultimately beneficial result or the fact that due care was applied is irrelevant. The Constitution is also in concurrence in terms of section 12(2)(c) and the absence of consent is therefore an infringement of the bodily and physiological integrity of a person and not merely a violation of their health. [36]

3 THE REQUIREMENTS FOR VALID CONSENT

To begin with, consent will only be valid where it is based on the provision of appropriate information regarding the nature and effect of the proposed intervention by the physician and a corresponding acquiring of knowledge and understanding by the patient as well as their acquiescence.[37]

Additionally, to the need for information, knowledge, understanding and acquiescence, certain other requirements for validity have been identified by various scholars and legal writers.[38] These requirements include the following:

1. Consent must be legally recognised and must not be *contra boni mores*. In other words, consent may not be contrary to public interest;
2. The consenting person must be legally capable of consenting. This means that such person must be able to form intention of or understanding of what they are consenting to;
3. Consent must be freely and voluntarily given meaning that it is not given under duress, coercion, fear, force or fraudulently;
4. The consenting party must have knowledge regarding the nature and extent of the risks involved in the consenting-to procedure. There must also be

[35] See chapter 3 paragraph 5 *supra* for the discussions of *Castell v De Greef, Stoffberg v Elliott*, *Lymbery v Jefferies* and *Louwrens v Oldwage*. See also *Recsie's Estate v Meine* 1943 EDL 277.
[36] Carstens & Pearmain (2007) 891. See in general, Van Oosten (1989) 455, Van Oosten (2006) in Blanpain & Nys (eds) paragraph 109 and Strauss (2006) in Blanpain & Nys (eds) paragraph 110.
[37] See in general, Dhai A (2008) "Informed consent-2008" *South African Journal of Bioethics and Law* 1(1): 27-30. Suggested further reading, Meisel A & Roth LH (1981) "What we do and do not know about informed consent" *Journal of the American Medical Association* 246(21): 2473-2477.
[38] See Van Oosten FFW (1991) *The doctrine of informed consent in medical law*: 17-19, McQuoid-Mason D & Strauss SA (1983) "Medical negligence" in Joubert WA & Scott TJ *Law of South Africa (LAWSA):* paragraph 147 and Claasen NJB & Verschoor T (1992) *Medical negligence in South Africa*: 60.

understanding and appreciation on the part of the patient. A physician or researcher, however, need not point out each and every risk and danger involved;

5. The consenting party must consent to the harm and the assumed risks and dangers;
6. The information provided by the physician or researcher must be comprehensive, extend to the whole transaction and must be inclusive of the consequences;
7. Consent must be clearly and unequivocally given;
8. Consent must be obtained prior to the proposed intervention;
9. Consent must qualify as a legal act meaning that there must be some external conduct revealing the intention of the parties such as submission to the intervention;
10. The consent must, in general, be given by the concerned person who will undergo the proposed treatment or intervention;[39] and
11. Conduct performed must fall within the boundaries of the consent.

Interestingly, the authors Lidz, Meisel, Zerubavel, Carter, Sestak and Roth have posited a model of informed consent and depict this model in a somewhat mathematical fashion. The mentioned authors identified several components of informed consent and ascribed a symbol to each and argue that together these components comprise informed consent.[40] These are firstly, the disclosure of information *(I)*. Certain information must be disclosed by the doctor to the patient and patients are generally presumed to possess certain information. Some patients may be presumed to have further information based on their personal experience. Secondly, competency is identified *(C)*. A legal presumption exists that a patient has the capacity to comprehend information. Where a patient is deemed to lack such capacity their decisions are not considered legally valid or binding. Thirdly, understanding is identified as a component of informed consent *(U)*. It is assumed that a person who is competent while receiving information will understand such information and as such competency and understanding are interconnected. Fourthly, they identify the component of voluntariness *(V)*. Patients must therefore arrive at a decision without pressure or coercion and fifthly, they identified the component of decision *(D)*. This means that the patient must actually make a decision to accept or refuse treatment.[41] The model of informed consent may then be depicted as follows:[42]

[39] Proxy consent is however permissible.
[40] The symbols are indicated in brackets.
[41] Lidz CW, Meisel A, Zerubavel E, Carter M, Sestak RM & Roth LH (1985) *Informed consent: A study of decisionmaking in psychiatry*: 22.
[42] *Idem* 23.

$$C + I \Rightarrow U$$
$$U + V \Rightarrow D$$

As was seen in the earlier discussion on the development of consent in case law,[43] the courts have also dealt with the requirements for valid consent and have greatly added to the corpus of consent related principles. It is suggested that consent procedures may vary in differing circumstances and as such, the requirements for valid consent should also be variable.[44] An example of such differing scenarios for the obtaining of consent may be evidenced by the distinction between therapeutic and non-therapeutic treatment and research.

4 THE TRADITIONAL DISTINCTION BETWEEN TREATMENT AND RESEARCH

Traditionally the terms treatment or therapy and research have been considered as having different meanings.[45] According to van Wyk, medical treatment or therapy and research are distinct activities and accordingly, should be regulated by different ethical principles and regulatory requirements.[46] Generally, the term "therapy" is used in context of medical procedures while "research" is used as a description of an act of scientific investigation or study which may or may not include experimentation. This thesis argues that in context of stem cell technology, this distinction falls away.[47]

It has been suggested that the distinction between treatment and research is relevant as different forms of consent may be obtained in each individual scenario according to the purpose for which consent is sought.[48] In context of stem cell treatment, normal medical law principles regarding consent would then apply as they would in any other medical intervention. The reasoning behind this was that the scope of a medical intervention would be determinable and thus the consent process stands free from complications. Consent for research then, would be a more complex process as the scope of a research study is uncertain. It is suggested in this thesis that, due to the ever-evolving nature and great potential of stem cell science that there is no real certainty and for this reason, consent procedures cannot follow the norm. In other words, stem

[43] See chapter 3 paragraph 5 *supra*.
[44] See in general, Veriava F (2004) "Ought the notion of 'informed consent' to be cast in stone? VRM v The Health Professions Council of South Africa" *South African Journal on Human Rights* 20(2): 309-320.
[45] See in general, Del Carmen MG & Joffe S (2005) "Informed consent for medical treatment and research: A review" *The Oncologist* 10: 636-641.
[46] Van Wyk C (2010) *Legal issues surrounding stem cell research including consent and ethics review* presented at the Transplantation Indaba, BMW Pavilion, Waterfront Cape Town, 2-3 August. Hereafter referred to as the Transplantation Indaba. See in general, Van Wyk C (2005) "HIV preventative vaccine research on children: Is this possible in terms of South African law and research guidelines?" *Journal for Contemporary Roman Dutch Law* 68: 35-38.
[47] See in general, Nienaber (2010) 120.
[48] Prinsen L (2010) *An analysis of the proposed regulatory framework for the procurement and distribution of stem cells* (LLM thesis unpublished, University of Pretoria):164.

cell therapy is of such an ever-changing nature that it should rather be considered as research and as such, a dynamic form of consent should be obtained. At this juncture, however, a brief explanation of the traditional understanding of treatment or therapy and research is necessary.

4.1 TREATMENT OR THERAPY

Treatment may be defined as an activity with the sole purpose of benefitting the patient where there is a reasonable chance of success.[49] Emphasis is thus placed on the individual patient and modification of a method of treatment by a physician does not constitute research and may be regarded as a normal feature of treatment. Treatment may also be described as an intervention governed by beneficence and non-maleficence.[50] An individual patient's health must therefore be promoted in the course of treatment and such promotion of health must be able to justify the risk to which the patient is subject due to the treatment. Any treatment administered to a patient must be done to standards of care which have been scientifically validated and must have the objective of providing the patient with the optimal level of care. A physician, in treating a patient, is not required to develop scientific knowledge to be used on future patients.[51]

In summary, treatment is not future or society orientated and seeks to benefit the individual patient without having the requirement of furthering knowledge or gain other than the promotion of the well-being of the concerned patient.

4.2 RESEARCH

Research may be defined as a "systematic search or inquiry of knowledge."[52] Research may thus be regarded as a systematic investigation which includes research development, testing and evaluation which has been designed to contribute or to develop general knowledge of a particular subject.[53] The Medical Research Council of South Africa (MRC) states that any activity aimed at obtaining knowledge which may affect a person beyond normal clinical care may be regarded as research.[54] New knowledge may therefore be regarded as research if it is generalised, submitted for publication or higher qualification, transferred to others or

[49] Medical Research Council of South Africa (2003) *Guidelines on ethics for medical research: General principles (Book 1)* paragraph 2.1.1.
[50] Van Wyk (2010) Transplantation Indaba.
[51] *Ibid*.
[52] Department of Health (2004) *Ethics in health research: Principles, structures and processes* available online at http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html accessed 12/10/2012.
[53] MRC SA (2003) paragraph 2.1.2.
[54] *Ibid*.

presented at a scientific meeting.[55] Research may also be considered to be any activity which is designed to answer a scientific question.[56] Researchers attempt to gain insight into and knowledge of disease and treatment in order to ultimately improve medical practices and the care of future patients. Research, in contrast to treatment, is almost utilitarian in nature and is focused on society as a whole and not on an individual patient only.

In summary, research is a future orientated systematic study which seeks to develop and contribute to furthering knowledge with the ultimate goal of societal benefit. Research may, however, be subdivided into therapeutic and non-therapeutic research. This distinction is discussed briefly.

4.2.1 Therapeutic and Non-Therapeutic Research

Research, as an umbrella term, may mean either therapeutic or non-therapeutic research. This distinction is relevant especially in interventions involving minors.[57] Therapeutic research, on the one hand, is of direct benefit to the research participant or subject. Non-therapeutic research, on the other hand is beneficial to general scientific knowledge and does not directly affect the subject.[58] In other words, the distinction is based on the potential direct benefit which may arise from participation by a subject. The object of both therapeutic and non-therapeutic research, however, is the acquisition of knowledge and not personal treatment.

Both therapeutic and non-therapeutic research are, however, governed by the same ethical principles and as a result many bioethicists have abandoned the distinction between the two forms of research. Distinguishing between therapeutic and non-therapeutic research may also be a difficult task in certain instances as research may entail components of both therapeutic and non-therapeutic research.[59] This is especially true in stem cell related research and therapy.

In conclusion, traditionally the term treatment or therapy denotes a procedure which is medical in nature while research describes an act of scientific investigation. Treatment is an act solely conducted for the benefit of the patient and the promotion of their health and well-being. For example, by making use of stem cell treatment technology, a soldier patient who has experienced a bomb blast trauma and lost some of his hearing as well as his earlobe may be

[55] *Idem* 2.1.3.
[56] Van Wyk (2010) Transplantation Indaba.
[57] See paragraph 5.1.2.3 *infra*.
[58] See in general, Department of Health (2006) *Guidelines for good practice in the conduct of clinical trials in human participants in South Africa*.
[59] Section 11 of the National Health Act, Act 61 of 2003 discussed in chapter 5 paragraph 4.1.5 *infra* makes provision for this difficult distinction and regulates experimental treatment which requires certain procedures to be undertaken where a health service is provided for research purposes. See Van Wyk (2010) Transplantation Indaba.

given a new lobe.[60] This is to the benefit of the patient and promotes his health and well-being. But what if in future it becomes possible for this ear to so fully integrate into the body of the patient that not only the lost lobe has been replaced but the patient's hearing has also been restored? At the time of the transplant, this may seem like science fiction and outside the scope of the intervention, but due to the rapidly evolving nature and development of stem cell technology it might well be a possibility. This new knowledge and development is no longer simply treatment, it is research. It is also not simply research, it is both therapeutic in that it directly benefits the participant and non-therapeutic research as it is beneficial to scientific knowledge in general. This example may seem extravagant but it is in this extravagant potential that the promise and excitement of stem cells lie. It must then further be noted that a patient is no longer simply a patient but also a research participant or subject. They are now a patient-subject and for this reason stem cell treatment may be deemed research involving human subjects. In the course of this thesis, attention is therefore given to medical treatment as well as research involving human subjects.

Traditionally the distinction between treatment and research weighs in when deciding what format of consent would be best suited to the circumstances. In medical interventions, consent may be obtained in accordance to established practice which involves a process of informed consent due to the determinable scope of the intervention. Consent for research, however, is more complex and while informed consent is preferred, broad consent is often used in practice as a result of the uncertain scope of the intervention. However, as illustrated above, stem cell technology entails a greatly uncertain scope and therefore borders on research, meaning that neither informed nor broad consent as it stands today are sufficient. It is this conundrum which this thesis endeavours to address and in the course of this thesis it suggested that a combination of informed and broad consent is necessary. At this juncture, the focus of this chapter is narrowed and after concluding this rather broad discussion, attention must now be given to more specific and particular aspects of consent.

[60] Weisberger M (2016) "11 Body parts grown in the lab" *LiveScience*, 26 January 2016 available online at http://www.livescience.com/53470-11-lab-grown-body-parts.html accessed 20/5/2016. See also Staedter T (2016) "Adult human ear grown on a rat" *Discovery News*, 25 January 2016 available online at http://news.discovery.com/tech/biotechnology/adult-human-ear-grown-on-a-rat-160125.htm#mkcpgn=rssnws1 accessed 20/5/2016.

5 SPECIFIC ASPECTS OF CONSENT

In the previous chapter, a brief history and introduction to the concept of consent was provided. A general *capita selecta* of relevant aspects of consent has now been discussed in this chapter so far and at this juncture the focus is narrowed to the who, when, what and how of consent.

5.1 WHO SHOULD OBTAIN CONSENT AND FROM WHOM

The discussion pertaining to the persons involved in the consent process may be divided into two sections dealing firstly with the obtainer of consent and secondly, the granter thereof.

5.1.1 Who Should Obtain Consent?

There are many different opinions with regards to who is responsible for obtaining consent from a patient or research subject. Traditionally in a medical treatment setting, the physician responsible for the patient will have the duty of obtaining consent. In a research setting it is also normally the researcher who must seek consent from the potential participant. Where there is a possibility of research related to the treatment, however, opinions start to differ as to who has the duty and responsibility to obtain consent. One such opinion is that a person other than an attending physician should, where possible, obtain consent for research purposes utilising material collected from a patient in the course of treatment.[61] This ensures that the health requirements of the patient remain the physician's main focus and the primary reason for the relationship between doctor and patient. Patients are in a dependant relationship based on trust with their physicians and as such they may be susceptible to suggestions made by the physician.[62] It is therefore considered preferable that someone other than an attending physician, who is not involved in any suggested research activity, obtain consent. This might ensure that consent is truly voluntary and informed while also avoiding a conflict of interest.[63] In circumstances where an attending physician is involved only in this capacity and not as a

[61] The Ethics Committee of the American Society for Reproductive Medicine (2002) "Donating spare embryos for embryonic stem cell research" *Fertility and Sterility* 78(5): 957-960. See also The Ethics Committee of the American Society for Reproductive Medicine (2004) "Donating spare embryos for embryonic stem-cell research" *Fertility and Sterility* 82(1): 224-227.
[62] Lo B, Chou V, Cedars MI, Gates E, Taylor RN, Wagner RM, Wolf L & Yamamoto KR (2004) "Informed consent in human oocyte, embryo and embryonic stem cell research" *Fertility & Sterility* 82(3): 562.
[63] See in general, National Bioethics Advisory Commission (1998) *Research involving persons with mental disorders that affect decision-making capacity* and Chen D, Miller F, Rosenstein D (2003) "Clinical research and the physician-patient relationship" *Annals of Internal Medicine* 138: 669-672.

researcher, the physician's sole focus will be the well-being of the patient and not the potential societal or scientific benefits of any proposed research.[64]

It would thus seem that it is preferable to have an unbiased third party obtain consent. An exception does, however, exist in which the physician ought to be the person who seeks consent, namely where the physician is also the relevant researcher.[65] As it has been argued that stem cell therapy is actually research, it is submitted that this exception must in context of stem cell therapy and research be considered the rule. It is therefore the duty of the attending physician-researcher to obtain consent from a potential patient-subject. Such approach is then also in line with international consent trends.[66]

Although this may leave the door open to undue influence, conflicts of interest and coercion, Lo *et al.* opine that it is possible to design the consent process as to minimise conflicts of interest or undue influence.[67] These authors suggest the following three-step approach to obtaining consent:[68]

1. The potential patients-subject or material donor must be informed and assured that their treatment will not be influenced by their decision to partake in the research or not;
2. Any relationships, be they financial or research related in nature, between the person obtaining consent and the research study must be disclosed to the potential patient-subject or donor; and
3. The actual attending physician may be withheld from the consent formalities and need not be informed of the patient-subject's ultimate decision, thereby decreasing any pressure the patient-subject or donor may experience.

It is suggested that it is preferable to have the physician-researcher obtain the required consent from the patient-subject as the physician-researcher possesses the necessary knowledge to truly and properly provide the patient-subject with all the required information to enable them to make an informed decision. Consent in such circumstances would then far more readily comply with the requirements of valid informed consent. Thus, in conclusion, the attending physician ought to be the person who obtains consent on the conditions that the patient-subject is adequately provided with the necessary information to make a decision, there are no potential conflicts of interest or where such interests exist, they have been disclosed to the

[64] National Bioethics Advisory Commission (2001) *Ethical and policy issues in research involving human participants* available online at http://bioethics.georgetown.edu/nbac/human/oversumm.pdf accessed 11/10/2015.
[65] Lo, Chou *et al.* (2004) 562.
[66] See chapter 6 as well as chapter 7 *infra*.
[67] Lo, Chou *et al.* (2004) 562.
[68] *Ibid*.

patient-subject. The question of who such a potential patient-subject might be must then also be discussed.

5.1.2 Who Must Provide Consent?

Normally, the patient who will undergo treatment, the research participant or donor of any material to be used in research is required to give their informed consent.[69] Consent may in certain circumstances be waived by an ethics committee or review board where the material or data is to be de-identified and can no longer be traced back to the donor. In such cases provision is usually made therefore in the initial consent. It is suggested that this is not sufficient in context of stem cell research due to the emotional and moral significance of some of the material. This means that consent should at least be explicit and specific[70] as donors of material or research subjects may feel violated where their material or data is to be used without their prior consent thereto. It is also not always desirable to de-identify material or data and de-identification does therefore not always warrant use of material without further consent.[71] The use of biological material such as stem cells in research should therefore only be permitted where it has been specifically consented to. Obtaining consent will differ depending on the nature of the donated material as well as the inherent risk involved.

Section 12(2)(c) of the Constitution[72] reads that a person may not be subjected to medical or scientific research without their informed consent. This, along with the discussion above, makes it clear that it is the person concerned who must consent to a proposed medical procedure or to their participation in research. A person is, however, only able to consent to a procedure or to participation where they have been given the required information and have knowledge, appreciation and acquiescence. As was previously mentioned, aspects of consent are governed by various different Acts in South Africa and these legislative documents identify broad categories of persons.[73] This means that not all persons are equally able to have knowledge, appreciation and acquiescence and at this juncture it thus becomes necessary to discuss the

[69] National Bioethics Advisory Commission (1999) *Research involving human biological materials: Ethical issues and policy guidance* available online at http://bioethics.georgetown.edu/nbac/hbm_exec.pdf accessed 11/10/2015.
[70] Lo, Chou *et al.* (2004) 560.
[71] *Ibid*. For example, where stem cells are to be used in therapy or transplantation, it may be necessary to retain a link to the donor in order to assess which tests were performed to determine the possibility of genetic or infectious diseases. See also regulation 9 of the Regulations Relating to Human Stem Cells in chapter 5 *infra* which states that "A stem cell establishment must ensure that (1) all its activities referred to in regulation 2(1)(a), (b) and (c) can be traced from donor to the recipient and vice versa; (2) it has a unique donor identification system which assigns a code to each donation and to each product associated with it; (3) all stem cells are identified with a label that contains the information or references allowing a link to the information referred to in regulation 5(1)(b) and (4) data necessary to ensure traceability at all stages is kept for a minimum of 30 years after donation or clinical use and such data storage may be in electronic form."
[72] As discussed in chapter 3 paragraph 6.1.1 *supra*.
[73] Such as minors, the mentally ill and adults otherwise incapacitated.

differing capacities to consent as found in adults with or without capacity, mentally ill persons and minors. Each group is discussed below in order to provide further information and understanding of the complex nature of informed consent.

5.1.2.1 Adults

For a patient to be able to give valid consent, the consenting person must be legally capable of giving such consent. To be considered as such, a person must be sane and sober.[74] Legally, a person who is over the age of 18 is considered an adult[75] and may therefore consent to a medical procedure or participation in a research study.[76]

However, age is not an absolute measure of a person's capacity as a person may be above the age of majority but suffer from temporary or permanent incapacity due to unconsciousness, delirium, coma, shock, trance or intoxication.[77] In such circumstances proxy consent may be required to give consent on behalf of an incapacitated person.[78]

As was mentioned above, the element of risk involved in a certain procedure or study will have an effect on the necessary form of consent. According to the MCR guidelines, however, risk should be limited to a minimum in both therapeutic and non-therapeutic research studies involving human subjects.[79] The benefits of a proposed therapy or research study must outweigh the risks. It is a rule of thumb that research which involves human subjects should therefore not entail risk which is greater than minimal.[80] The only exception to this rule is where the research holds great potential benefit to the particular participant.[81]

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[74] See *Recsei's Estate v Meine* 1943 EDL 277 wherein it was held "ordinarily the consent of an adult in full possession of his mental faculties…would be sufficient authority for the performance of a surgical operation."
[75] Section 1 of the Children's Act defines a child as a person under the age of 18 years. An adult is therefore a person above the age of 18. See also section 129 of the Children's Act regarding medical treatment of children and the required consent.
[76] See in general, McQuoid-Mason D (2006) "The National Health Act and refusal of consent to health services by children" *South African Medical Journal* 96(6): 530-532.
[77] Carstens & Pearmain (2007) 899.
[78] Section 7 of the National Health Act makes such provisions. See chapter 5 paragraph 4.1.2 *infra* for a detailed discussion of this section.
[79] MRC SA (2003) paragraph 9.12.
[80] According to the Regulations relating to Research on Human Subjects of 23 February 2007, "minimal risk" means the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that which may be ordinarily encountered in daily life. Hereafter referred to as the 2007 Human Subjects Regulations. See chapter 5 paragraph 5.5 *infra*.
[81] See in general, Van Wyk (2010) Transplantation Indaba. Suggested further reading, McLean SAM (2001) "Informed consent, medical research and the competent adult" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 166-172.

5.1.2.2 The mentally ill

As was mentioned in the previous chapter, certain requirements must be met for consent to qualify as lawful.[82] Some of these requirements are, however, rather problematic in circumstances regarding mentally ill persons such as the requirement that consent is free and voluntary and that the consenting person must have the capacity to legally consent. These issues will be touched upon in the course of this discussion.[83]

The Mental Health Care Act[84] provides for certain requirements to be met when obtaining consent from persons suffering from mental illness.[85] The Act defines mental illness as "a positive diagnosis of a mental health related illness in terms of accepted diagnostic criteria made by a mental health care practitioner authorized to make such a diagnosis." "Mental health care" is, however, not defined and the Act does mention mental health care as including research.[86] These so-called "mental health care users" include persons who are receiving care, treatment or rehabilitation services;[87] persons who are making use of a health service provided by a health establishment which attempts to enhance the mental health status of the person concerned; a patient of the State or a mentally ill prisoner and a person who is below the age of 18 and is not capable of making decisions. In certain circumstances this may be extended to include a prospective user, the next of kin of the concerned user, legally authorised persons who act on behalf of the mentally ill person or an administrator or executor of a deceased estate.[88]

It is important to note that a mentally ill person is not unable to give consent to treatment *per se*[89] and the legislator must therefore assume that such a person is capacitated to consent to care, treatment or rehabilitation since a distinction is made between voluntary and involuntary

[82] See chapter 3 paragraph 5.10 *supra*.
[83] Nienaber (2010) 120.
[84] Mental Health Care Act, Act 17 of 2002.
[85] See in general, Van Staden CW & Krüger C (2003) "Incapacity to give informed consent owning to mental disorder" *Journal of Medical Ethics* 29(1): 41-43. See also Strauss SA (1998) "Clinical trials involving mental patients: Some legal and ethical issues" *South African Practice Management* 1: 20.
[86] In light of the Mental Health Care Act 2002 repeatedly making use of the phrase "care, treatment and rehabilitation" it is highly doubtful that mental health care may be understood as including research. See Nienaber (2010) 122. See also Nienaber A (2013) "Consent to research by mentally ill children and adolescents: The implications of chapter 9 of the National Health Act" *South African Journal of Psychiatry* 19(1): 20.
[87] "Care," "treatment" and "rehabilitation" have corresponding meanings.
[88] Section 1 of the Mental Health Care Act 2002.
[89] See in general, Strauss (2006) in Blanpain & Nys (eds) paragraph 116. See also section 26 of the Medical Health Care Act 2002 for provisions regarding consent where a person is incapable thereof to give such consent, section 31 which deals with the recovery of capacity of an assisted mental health care user, section 32 for circumstances where no consent was provided and section 38 which governs situations wherein an involuntary patient regains the ability to make informed decisions regarding their care, treatment or rehabilitation. See further chapter 5 paragraph 4.1.1 *infra* for a discussion of section 6 of the National Health Act which provides for circumstances where a person other than the health care user consents to medical intervention. See for interest sake Janofsky JS, McCarthy RJ & Foistein MF (1992) "The Hopkins competency assessment test: A brief method for evaluating patients' capacity to give informed consent" *Hospital Community Psychiatry* 43(2): 132-136.

care, treatment and rehabilitation.[90] Voluntary care, treatment and rehabilitation mean that health interventions are provided to persons who consent to such interventions. Involuntary care, treatment or rehabilitation means the provision of health interventions to persons who are incapable of making informed decisions due to their mental health status and who refuse a health intervention but require such services for their own protection or for the protection of others.[91]

In terms of the Mental Health Care Act, consent is a prerequisite for any treatment or rehabilitation of a mentally ill person and states that a health care provider or establishment may only admit a patient where the patient or user has consented to care, treatment or rehabilitation services.[92] The Act thus distinguishes between care, treatment and rehabilitation with consent on the one hand and without consent on the other. Section 26 states that a patient or user may not be provided with the mentioned services without their consent unless an application has been made for such services to the head of the relevant health care establishment and there is a reasonable belief that the patient is incapable of making an informed decision regarding their need of the services. Section 32 elaborates on the grounds whereon a person may be cared for, treated or rehabilitated without their consent by stating that consent of the patient or user may be waived where it is reasonably believed that the patient suffers from a mental illness of such nature that they are likely to inflict serious harm on themselves or others; the health services are required to protect the finances or reputation of the patient; or the patient is incapable of making decisions and is unwilling to receive the services.

The Mental Health Care Act is silent on the issue of research involving mentally ill persons.[93] It is, however, submitted that such persons need not be excluded from participation in research. Strict conditions regarding consent will be required and where a person is capable of making an informed decision they should be permitted to do so and to participate. Their knowledge, understanding and acquiescence should be the deciding factors in such instances. Such research

[90] See sections 9, 26 and 32 of the Mental Health Care Act 2002. See in general, Van Staden & Krüger (2003) 41-43.
[91] Section 1 of the Mental Health Care Act 2002. See also Van Staden CW & Krüger C (2007) "Can involuntary admitted patients give informed consent to participation is research" *South African Journal of Psychiatry* 13(1): 10-12. See also Weiss Roberts L (2003) "Mental illness and informed consent: Seeking an empirically derived understanding of voluntarism" *Current Opinion in Psychiatry* 16(5): 543-545. Suggested further reading, Kersop M & Van den Berg F (2015) "Obtaining involuntary mental health care in the South African constitutional dispensation" *Obiter* 36(3): 679-701.
[92] Section 9 of the Mental Health Care Act 2002.
[93] Nienaber (2013) 20.

should also only be permitted where it is essential to the research that mentally ill persons participate and are indispensable to the object of the study.[94]

The National Health Act also makes no express reference to research involving mentally ill research participants. In fact, the National Health Act (NHA) only makes use of children as a vulnerable group in context of consent to participation in research.[95] The Regulations relating to Research on Human Subjects, however, deal with this subject extensively and are discussed in detail in the course of this thesis.[96] At this juncture, however, it is sufficient to briefly summarise the position as provided for in the mentioned Regulations. According to the Regulations, a mentally ill person may participate in research provided that the research is strictly concerned with mental illness, thereby necessitating the participation of the mentally ill; there exists adequate justification for the involvement of institutionalised mentally ill persons; suitable evaluation procedures are in place to asses and ensure that the person concerned is capable of providing informed consent to participation; such consent is freely and voluntary given and the research to be carried out does not entail more than minimal risk or the risk is outweighed by the expected benefits to the participants.[97]

5.1.2.3 Minors

As was mentioned previously, children are recognised as a vulnerable group and as such care must be taken to ensure that the rights and interests of minors are optimally protected. This is in concordance with section 28 of the Constitution which mandates that the best interests of the child are of paramount importance in all matters concerning the child.[98] Due to the stringent need that children be protected and that their best interests be served, it is necessary to distinguish between medical and scientific interventions involving minors as varying degrees of protection may be or are required in different settings.

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[94] See in general, Derrickson D (1997) "Informed consent to human subject research: Improving the process of obtaining informed consent from mentally ill persons" *Fordham Urban Law Journal* 25(1): 143-165. Participation of vulnerable groups such as children and the mentally ill is imperative to research as it allows for the identification of group-specific characteristics. It may even be argued that an ethical duty exists to conduct such research as to alleviate the burden of the specific illness or disease. See Nienaber (2013) 19.

[95] *Ibid*. Mentally ill persons are generally considered vulnerable to exploitation as their illness has the potential of compromising their judgment and reducing their ability to give fully informed consent.

[96] See chapter 5 paragraph 5.5 *infra*.

[97] See in general, Swanepoel M (2011) "A selection of constitutional aspects that impact on the mentally disordered patient in South Africa" *Obiter* 32(2): 282-302.

[98] See in general, Du Plessis E, Van der Walt G & Govindjee A (2014) "The constitutional rights of children to bodily integrity and autonomy" *Obiter* 35(1): 1-23. Suggested further reading, Du Plessis E, Govindjee A & Van der Walt G (2014) "A legal analysis of 'saviour siblings' and 'benefactor children' in South Africa" *Obiter* 35(2): 224-253.

The first aspect to be discussed is the consent of a minor[99] for medical purposes. At the onset of this discussion it is important to discuss the provisions of section 129 of the Children's Act[100] which governs the consent of a minor to medical treatment and surgical operations.[101] Although the Act does not provide for definitions of "medical treatment" or "surgical operations," guiding literature on the Children's Act[102] states that "medical treatment" refers to a non-invasive procedure such as inoculation whereas "surgical operation" denotes an invasive procedure.[103] According to section 129 of the Act, a minor as young as 12 years of age may give consent on their own behalf or on behalf of their children, to medical treatment. There are certain factors which are taken into account in such circumstances other than age, which includes the child's level of maturity and capacity to understand the benefits, risks and implications of the procedure.[104] In order to determine a child's level of maturity the minor must have full knowledge regarding the proposed procedure as well as an understanding of the risks involved. Different treatments will involve different levels of risk and will therefore require different levels of understanding and responsibility on behalf of the minor.[105] Where a minor is however, unable to give consent due to a lack of maturity or understanding, the parent or guardian of such minor will have to give consent to a proposed procedure. A parent or guardian may include the biological mother or father of the child, a caregiver,[106] a hospital superintendent, the Minister of Social Development or a court.[107]

In conclusion, a child may consent to a medical intervention without the consent of a parent or guardian but only where such child is capable of understanding what they are consenting to. Attention may now be given to the consent of a minor in the context of research.

Section 12(2)(c) of the Constitution which was previously discussed, states that a person must give consent to medical or scientific experimentation in which they will be involved. The NHA further addresses this subject and makes provision for the participation of children in

[99] "Minor" and "child" are used interchangeably throughout the course of this thesis.
[100] Children's Act, Act 38 of 2005.
[101] See in general, Mahery P (2006) "Consent laws influencing children's access to health care services" in Ijumba P & Padarath A (eds) *South African Health Review*: 167-180.
[102] Mahery P, Proudlock P & Jamieson L (2010) *A guide to the Children's Act for health professionals*: 9.
[103] See in general, Strode AE (2013) "The parameters of the current legal framework for health research: Forms of health research which are regulated and obligations imposed on researchers" *South African Journal of Bioethics and Law* 6(2): 69-71.
[104] Mahery, Proudlock *et al*. (2010) 9.
[105] This is in line with the National Health Act section 71(2)(d) and section 71(3)(a)(iii). See the discussion on the traditional distinction between consent in therapeutic and non-therapeutic research in paragraph 4 *supra* as it also relates to differences in risk and what the procedure entails.
[106] A caregiver need not have parental rights or responsibilities. See in this regard section 32 read with section 129(3) of the Children's Act 2005. See Nienaber (2013) 21.
[107] Section 129(9) of the Children's Act 2005. See in general, Nienaber (2013) 23.

research.[108] The National Health Act provides for strict conditions to be adhered to and states that a parent or guardian's consent must accompany the consent of the minor. The Act further distinguishes between therapeutic and non-therapeutic research and the process of consent in each case.[109]

The provisions regarding consent to therapeutic research are found in section 71(2) of the NHA which states that research involving a minor may only be conducted where the research is in the child's interests; the research is conducted in accordance to a specified method and under prescribed conditions; the parent or guardian of the child has also consented to the child's participation in the research and where the minor is capable of understanding, they may consent themselves.[110] It is interesting to note that the consent of the child is given precedence over the consent of the parent or guardian and where a child refuses to participate in therapeutic and non-therapeutic research, a parent's consent to the contrary is void.[111] In the context of a medical procedure where a child will not or is not able to consent, a parent or guardian may do so.[112]

Section 71(3) provides for consent of a minor to non-therapeutic research and states that the research may only be done under prescribed conditions: the consent of a parent or guardian is required; that a child may consent where they have the capacity to do so and the Minister of Health also consents to such research.[113]

In terms of section 71(3)(b)(i) to (v) the Minister may not consent to non-therapeutic research involving a minor where the object of the research may be easily achieved making use of adult subjects; the research is unlikely to yield a significantly improved understanding of the disease, disorder or condition; where the underlying motivation of the consent of the child, parent or guardian is *contra boni mores*;[114] such research may pose a significant risk to the health of the child and the risk involved in the research outweighs the potential benefit of the research study.[115]

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[108] See section 71 of the National Health Act. See in general, Buchner-Eveleigh M & Vogel F (2015) "Section 71 of the National Health Act: A call for a review of the consent requirement for child participation in health research" *De Jure* 48(2): 280-292. See also chapter 5 *infra*.
[109] See in general, Burchell JM (1978) "Non-therapeutic medical research on children" *South African Law Journal* 95: 193-216.
[110] Section 71(2)(a)-(d) of the National Health Act.
[111] Mahery, Proudlock *et al*. (2010) 13-14.
[112] See in general, McQuoid-Mason (2006) 530-532.
[113] Section 71(3)(a)(i)-(iv) of the National Health Act.
[114] *Contra boni mores* means "against good morals."
[115] See in general, Pope A (2007) "HIV preventative research in minors" *South African Law Journal* 124(1): 165-187. See also Strode A, Slack C, Grant C & Mushariwa M (2005) "Ethical and legal challenges in enrolling adolescents in medical research in South Africa: Implications for HIV vaccine trials" *South African Journal of Science* 101: 224-228.

Once again the role of risk is quite prominent and research involving a minor may therefore only be conducted where it poses a minimal risk to the child. The Regulations Relating to Research on Human Subjects[116] define minimal risk as "the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life."[117] In conclusion, a child may consent to therapeutic and non-therapeutic research on the condition that their consent is accompanied by the consent of a parent, guardian or Minister and in compliance with all other conditions as stipulated in legislation.

5.2 WHEN TO OBTAIN CONSENT

The sentiment of "timing is everything" rings true in various aspects of human life and so also in the process of obtaining consent. The time at which consent should or must be obtained is important in the general context of therapy and research as well as the more specific stem cell related context, as it is an emotionally loaded and controversial subject. The timing of consent may have an impact on the available options and alternatives in a treatment scenario and could determine whether or not a person is willing and able to participate in research.[118] Normally, consent is obtained prior to any medical intervention or research participation.[119] In context of stem cell therapy and treatment, consent must therefore be obtained prior to the application thereof or the removal, withdrawal, use, storage or disposal of biological samples.

The importance of timing may be motivated by making use of the example of embryo donation in context of fertility treatment. As was previously explained, stem cells may be derived from embryos and therefore constitute a valuable source of potential research material. Decisions regarding the ultimate disposal of embryonic material may arise in the process of treatment for infertility since patients discuss their preferences on various subjects such as harvesting of the embryos, the number of embryos to be implanted during treatment and the possibility of storing a number of embryos. A discussion regarding the disposal of embryos fits easily and naturally into these discussions and it is therefore fitting to discuss these options prior to the

[116] The 2007 Human Subjects Regulations. See regulation 1 of the 2007 Human Subjects Regulations. See chapter 5 paragraph 5.5 *infra* for more on the Regulations.
[117] "Daily life" means daily life in a stable society. See Van Wyk (2010) Transplantation Indaba. Suggested further reading, Montgomery J (2001) "Informed consent and clinical research with children" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 173-181.
[118] Interestingly, the American National Institute of Health and the National Bioethics Advisory Commission states that only after infertility treatment has been completed and a decision has been made to discard of spare embryos, should consent discussions regarding the donation of material for embryo research be undertaken. See in general, National Bioethics Advisory Commission (1999) *Ethical issues in stem cell research*. See also The President's Council on Bioethics (2002) *Human cloning and human dignity: An ethical inquiry* and also National Institute of Health (1994) *Report of the human embryo research panel* available online at http://www.bioethics.gov/commissions/ accessed 8/10/2011.
[119] Exceptional circumstances do however exist such as emergency treatments where prior consent may be waived.

onset of therapy. It may be argued that where consent is obtained for later research at the onset of fertility treatment, it is not a question of whether the material may be used but rather of how it could be used. It becomes a matter of how the embryos will be used and not whether they will be used.[120] It must, however, be emphasised that the person wishing to obtain consent must act in accordance with the required level of sensitivity[121] and must allow for an appropriate amount of time wherein the person concerned may contemplate the available options and information.[122]

However, making use of this same example, it becomes obvious that consent, although given prior to an intervention, is based on certain conditions and as these conditions change, so too must consent change. In other words, consent ought not to be a stagnant, once-off action. In context of fertility treatment and the fertilisation of embryos, the persons concerned are often urged to plan ahead for the disposal of embryonic material. In this regard, fertility institutions frequently require that these persons provide them with written directives for future events such as death, failure to pay storage fees, the inability to agree on the disposition of the material and loss of contact with the program.[123] This indicates that a change in circumstances does have an impact on the continuance of consent and that obtaining consent only once is no longer satisfactory. Where possible, consent for whatever has been decided on must be reaffirmed at a later stage, regardless of the amount of time which has elapsed.[124] Where embryonic material is used without obtaining consent for the proposed purpose, such research would constitute a gross violation of the autonomy rights of the persons concerned.

In conclusion, it is emphasised that consent must be obtained prior to any medical or scientific intervention. This consent, however, is based on information and preferences which are subject to change over time. As such, consent timing must also have a flexible and changeable element and for this reason it is submitted that consent must be viewed as a living and constantly altering process which needs to be continually revised, renewed or where appropriate, revoked.

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[120] Lo B, Chou V, Cedars MI, Gates E, Taylor RN, Wagner RM, Wolf L & Yamamoto KR (2003) "Informed consent in embryo and stem cell research: A key to research progress" *Science* 301(5637): 561.
[121] For example, it would be insensitive of a person to discuss consent to research where embryos intended for fertilisation treatment are found to be of a poor quality which does not allow for fertilisation due to some anomaly.
[122] Lo, Chou *et al*. (2003) 561.
[123] The Ethics Committee of the American Society for Reproductive Medicine (1997) "Ethical considerations for assisted reproductive technologies" *Fertility and Sterility* 67(5)1: S1-S9.
[124] Where contact between the donor and the institution has been lost and there was no revocation of consent, it may be considered ethically permissible to make use of the donated material for research purposes. See Lo, Chou *et al*. (2003) 561.

5.3 THE SCOPE OF CONSENT

Informed consent relates to the process whereby a patient is given information in the process of consenting to treatment or research in order to establish knowledge, appreciation and acquiescence on the part of a patient or research participant. This means that the person concerned must be furnished with all the information reasonably considered pertinent to decision making.[125]

The consent process should also cover an explanation of pertinent aspects of the research which include *inter alia* the objects of the intervention as well as the methods or techniques to be employed. A prospective patient or research subject should be assured that they or their material will only be used in accordance with medical, scientific and ethical standards and should be allowed an opportunity to ask questions and to fully participate in the consent process. This allows a patient or subject to identify information which they may consider relevant in the process of making their decision.[126] In research, the consent requirement is broader than in a treatment context where a patient need only be informed of the benefits, risks and general consequences of the treatment. In the context of research, the NHA and its Regulations[127] require that a research participant must be informed of additional aspects such as the methods and procedures to be used in the course of the research.

Confidentiality issues should also be discussed with a patient or participant during the process of obtaining consent, such as the use of an identifying code which links a donor to their material.[128] Donors or participants must then be informed of who will have access to the code and to what extent their confidentiality will be protected. Retention of an identifying link between material or data and donor is thus a further aspect to which a patient or subject must consent.[129]

From the above it should be clear that the better informed a patient or participant, the better. The more fully a person understands what they are consenting to, the more valid the consent. For this reason it is submitted that the following aspects need to be covered in the process of consenting to research: the title of the research; the person or institution undertaking the

[125] See in general, Berg J, Lidz CW & Appelbaum PS (2001) *Informed consent: Legal theory and clinical practice*.
[126] See in general, Wendler D & Emanuel E (2002) "The debate over research on stored biological samples: What do sources think?" *Archives of Internal Medicine* 162(13): 1457-1462. For example, research participants must understand that a donation may lead to commercially valuable products or that their data might perhaps be shared with other researchers or that their material may be destroyed. See also National Bioethics Advisory Commission (1999) *Research involving human biological materials: Ethical issues and policy guidance*.
[127] See chapter 5 *infra* for an in depth discussion of the NHA and relevant regulations.
[128] This is usually done in cases where the material will be used in transplantation in order to determine whether or not such material has been subjected to the appropriate screening procedures testing for genetic or infectious diseases. See Lo, Chou *et al.* (2004) 561.
[129] Lo, Chou *et al*. (2003) opine that it is perhaps preferential to make use of material in research where consent has been granted to be re-contacted.

research or performing the treatment; any conflicts of interest should be disclosed; background information and an explanation of the proposed research or treatment, the methods which will be used during treatment or research; a statement of the purpose and benefits as well as of the risks of the research or treatment and the expected duration of approval of an applicable ethics committee if any. The required consent form which should comply with general consent requirements must contain at least an in-depth explanation of what is being consented to, be it treatment, research or a combination thereof; where a research subject donates material, an explanation of the specific biological material; an explanation of the procedure to be used in collecting the material; the purpose of the proposed research study; any alternative options of use such as research, therapy or education; an explanation of the research process and what methods or techniques will be used; potential or real harm or risks involved in participation; any expected or potential benefits; options regarding storage of material or data and any time limits attached thereto; the manner in which material may be destroyed or disposed of; the extent to which the privacy and confidentiality of the patient or participant will be protected; incentives to participate in the research study and proof of ethics committee approval.[130] The last aspect to be discussed here is the how, or format of consent most suited to stem cell technology.

5.4 FORMAT OF CONSENT

Much has already been said about informed consent as consent model and it is commonly seen as the key to respecting the autonomy of a patient or research participant. Dworkin equated autonomy with liberty, dignity, integrity, individuality, independence and self-knowledge while other writers have compared it with privacy, voluntariness, self-mastery and free choice.[131] Generally understood, informed consent contains the elements of provision of information, voluntariness and competence to make decisions based on the information.[132] This means that the person concerned is able to assimilate the information into their own set of values and preferences. What this boils down to is that informed consent is a process used to enhance patient autonomy and is appropriate for all instances involving risk regardless of the number of options available.[133]

[130] Prinsen (2010) 227.
[131] O'Neill O (2003) "Some limits of informed consent" *Journal of Medical Ethics* 29: 5.
[132] Sheenan M (2011) "Can broad consent be informed consent?" *Public Health Ethics* 4(3): 227-228.
[133] Whitney SN, McGuire AL & McCullough LB (2004) "A typology of shared decision making, informed consent and simple consent" *Annals of Internal Medicine* 140(1): 54.

As discussed in the previous chapter of this thesis, ethically speaking, informed consent is the autonomous authorisation of an individual to a medical intervention and also a formal process required by institutions prior to permitting any procedures. Legally, it is a safeguard against the physician's liability. At the heart of the matter, however, informed consent is a conversation between the physician and patient or the researcher and the participant regarding the proposed intervention. This means that informed consent is a process and not a mere signature on a form. It is appropriate where an intervention entails high risk and requires a discussion of the nature, purpose, risks and benefits as well as any alternatives or the effect of no action taken and must then conclude with an explicit agreement between the parties.[134]

The legal scope of informed consent is thus dependent on risk.[135] This means that informed consent is required in decisions involving high risk but also in circumstances where there are alternative options to the procedure being proposed.[136] At this juncture it should be clear that informed consent cannot be done away with. It is, however, possible to identify four arguments as to why informed consent results in difficulty in a medical sphere. Firstly, informed consent is only possible where a person is competent to consent and this is not always the case in medicine as persons may be permanently or temporarily incompetent. Secondly, informed consent is of little to no use in selecting public health policies. Thirdly, the process of informed consent entails the disclosure of information regarding third parties without their consent such as family medical history or genetic information. Lastly, informed consent is limited where a person is competent to consent but is placed under some form of force to provide consent.[137]

In context of stem cells, therapy and research, informed consent may be problematic in that it is not feasible in obtaining consent to future uses of donated materials.[138] It is here that the focus of this thesis falls as the object of this thesis is an examination of the most appropriate model of consent in stem cell therapy and research. In order to address this issue, the other forms of consent should, however, be explained in order to facilitate comprehension of the complex nature of the issue at hand. What follows is an explanation of the numerous different types or models of consent which have been identified by legal scholars[139] and applied in practice.

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[134] *Ibid*.
[135] *Idem* 55.
[136] *Idem* 56. See also Howard M, Howarth G, Dinwoodie M, Nisselle P & Whitehouse S (2014) "From informed consent to shared decision-making" *South African Medical Journal* 104(8): 561-562.
[137] O'Neill (2003) 4-5.
[138] *Idem* 5.
[139] These scholars include Mason, Laurie, McCall Smith, Campbell and McLean.

5.4.1 Express Consent

Express or explicit consent may be granted orally or in writing where it is required by law. At times in medical practice, express consent of a patient is obtained orally but as a general rule where a patient is admitted to hospital or other health care institution, written consent is obtained by way of an express consent clause contained in the admissions forms.[140] In the absence of express consent, consent may be presumed or implied.[141]

Strauss stated that written, signed consent is of utmost importance in safeguarding a doctor against legal action, meaning that express consent is advantageous.[142] In other words, express or explicit consent, especially where the type of treatment or procedure is included in the consent form, provides strong evidence that the permission of the patient has been obtained. Express consent, however, may be exploited by health care institutions in an attempt to exempt themselves from liability by the inclusion of exemption or exculpatory clauses.[143]

5.4.2 Implied Consent

Implied, presumed, tacit or assumed consent is consent which is inferred from the words or conduct of the patient.[144] In certain cases it is easy to imply consent such as where a patient holds out his arm for an injection while in the doctor's consultation room. The mere submission of a patient to a certain procedure, however, does not constitute consent. There must be a submission to treatment as well as a manifestation of the will to consent. The manifestation of the will to consent is described by Dada and McQuoid-Mason as "patients capable of submitting themselves to medical treatment in the full knowledge of the nature thereof, and offering no resistance or making no objection to medical treatment."[145] This means that a person must have knowledge and for this reason, implied consent is not a valid form of consent in cases involving children or mentally ill persons.[146] However, this form of consent may perhaps be applicable to the use of already obtained materials and is akin to certain opt-out models of consent.[147]

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[140] Laurie G & Postan E (2012) "Rhetoric or reality: What is the legal status of the consent form in health-related research?" *Medical Law Review* 21: 386-388.
[141] Otlowski M (2012) "Tackling legal challenges posed by population biobanks: Reconceptualising consent requirements" *Medical Law Review* 20(2): 212.
[142] Strauss (1991) 9.
[143] Cronje-Retief M (2000) *The legal liability of hospitals*: 440.
[144] See in general, Potts M, Verheijde L, Rady MY & Evans DW (2010) "Normative consent and presumed consent for organ donation: A critique" *Journal of Medical Ethics* 36: 498-499 and Veatch RM (2007) "Implied, presumed and waived consent: The relative moral wrongs of under- and over-informing" *The American Journal of Bioethics* 7(12): 39-54.
[145] Dada MA & McQuoid-Mason DJ (eds)(2001) *Introduction to medico-legal practice*: 9.
[146] *Ibid*.
[147] Otlowski (2012) 212.

Although this model of consent offers great efficiency it does not respect the autonomy of the participant or their right to make informed decisions.[148] In context of stem cell research, an individual may be informed that their sample will be used in a research project unless they opt-out of the project.

5.4.3 Simple Consent

Consent is required for all instances of medical care and research prior to the intervention. Simple consent may be identified where a person simply approves or agrees with the recommended or proposed plan of action. Scholars opine that simple consent is ethically adequate in low risk decisions. Simple consent is therefore appropriate where an intervention poses little risk. It entails an explanation of the intervention which is then followed by either agreement or refusal by the patient.[149] This is true where there is one clear option as well as alternative options available to the person concerned.[150]

Whereas in instances of informed consent the consent is provided expressly, in simple consent it may thus also be implicitly indicated through submission to a proposed treatment.[151] Where a person concerned asks questions and is given further information, simple consent may in some cases expand to such an extent that it resembles informed consent. The information provided must, however, be in line with the circumstances and the level of interest and understanding of the patient.[152]

5.4.4 Specific Consent

Specific consent may be appropriate and is also advocated in circumstances of commonly performed procedures.[153] This consent model may even be regarded as the optimal or quintessential form of consent and it most definitely satisfies the core principles of consent.[154] It is also important to mention that it is not impossible to request specific consent for each new research project. Compelling reasons do, however, exist for not insisting on the model of consent such as the costliness thereof, the increasing difficulty in contacting persons repeatedly

[148] *Idem* 213.
[149] Whitney, McGuire *et al*. (2004) 55. See also McCullough LB, McGuire AL & Whitney SN (2007) "Consent: Informed, simple, implied and presumed" *The American Journal of Bioethics* 7(12): 49-50.
[150] Whitney, McGuire *et al*. (2004) 57.
[151] *Idem* 55.
[152] *Idem* 57. Such instances must however not be confused with impaired informed consent.
[153] Pawa N & Ypsilantis E (2009) "Inguinal hernia repair–Trends in litigation" *Annals of the Royal College of Surgeons of England* 91: 180.
[154] Otlowski (2012) 211.

over a long period of time, the multiplicity of projects which would result in repeated requests and the onerous duty placed on researchers which may result in lost research opportunities.[155]

Proponents of specific consent state that specific consent extends to the expected consequences of an intervention which renders further consent unnecessary.[156] Detractors, however, critique specific consent by arguing that it denies an individual of their autonomy for the sake of generic risks. This may be prevented by patient information sheets and extra or lesser information. This means that information may be unique to the patient.[157] As mentioned above, specific consent may also be burdensome for the research participants and have a disincentive influence.[158]

The problem with research such as the research focussed on in this thesis is that it is only specifiable in general terms if at all. In such instances broad consent may seem preferable.[159]

5.4.5 Generic Consent

It has been suggested that informed consent and general consent cannot coexist as the more general consent becomes, the less informed it becomes.[160] The type of consent to be obtained must be considered in any research or treatment scenario. It must be determined whether generic or specific consent, for example, would be most appropriate. Generic consent for storage and future use has been proposed as appropriate in context of tissue banks as without such consent, the bank would not be able to function properly.[161]

The MRC, however, opine that two options should be available to research participants. The first is to consent to a specific study only and the second is to consent to a specific study and storage and future use of their samples or data. The seeming approval of generic consent, however, depends on the provision of as much information as possible regarding future research projects, exact information where material is to be stored,[162] the potential of sharing the material or data with third parties, disclosure of genetic analysis to be conducted, the clinical significance of the information must be explained as well as the review procedures.[163] This means that research

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[155] *Ibid*.
[156] O'Neill (2003) 6.
[157] McIlwain JC (2009) "Procedure-specific consent forms" *Annals of the Royal College of Surgeons of England* 91: 629.
[158] Otlowski (2012) 212.
[159] See in general, Sheenan (2011) 226-235.
[160] Caulfield T (2007) "Biobanks and blanket consent: The proper place of the public good and public perception rationales" *Kings Law Journal* 18(2): 215.
[161] Medical Research Council of South Africa (2014) "Consent arrangements: Generic or project-specific consent" available online at http://www.dt-toolkit.ac.uk/routemaps/station.cfm?current_station_id=409 accessed 5/11/2015.
[162] Such as what specifically the dataset will contain, the maintenance of privacy, who will have access to the material or data and to what extent, the possibility or re-contact and the possibility of withdrawing consent.
[163] MRC SA (2014) online.

participant may be able to place certain limitations on the use of their material or data. It is suggested that this is not generic consent and as such it leans more towards informed consent.

Generic consent may only be considered acceptable in context of stem cell technology where the use thereof is subject to the approval of ethics committees and the material or data is de-identified.[164]

5.4.6 Blanket Consent

Blanket consent may be understood as an unrestricted agreement to make use of a biological sample and related data for any research in general.[165] It is not the same as broad consent as some limitations are applicable in giving broad consent and it is therefore not unrestricted.[166]

Blanket consent may decrease the administrative burden on research establishments as it is a uniform, once-off request which does not offer any limitations to the use of material.[167] However, it cannot be given any real weight as it is too general and cannot validly qualify as consent and may lead to the wastage of samples where no oversight or control is exercised. Blanket consent may be regarded as a move away from the traditional standards of consent and some scholars have opined that the use of blanket consent amounts to lowering or altering accepted consent models in an attempt to accommodate scientific need.[168]

Blanket consent is therefore regarded as ethically impermissible and should only ever be used where samples or data have been completely de-identified and the proposed research project has been ethically reviewed and approved.[169]

5.4.7 Broad consent

Researchers use a number of processes and practices to obtain consent for future research purposes using human materials which include obtaining consent at the time of collecting the specimen for a particular use, with re-consent for any subsequent uses, selection of permitted

[164] Caulfield (2007) 218.
[165] Otlowski (2012) 212.
[166] *Ibid*.
[167] Ploug T & Holm S (2015) "Going beyond the false dichotomy of broad or specific consent: A meta-perspective on participant choice in research using human tissue" *The American Journal of Bioethics* 15(9): 45.
[168] Caulfield (2007) 214.
[169] See in general, Caulfield (2007) 209-226.

purposes on a checklist and even no consent at all.[170] Broad consent is viewed by some as the best suited consent model in context of stem cell treatment and research and is therefore the nearest contender to informed consent. Some concerns exist that certain specimens may not be used in research due to the uncertainty and confusion regarding consent and that this would lead to loss in public benefit. Broad or general consent is therefore advocated as a way of addressing these concerns.[171] As a result of the prevalence and popularity of this model, it must be given somewhat more attention than the other types of consent discussed above.

Broad consent is not envisaged in the declaration of Helsinki[172] and was introduced by the emergence of biobanking in order to solve a practical problem.[173] Essentially, broad consent is a strategy which enables the accommodation of future research and novel technologies making use of stored biological samples and related data without having to renew consent.[174] Certain parallel concepts also emerged with broad consent namely open,[175] blanket, generic and general consent.[176]

Broad consent in context of research, and specifically biobanking related research, is often justified by referencing the potential benefits thereof, the low level of risk involved and by questioning the centrality of informed consent.[177] As such, broad consent coupled with oversight is deemed feasible in biobanking.[178] This consent type is viewed as encapsulating consent to various different conditions which require that a person other than the consenting person is permitted to make decisions regarding the material.[179]

Broad consent may be defined as "consent for an unspecified range of future research subjects to a few content and/or process restrictions."[180] In other words, broad consent is less specific than consent for each individual use, but more narrow than open-ended or blanket consent with no limitations. Broad consent is thus placed between a consent to each specific use of human material on the one hand and a single blanket consent for any unspecified future research on

[170] Grady C, Eckstein L, Berkman B, Brock D, Cook-Deegan R, Fullerton SM, Greely H, Hansson MG, Hull S, Kim S, Lo B, Pentz R, Rodriquez L, Weil C, Wilfond BS & Wendler D (2015) "Broad consent for research with biological samples: Workshop conclusions" *The American Journal of Bioethics* 15(9): 35.
[171] *Ibid*.
[172] See chapter 6 paragraph 3.3.2 *infra* for a discussion of the Declaration of Helsinki.
[173] Steinbekk KS & Solberg B (2011) "Biobanks-When is re-consent necessary?" *Public Health Ethics* 4(3): 236. See also Caulfield T (2009) "Broad consent in biobanking: Reflections on seemingly insurmountable dilemmas" *Medical Law International* 20: 88-89 and Parker L (2011) "Using human tissue: When do we need consent?" *Journal of Medical Ethics* 37: 759-761.
[174] Steinbekk & Solberg (2011) 236.
[175] See in general, Lunshof JE, Chadwick R, Vorhaus DB & Church GM (2008) "From genetic privacy to open consent" *Nature Reviews Genetics* 9(5): 406-411.
[176] See again paragraphs 5.4.5 and 5.4.6 *supra*.
[177] Sheenan (2011) 226.
[178] Grady, Eckstein *et al*. (2015) 34.
[179] Sheenan (2011) 227.
[180] Grady, Eckstein *et al*. (2015) 35.

the other.[181] A different definition of broad consent holds that it is consent to a framework for future research of certain types and it is not open or blanket consent.[182]

Some proponents of broad consent have suggested that consent procedures should allow for categories of research to which a concerned person may consent in general.[183] These categories, it is suggested, is the same as the previously mentioned frameworks of future research. This means that a study-specific research description would not be necessary and that patients or participants need only be furnished with sufficient information to make a reasonably informed decision. When applying the reasonable person standard in determining the validity of consent, it may be argued that the information provided to a concerned person must be based on what a reasonable person would consider relevant in making their decision. Based on this, it is suggested that persons are willing to participate in research and to provide broad consent for such research, but subject to certain exceptions or limitations.[184]

In examining broad consent, it may be asked what exactly participants are consenting to in context of medical research. Are they consenting to the specifics of a project or to the broad nature thereof?[185] Broad consent, it may be argued, is not a decision based on information regarding the specific research study, but rather a decision to let others decide. This then means that although broad consent decisions may be autonomous, they are not worthy of respect in the same manner as informed consent, as consent which is not fully informed is ethically problematic.[186] As such, it is submitted that decision making is less about processing as much information as possible and more about identifying the most relevant information. In order to make an autonomous decision a person must therefore identify the information which is likely to affect their willingness to participate or not.[187] For this reason it is suggested that broad consent is consent to certain frameworks of information. A framework encompasses the aims, conditions of use and governance of a research project. However, where any of these components of the framework change, the foundation of the framework alters and re-consent is required in order to lawfully continue making use of the participant's material or data.[188] A participant is therefore only informed where they have knowledge, understanding and

[181] Ploug & Holm (2015) 45.
[182] Steinbekk KS, Myskja BK & Solberg B (2013) "Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?" *European Journal of Human Genetics* 21(9): 897.
[183] Grady, Eckstein *et al*. (2015) 35. These categories might include the creation of a cell line or reproductive research.
[184] *Idem* 36. Broad consent may be problematic for a few individuals who are willing to donate material for certain studies but who are not willing to donate material for unspecified future research.
[185] Steinbekk & Solberg (2011) 237.
[186] Sheenan (2011) 232-233.
[187] Steinbekk & Solberg (2011) 237. Such information is described as that which matters to the participant and may include *inter alia* the possibility of physical harm, the possibility of finding out that they have a disposition to a terrible disease, whether or not the project entails private profit or public benefit.
[188] *Ibid*.

acquiescence of the framework.[189] The moment where an activity is considered outside of the framework consented to, new consent must be sought.[190]

Arguments against broad consent hold that it is not in the best interest of the concerned person's autonomy or in that of research.[191] It has, for example, been argued that broad consent consolidates economic exploitation of donors of material as well as giving moral precedence to organisational designs which interfere in the exercise of an individual's fundamental rights and freedoms.[192]

It would, however, seem from the literature that broad consent is deemed ethically permissible and perhaps even optimal where it includes initial consent, a process of oversight and approval of future research activities and a process of ongoing provision of information to or communication with donors and participants.[193] It is, however, suggested that this is more in line with a process of dynamic consent than with the traditional understanding of broad consent and these conditions indicate that broad consent is therefore not optimal.[194] At this juncture, some attention must be given to the conditions required to render broad consent permissible and preferential. Each condition is subsequently discussed below:[195]

1. Initial consent. The initial broad consent form must advise prospective participants and donors of the possibility of future uses of their material and the oversight process used to review these specific studies. Also, during the initial consent process, information ought to be provided regarding the storage of samples, the possibility that samples may be shared with other researchers and institutions, the conditions attached to such sharing, the potential commercial and therapeutic applications of the material, the process of oversight in the proposed research, the potential for re-contact or ongoing communication and the possibility of opting out of future research. Suggestions have been made that participants or donors would be informed that any research is possible unless specifically limited or even that material from persons who gave broad consent may not be used for controversial research without additional consent. It has even been suggested that a checklist be provided whereby participants or donors may indicate the research they are not comfortable with.

[189] In this regard broad consent differs from blanket consent.
[190] See in general, on who bears the responsibility of deciding whether or not an activity falls outside of the initial framework, Steinbekk & Solberg (2011) 242-243.
[191] Ploug & Holm (2015) 44.
[192] Steinbekk & Solberg (2011) 237.
[193] Grady, Eckstein *et al*. (2015) 37.
[194] See paragraph 6 *infra*.
[195] These conditions were identified during a workshop hosted by the National Institutes of Health Clinical Centre's Department of Bioethics in order to consider the ethical acceptability of broad consent in research involving human material. See Grady, Eckstein *et al*. (2015) 38-39.

2. Oversight and approval. A process of oversight and approval of future research involving already obtained samples may help in ensuring the ethical acceptability and scientific value of research. Oversight may then also offer further protections as all future uses are impossible to explain or predict or know. Where there are concerns regarding the scientific value or rationale of future research, the risks involved are more than minimal, the proposed future research is in conflict with the limitations in the initial consent or the research may be in conflict with the participant's values, further review will be required.
3. Ongoing information and communication. Although this may not always be possible, this condition is of great importance. It has been suggested that this may be achieved by creating a website or by making use of other information technology systems. These mechanisms would then also be able to provide for a method of withdrawing consent for future research uses where participants do not agree with the research.[196]

Once again these conditions are, it is submitted, indicative of the potential of dynamic consent as a valid method of consent in treatment and research involving human subjects. It should be mentioned shortly however that the more control offered to participants and donors, the more the costs and burdens associated with the consent process increase.[197] The expenses related to consent are just one of many problematic aspects pertaining to the consent process and at this juncture it becomes necessary to discuss these issues or concerns in further detail. This discussion is of importance in context of this thesis as it highlights and motivates the need for a new perspective and even format of consent in instances of biomedical interventions.

6 THE CONSENT CONCERN

Few issues have been as controversial as stem cell therapy and research and as such it is only expected that the development of this technology has raised numerous vexing questions.[198] The question raised here and which is relevant to this thesis relates to the most appropriate and valid manner of obtaining consent for such interventions and procedures. Specifically, what is the most appropriate consent format in instances where medical treatment borders on research due to the ever-changing and mostly uncertain scope of the intervention? Concerns regarding consent take into account not only the persons involved but also their biological material and data. It is impossible to know at the onset of these interventions the range or scope thereof,

[196] See chapter 9 paragraph 3 *infra*.
[197] Grady, Eckstein *et al*. (2015) 37.
[198] See in general, Liddell K & Wallace S (2005) "Emerging regulatory issues for human stem cell medicine" *Genomics, Society and Policy* 1(1): 54-73.

which calls into question the validity of consent.[199] Consent is so strongly relied upon in the protection and promotion of the interests of persons across the medico-legal sphere which includes treatment and research, that it now takes an astounding number of forms. Different types of consent are used in obtaining biospecimens intended for future research and this variation has resulted in confusion surrounding the research permitted, what the constraints are to future research and when research may proceed in the absence of consent.[200] Mason and McCall-Smith identify numerous different forms of consent including informed, broad, open, blanket, generic, specific, implied, explicit, appropriate, valid and written consent.[201] Campbell in McLean adds to this list by the inclusion of general, generalised and advanced consent.[202] It has even been suggested that the distinction between the different types of consent is not so much a distinction of consent but of the different choices a person may make.[203]

Clearly the vast amount of contradictory literature on the subject reflects the confusion surrounding this issue. Some writers have opined that due to the range of possible consents, open consent should be favoured. Open consent is described as "a research subject's affirmative agreement to participate in a population genetic database and in research projects that use tissue and data from that database" and denotes that consent is thus fully informed where a research participant is made aware of data protection provisions, control of use and decisions regarding appropriate uses which are in line with the broad description of the purpose of the research.[204] This opinion does not sit well with a number of other writers who argue that such open consent is not ethically permissible, that research participants should be re-contacted to consent to each new use of their material or at least be able to request such re-contact and even those writers who argue that open consent will never be valid and rather recommend the use of authorisation or general permission. Kaye suggests that a moral obligation exists to provide individuals with information and to allow them to make decisions based on such information and recommends a system of opting in or out of certain research projects.[205] This is due to the sensitive nature of the material, data and research itself.

Some might ask why, in spite of the ethical and legal arguments in favour of consent, attempt to obtain consent and not simply implement mandatory biotechnological treatment and research.

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[199] See in general, Campbell AV (2013) "The ethical challenges of biobanks: Safeguarding altruism and trust" in McLean SAM (ed) *First do no harm: Law, ethics and healthcare*: 203-214.
[200] Grady, Eckstein *et al*. (2015) 34.
[201] Mason K, Laurie G & McCall Smith (2011) *Mason and McCall Smith's law and medical ethics*: 116.
[202] Campbell (2013) in McLean (ed) 204-205.
[203] Sheenan (2011) 226.
[204] Nõmper A as discussed in Campbell (2013) in McLean (ed) 205.
[205] *Ibid*. Kaye also recommends that where broad consent is used, research participants should be re-contacted at least every five years to renew their initial broad consent.

In answer to this, scholars have identified at least five arguments in support of obtaining consent in research on human biological samples. They are:[206]

1. Obtaining consent shows respect for the participants and donors of the material;
2. Consent allows participants and donors to have control over the use of their samples;
3. Consent allows the persons concerned to decide whether they find the risks and burdens of the research acceptable;
4. Participants and donors are given the opportunity to decide to contribute to research or not and in so doing their fundamental values are protected and possibly even promoted; and
5. Obtaining consent results in transparent decision making in the sphere of biotechnology.

A concern exists that in context of stem cell research, the details of the research are unknown at the time of making a decision to participate and as a result the participant or donor cannot be informed of the precise nature of the research.[207] This means that the person concerned is not aware of all the relevant facts, which calls into question the validity of the consent altogether.

In context of research, the need to obtain consent is not primarily justified by the need to protect a person from harm or risk but to respect autonomy.[208] In context of broad consent, it may be stated that although a decision to participate and the conclusion of broadly given consent may be an autonomous decision, it may not be worthy of respect.[209] This is due to the fact that broad consent is premised thereon that a person may make a decision to allow a third party to make decisions regarding their material. However, genuine consent is achieved where persons are in control of the amount of information they receive and what they allow to be done with their material.[210]

Research is only truly safeguarded by providing participants with a flexible model of consent which is able to handle such participants' different preferences.[211] In determining what information is relevant to decision making, a person's values act as a filter. It must therefore be guarded against that completeness and comprehensibility do not exclude one another. The process of consent must therefore not become less understandable by overloading a potential patient or subject with too much information for the sake of completeness.[212] Such a model of

[206] Grady, Eckstein *et al*. (2015) 36.
[207] See in general, Waltz & Scheuneman (1970) 632.
[208] Sheenan (2011) 228.
[209] *Idem* 230. See also McLean SAM (2001) "No consent means not treating the patient with respect (commentary)" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 73.
[210] O'Neill (2003) 6.
[211] Ploug & Holm (2015) 45.
[212] Spellecy R (2015) "Facilitating autonomy with broad consent" *The American Journal of Bioethics* 15(9): 43. See also Hofmann B (2009) "Broadening consent- and diluting ethics?" *Journal of Medical Ethics* 35: 125-129.

consent not only safeguards research but also protects the interests of the concerned individual as by protecting their autonomy their desire to give consent in a certain manner must also be respected and protected.[213]

Ploug and Holm refer to the term "meta-consent" which denotes the process whereby a person is enabled to design the method of their consent. This means that an individual is able to choose between the different types of consent such as informed, broad or dynamic consent and then for various categories of research.[214] Meta-consent allows an individual to monitor research using their material while also allowing them the altruistic means of participating in research which may benefit future generations.

The uncertain nature of future research renders consent processes in stem cell treatment and research challenging and often the question is asked whether consent should be informed, broad or narrow. In the classical understanding of the doctrine of informed consent, any consent to future research projects which is not clearly described is invalid by definition as it is not informed.[215] Consent is dependent on risk and as such it must be noted that in context of biobanking the risk of physical harm is absent as research is conducted on material already removed from the donor thereof. The most significant risk in this context is the risk of informational harm in the form of disclosure of information.[216]

O'Neill opines that genuine consent is not reliant on an overwhelming amount of information but rather on access to extendable information as well as the concept of rescindable consent and the right to *veto* certain activities.[217] When taking this into consideration it becomes clear that patients and research participants ought to have a method of controlling the amount of information they receive. Dynamic consent and EnCoRe provide an impressive example of this and are discussed in greater detail in the course of this thesis.[218] Regardless of the later and more detailed discussion of dynamic consent and EnCoRe however, it has been made mention of in the course of this chapter and a brief introduction thereto is therefore warranted.

[213] See in general, Kozlakidis Z, Cason RJS, Mant C & Cason J (2012) "Human tissue biobanks: The balance between consent and the common good" *Research Ethics* 8(2): 113-123.
[214] Such as data or material, public or private, national or international *etcetera*. See Ploug & Holm (2015) 46.
[215] Steinbekk & Solberg (2011) 236.
[216] *Idem* 244.
[217] Campbell (2013) in McLean (ed) 206.
[218] See chapter 9 *infra* for an in depth discussion of dynamic consent and the EnCoRe project.

6.1 DYNAMIC CONSENT

The appropriate type of consent and the most ethical participant-researcher relationship is currently a hotly disputed subject in context of stem cell technology and research. Broad consent which has been most commonly used is deemed as pragmatic but not ethically acceptable and numerous calls have been made for change based on arguments surrounding the avoidance of paternalism,[219] intentions to promote autonomy, the wish to increase user participation and questioning the role of so-called experts.[220] Dynamic consent has been recommended as offering a solution to the issue of consent and is discussed in much greater detail in the course of this thesis. At this juncture some attention must, however, be given to this model of consent.

In contrast to broad consent, dynamic consent holds that where anything in a consented-to framework changes, re-consent ought to be obtained.[221] Dynamic consent may thus be described as a model of consent wherein a research participant or donor is required to re-consent to every new experiment or slight change in research which involves them or their material. In contrast, broad consent holds that a participant or donor consents to research at the onset of the study and where additional research is to be conducted, the participant is not re-contacted as long as the research is not a significant deviation of the initially consented-to study.[222] Stem cell therapy and research is, it is submitted, a constant deviation of a proposed study and this thesis therefore argues that dynamic consent is the format of consent most capable of accommodating such deviations due to the flexibility of the model.

The best model of consent should, in theory, balance the ethical responsibility of informing patients or research subjects of the process they are enabling with the need to continuously explore new frontiers. Dynamic consent thus raises some valid considerations in determining the most valid model of consent in stem cell research. Amongst these considerations it may be mentioned that dynamic consent allows for keeping participants up-to-date on new developments; re-obtaining consent is, however, not an easy task and dynamic consent would eliminate ethical review boards' necessity.[223]

Launched over the last decade, dynamic consent is a patient-centric initiative (PCI) which utilises information technology to enable a continuous consent process. A recent and interesting

[219] See in general, Buchanan A (1978) "Medical Paternalism" *Philosophy & Public Affairs* 7(4): 370-390.
[220] Steinbekk, Myskja *et al*. (2013) 897.
[221] *Ibid*.
[222] Biobanking Staff (2014) "Broad consent versus dynamic consent: Pros and cons for biobankers to consider" available online at http://acceleratingscience.com/biobanking/broad-consent-versus-dynamic-consent-pros-and-cons-for-biobankers-to-consider/ accessed 16/11/2015.
[223] *Ibid*.

dynamic consent proposal is made manifest in the Ensuring Consent and Revocation (EnCoRe) project which is also discussed in greater detail in the course of this thesis. By making use of EnCoRe systems and the dynamic consent model, a research participant is provided with real-time information on research projects as well as options regarding their participation such as re-contact and revocation of previously given consent.

Dynamic consent offers a narrower and more specific consent with opt-in requirements and is flexible as it always takes into consideration the preferences of the research participant.

Six claims of the superiority of dynamic consent have been identified and are briefly listed here:[224]

1. Dynamic consent is far more respectful of participant autonomy;
2. Participants are better informed by a model of dynamic consent than by broad consent;
3. Dynamic consent promotes participation in research;
4. Control and governance of material is transferred to the participant;
5. Ethical responsibility is transferred to the research participant rather than to an ethics committee; and
6. Dynamic consent enables the return of research results and incidental findings to participants in a way that is simple and tailored.

As stated, more attention is given to dynamic consent in the course of this thesis. The above mentioned EnCoRe project is an online initiative, however, and consent in the digital age must therefore be discussed briefly.

6.1.1 Consent in the Digital Age

Today, it is not only medicine and bioscience which are developing at an alarming rate but also information and computer technology. This means that medical practitioners and researchers are able to make use of these developments to help ensure that proper consent is obtained. This of course raises the question as to how such technology may affect a physician's role and responsibility for obtaining consent.[225] Cartsens and Pearmain identify six factors to be considered in this regard:[226]

[224] Steinbekk, Myskja *et al*. (2013) 898-901. See chapter 9 *infra* for a detailed discussion of these claims as well as counterarguments thereto.
[225] See in general, Le Roux A (2008) "Telemedicine: A South African perspective" *Tydskrif vir Suid-Afrikaanse Reg* 1: 99-114.
[226] Carstens & Pearmain (2007) 895-896.

1. The abundance of health information available on the internet;
2. The increasing use of e-mail and other forms of electronic communication mediums between physicians and patients;
3. The introduction of computer-based clinical decision-support mechanisms supplementing the judgement of physicians;
4. The development of electronic health records and their potential positive and negative impact;
5. Consumer use of the internet and "comparison shopping" amongst different physicians, health plans, treatment options and medications; and
6. Telemedicine.

There are also numerous ethical and legal concerns with this electronic cybermedicine culture relating to the quality and quantity of available information, as patients are not always best suited to distinguish between the different qualities of information. This places a growing burden on physicians to interpret such information and to guard patients against being misled.[227]

There are, however, positive aspects to the emergence of new sources of information such as an expansion of health care to include truly shared decision making. No longer will it be the sole responsibility of a physician to provide information regarding a proposed treatment or procedure and the patient will now be able to do their own research and form an opinion. Physicians will increasingly fulfil the role of aiding the patient in understanding medical information and applying such information in decisions regarding treatment options.[228] The role of the physician may be influenced by the electronic age but they will remain an indispensable link in the doctor-patient relationship.[229] Currently, it appears as though e-consent formats are used as supplements rather than replacements for face-to-face consultations with medical practitioners.[230]

Today, there is widespread access to the internet and a general level of information technology literacy which leads some writers to believe that a flexible model of consent making use of such technology is within reach.[231] In context of South Africa, cybermedicine is in its infancy as the majority of the population do not have access to computers or the internet other than on a mobile device. This also applies to electronic consent formats. In time, electronic technology will

[227] Dierickx K (2003) "Enhancing our health through E-health and cybermedicine?" in Callens S (ed) *E-health and the law*: 71.
[228] *Idem* 77.
[229] *Idem* 78.
[230] Harper B (2013) "Informed consent: A look at multi-media usage and timing" available online at http://forteresearch.com/news/informed-consent-look-multi-media-usage-timing/ accessed 3/11/2015.
[231] Ploug & Holm (2015) 46.

become more prominent and accessible and as such it would be wise of the law to take notice thereof.[232]

7 CONCLUSION

In the previous chapter consent was discussed in broad and abstract strokes initially, after which the examination was whittled down to a narrower understanding thereof. In this chapter, this process of narrowing the focus was continued and therefore a *capita selecta* of consent issues was examined which was done by discussing consent in medical law, the requirements of valid consent and the traditional distinction between therapy and research and the impact thereof on consent. The whittling process continued even more by an in-depth discussion of specific aspects of importance relating to informed consent namely who must obtain and provide consent, when must consent be obtained, what should the consent process cover and in what format consent should be given or obtained.

The doctrine of informed consent has a multitude of purposes in South African law, such as ensuring autonomy, encouraging rational decision making, establishing a proper doctor-patient relationship and acting as a legal defence. It was therefore shown to have special status in the mind of ethics, medicine, research and the law. In spite of this, certain circumstances exist where consent may be waived, such as in deviations or extensions; emergency interventions; on statutory authority and where a court authorises such waiving of consent. Consent is also not without its controversy.

Very simply stated, informed consent means that a consenting person shows knowledge, appreciation and acquiescence. It is also closely linked to the duty of disclosure of a physician which entails that a patient or research participant must be provided with information pertaining to the scope, nature, benefits, risks, consequences and prognosis of an intervention. Due to the infinite possibilities and scope of stem cell technology, the duty of disclosure is not a simple one. It was found that in a medical context, the duty of disclosure is narrower than in research, as the physician need only disclose risks normally associated with a proposed procedure and not also those deemed remote or unusual and thus immaterial. Reference was made to the *Castell* case wherein the materiality of risk was formulated. The case held that inherent risk is material where a reasonable patient if warned of the risk or danger would attach significance thereto and where a physician is or should reasonably be aware that the patient, if warned of the risk or danger, is likely to attach significance thereto. This attempts to

[232] Carstens & Pearmain (2007) 897. See also Carstens & Pearmain (2007) 822-827.

spare a patient unnecessary anxiety and fear. The duty of disclosure was also shown entail a justifiable limitation of the freedom of self-determination and choice on the part of the patient. Therapeutic privilege, whereby information is withheld from a patient in their own interest, is thus deemed permissible as the right to informed consent is not absolute.[233]

In a research context, however, the minimum standard of disclosure is that of full disclosure, meaning that a subject must be informed of the exact scope, nature, duration and purpose of the research; the scope, nature and consequences of the proposed research intervention; the hoped for benefits and advantages of the research for the patient and society; the foreseeable risks, dangers, complications and prognosis of the experimental therapy; that they are under no obligation to participate and that participation is voluntary. In context of this thesis which posits that stem cell therapy is actually research, this means that full disclosure is required. It is therefore submitted that the standard of disclosure for stem cell treatment is full disclosure and that therapeutic privilege is not acceptable in these circumstances.

The duty of disclosure which includes therapeutic privilege is not the same as absence of consent. Where consent is absent it may lead to liability as an intervention without the proper informed consent is deemed a violation of bodily integrity, dignity, privacy and certain other constitutionally protected rights. The basis of such liability may lie in breach of contract, in civil or criminal assault or *inuiria* or in contravention of section 12(2)(c) of the Constitution.

For consent to act as defence against the above mentioned liability and to guard against infringing on the Constitution, certain requirements must be met in order to render the consent valid. The requirements for valid consent are various and in this chapter it was shown to include the following:

1. There must exist knowledge, appreciation and acquiescence on the part of the persons consenting;
2. Consent will only be valid where it is based on appropriate information regarding the nature and effect of the proposed intervention;
3. Consent must be recognised by law and may not be *contra boni mores*;
4. The person consenting must be legally capable of consenting;
5. Consent must be free and voluntary without duress, coercion, fear, force or fraud;

[233] See in general, Tobias JS & Souhami RL (1993) "Fully informed consent can be needlessly cruel" *British Medical Journal* 307(6919): 1199-1201. See also Waltz & Scheuneman (1970) 635-641. Suggested further reading, Coetzee LC (2004) "Medical therapeutic privilege, a separate and independent defence eo nomine" *Tydskrif vir die Suid-Afrikaanse Reg* 3(2): 464-481. See also Van den Heever P (2005) "Pleading the defence of therapeutic privilege" *South African Medical Journal* 95(6): 450-421.

6. The consenting person must consent to the harm and the assumed risks and dangers of the intervention;
7. The information provided by the doctor or researcher must be comprehensive, extend to the entire transaction and be inclusive of the consequences;
8. Consent must be clear and unequivocal;
9. Consent must be obtained prior to the proposed intervention;
10. Consent must qualify as a legal act in that some external conduct must reveal the intention of the parties;
11. Generally, consent must be given by the concerned person who will undergo the proposed treatment or intervention; and
12. The undertaken activity must fall within the boundaries of the given consent.

It was also shown that informed consent may be expressed as the disclosure of information *(I)* and competency *(C)* which leads to understanding *(U)*. Understanding and voluntariness *(V)* then lead to a decision *(D)* which is then informed.

It was shown that medical therapy and scientific research have traditionally been regarded as separate disciplines and different consent models are therefore advocated by each separate group. In context of this thesis therapy and treatment usually denote a medical setting where the objective of the intervention is the direct benefit of the patient and their health. Research is an investigation of knowledge, which may be therapeutic or non-therapeutic in nature. The objective of a research intervention is broad in nature and may benefit the participant and the community as a whole.

It was found in the course of this chapter that medical treatment is an activity with the sole object of benefitting the patient concerned and is not future or community orientated. It therefore does not necessitate the furthering of knowledge. Research is divided into therapeutic and non-therapeutic in nature and entails an inquiry into knowledge. Therapeutic research entails a direct benefit to the participant while non-therapeutic research does not and is more community orientated.

This distinction has become somewhat obsolete, however, as both forms of research are governed by the same ethical principles. Medical treatment which goes beyond the norm of clinical care may also qualify as research. Research is future orientated and contributes to the understanding of a topic. This thesis posits that especially in context of stem cells, the distinction between medicine and science falls away and treatment borders on research due to the uncertain nature and scope of stem cell applications. The patient thus becomes the participant and in the course of this thesis is often referred to as a patient-participant or

patient-subject. As medicine is now research, traditionally accepted forms of consent used in either are not sufficient and a new format of consent must be developed or at least considered. It is suggested that a combination of informed and broad consent might be the most appropriate model of consent in these instances.

The examination of consent as contained in this chapter focussed even more narrowly and specific aspects of consent were discussed. This entailed an assessment of who bears the responsibility of obtaining consent and from whom, with specific attention to adults, the mentally ill and minors. It was found that it is the responsibility of the attending physician or the relevant researcher to obtain consent subject to the conditions that the patient-subject is provided with the proper information to make a decision, no conflicts of interest exist and that in the event of any such conflicts, they be disclosed to the patient-subject. It was further found that it is the person concerned, who will receive treatment or participate in research, who must give their consent to the proposed intervention. Where this person is a competent adult it is not a complicated issue. Age, however, is not an absolute measure of a person's capacity and where a person suffers from some sort of incapacity such as mental illness, proxy consent must be obtained. A minor may consent to an intervention where such child has the capacity to understand what they are consenting to in context of a medical intervention. In context of research participation however, the consent of a child must be accompanied by the consent of a parent, guardian or the Minister and must adhere to all other legally required preconditions. In context of this thesis, since it is argued that stem cell therapy should rather be deemed as a research process, it is submitted that the additional consent requirements must be met where a minor is to be subjected to stem cell therapy.

The next issue which was addressed was the timing of obtaining consent. It was shown that consent must be obtained prior to any medical or scientific intervention. However, consent is based on preferences which exist in a certain moment and is therefore subject to change. Consent procedures must therefore allow for flexibility and consent should be changeable when the preferences of the patient-subject alter.

The scope of consent was then addressed. It was found that the scope of the consent process protocol must include the title of the intervention; the person or institution undertaking the therapy-research; any conflicts of interest should be disclosed; background information and an explanation of the proposed therapy-research; the methods to be employed during treatment-research; a statement of the purpose and benefits as well as of the risks involved and the expected duration of approval of an applicable ethics committee, if any. The required consent

form which should comply with general consent requirements must contain at least the following information:

1. An in-depth explanation of what is being consented to, be it treatment, research or a combination thereof as is the case in context of this thesis;
2. Where a subject donates material, an explanation of the specific biological material;
3. An explanation of the procedure to be used in collecting the material;
4. The purpose of the proposed research study in which the material will be used;
5. Alternative options of use such as other studies, therapeutic application or education;
6. An explanation of the research process and what methods or techniques will be used;
7. The potential or real harm or risks involved in participation;
8. Any expected or potential benefits;
9. The options regarding storage of material or data and any time limits attached thereto;
10. The manner in which material may be destroyed or disposed of;
11. The option to renew or revoke consent for any of the above and at any time;
12. The extent to which the privacy and confidentiality of the patient or participant will be protected;
13. Incentives to participate in the research study; and
14. Proof of Ethics Committee approval.

Lastly, specific attention was given to the format of consent. Various consent models were discussed including express, implied, simple, specific, generic, blanket and broad consent. In short, it was argued that express consent is too narrow, implied consent is inappropriate in context of stem cells, simple consent is too simple, specific consent does not allow for any alteration of preference and generic and blanket consent are not ethical enough. Broad consent, which is, after informed consent, probably the most popular approach which also offers a pragmatic solution to the consent issue, was discussed in great detail. Broad consent was described as a consent strategy which accommodates future research and new technologies but it entails consenting to unspecified future applications. Some literature stated that it may be subject to limitations and to re-consent. It is suggested that this is a departure from the traditional understanding of broad consent and that any additions or alterations to broad consent are more in line with the model of dynamic consent.

It was stated that few issues have been as controversial as stem cell therapy and research and it is thus only to be expected that the development of this technology raises numerous vexing questions such as which model of consent is best suited and valid where medical treatment

borders on research and a "patient" becomes a "subject." At the onset of these interventions the range or scope thereof is impossible to know and this calls into question the validity of consent.

Different types of consent are utilised in obtaining biospecimens intended for future research and these different types have caused confusion surrounding what research is permitted, what the constraints are to future research and in what research studies may proceed in the absence of consent. In context of stem cell research, a concern exists that since the details of the research are unknown at the time of making a decision, the subject is not able to be informed of the precise nature of the research. This has the effect that the validity of the consent is called into question since the person concerned is not aware of all the relevant facts. Research may truly be safeguarded by providing participants with a flexible model of consent, capable of handling the different preferences of the subject.

Future research's uncertain nature renders consent processes in stem cell treatment and research challenging and often the question is raised whether consent should be informed or broad or narrow. The classic understanding of the doctrine of informed consent would invalidate any consent to future research projects which is not clearly described. Genuine consent is reliant on access to extendable information and rescindable consent. Patients and research participants therefore ought to have control over the amount of information they receive and dynamic consent and EnCoRe provide a possible solution to the issue of consent.

Broad consent has been commonly used in research since it offers a pragmatic solution but it is not considered ethically acceptable. Dynamic consent was thus suggested as offering a solution to the issue of consent in the course of this chapter. Dynamic consent supposes that where any aspect of a consented-to framework changes, re-consent must be obtained. Dynamic consent may therefore be described as a consent model wherein a research subject is required to re-consent to every new experiment or even slight change in any research in which they are involved. Broad consent on the other hand holds that a subject gives their consent to research at the onset of the study and if any additional research is to be conducted, the subject need not be re-contacted so long as the research is not a significant deviation of the initially consented to framework. In theory, the best model of consent balances the ethical responsibility of informing patients or subjects of the process they are taking part in with the need to continuously explore new scientific knowledge frontiers. It is recommended that a combination of informed and broad consent be developed.

The last aspect considered in this chapter was that of consent in the digital age. In the South African context, cybermedicine is still in its infancy and as the majority of the population do not have access to technology such as computers or the internet, this phenomenon seems rather

outlandish. This concern may also apply to electronic consent formats but more and more people are making use of mobile devices and for this reason it is suggested that, in time, electronic technology will become more prominent and the law should anticipate this shift in patient-subject behaviour and may in the interim establish procedures, methods and protocols enabling this development.

The next chapter relates to the National Health Act and therefore represents the ultimate whittling of the discussion and examination of the concept of consent and the science of stem cells in South Africa as analysed in this component, Part B, of this thesis.

CHAPTER 5
THE NATIONAL HEALTH ACT, ACT 61 OF 2003

1 INTRODUCTION

This thesis follows a process of discussing pertinent aspects in the broad sense at first and then narrowing the focus of the discussion to the quintessential aspects. The first chapter in this part of the thesis introduced in the most general sense the concept of consent. The previous chapter focussed more narrowly on consent and provided for a *capita selecta* examination of consent-related issues. This chapter then follows suit in this process of whittling and offers an investigation into the South African position as it relates to stem cells and consent.

The purpose of this chapter is therefore an investigation and dissection of relevant provisions as found in the National Health Act, Act 61 of 2003[1] which has a bearing on key terms which may be identified when considering the hypothesis posed in the course of this thesis. It is argued that as the efficacy of stem cell treatment is greatly untested and the application of such therapy is still so novel, that stem cell treatment is tantamount to research. Since the distinction between therapy and research falls away, the traditionally prescribed forms of consent, namely informed or broad consent must also fall away and a new consent format must be used. Also, as patients seeking or making use of this experimental treatment are involved, the patients serve as human research subjects. Working from this premise, the key terms of stem cells, consent, treatment and research may be identified.

This chapter therefore endeavours to dissect and investigate the provisions of the NHA with a bearing on these identified key terms. In so doing, the regulatory body as found in the Act and the Regulations proclaimed in terms of the Act will be discussed. The Act and Regulations as published will be discussed and throughout the course of this chapter it will then also be argued that by way of interpretation, the Act and Regulations already permit or support a different format of consent. In context of this thesis it is suggested that this new format of consent is dynamic consent as introduced at a later stage.

The NHA is based strongly on and aligned with the South African Constitution and also recognises "the socio-economic injustices, imbalances and inequities of health services in the

[1] Hereafter referred to as the NHA or the Act.

past; the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and the need to improve the quality of life of all citizens and to free the potential of each person."[2] As such it is regarded as embodying a paradigm shift in the South African medico-legal environment and is the final break from apartheid era health legislation. However, the NHA finds its roots in these older Acts which demonstrates the development of a certain attitude towards health legislation. To this end the Public Health Act of 1919, the Health Act of 1977, the Human Tissue Act of 1983 and the Choice on Termination of Pregnancy Act of 1996 will be discussed and specific attention will be given to the development of the concept of consent in these Acts.

The discussion of the NHA itself will then commence by firstly discussing Chapter 2 of the Act which provides for the rights and duties of health care users and personnel. Attention is given to section 6 which states that the user has the right to be informed of all possible treatment options and the risks, benefits and the costs of these options prior to the administration thereof; section 7 which requires the consent of the user; section 8 which makes provision for the right of a user to participate in decisions regarding their treatment; section 9 which pertains to health services without consent and section 11 which regulates health services for experimental or research purposes. Throughout the course of this discussion, arguments will be made where it is suggested that interpretation of the relevant section indicates the possible application of dynamic consent.

Chapter 8 which provides for the control and use of blood, blood products, tissue and gametes in humans will then be examined. This chapter is discussed as a necessary part of the debate and background to stem cell regulation in South Africa. In context of this thesis, however, chapters 2 and 9 are of more importance. As the ambit of this thesis does not include an in-depth critical analysis of the failings of this particular chapter of the Act, it merely serves as an investigation and discussion of the law as it stands at the time of publication of this thesis.[3]

Attention will then be given to Chapter 9 of the NHA which regulates national health research and information. In particular, the provisions related to research or experimentation with human subjects as found in section 71 will be addressed.

This thesis chapter will show that the NHA is framework legislation and as such it is greatly supplemented by subordinate legislation in the form of Regulations. The numerous relevant

[2] Preamble to the NHA.
[3] For a critical discussion of Chapter 8 of the NHA, see Prinsen L (2010) *An analysis of the proposed regulatory framework for the procurement and distribution of stem cells* (LLM thesis unpublished, University of Pretoria): 228-260. See also Prinsen L (2013) "Flawed law: A critical analysis of the faults and shortcomings of Chapter 8 of the National Health Act of 2003" *Obiter* 34(3): 522-532.

Regulations which have been created under the NHA as examined in the course of this chapter by grouping the Regulations providing for a common subject matter together. This also allows for an explanation of how the Regulations have been "fine-tuned" and improved on as time has passed in an attempt to perfect the regulation of this field of science. The Regulations will be addresseded as they pertain to the use of biological material, artificial fertilisation, the national health research ethics council and national health research committee, research on human subjects and participants, human stem cells, import and export, tissue and stem cell banks, general control as well as blood and blood products. At this juncture, however, and considering the role of the NHA in general in the health legislation environment of South Africa, a proper introduction to the Act is necessary.

2 INTRODUCTION TO THE NATIONAL HEALTH ACT

Health legislation may encompass any legal instrument which has a bearing on the health of a community.[4] The NHA is the fundamental piece of legislation to shape the future of the South African health system. It mostly came into force on the 2nd of May 2005[5] and limped into existence as chapter 8 only came into force piece by piece in the following years and various issues were still in need of review and supplementation.[6] Although the main objective of this thesis is an analysis of consent in instances where medical treatment is equal to or borders on research such as the case of stem cells, attention must be given to the regulation of stem cells in its entirety. This requires a discussion and understanding of the NHA which is deemed the legislative tool whereby stem cells and related matters are to be regulated in South Africa.

The NHA is complex legislation in scope and objects and entrenches health policy principles which have been developed over many years. The provisions contained in the NHA fundamentally alter the manner in which health policy will be formulated in South Africa,[7] the manner in which patients will be treated and it will impose new obligations on the persons in

[4] Gray A, Gengiah T, Govendor M & Singh J (2005) "Legislation" *South African Health Review*: 16.
[5] As proclaimed in the Government Gazette No.27503 of 18 April 2005. See *Figure H infra*.
[6] See in general, Kahn T (2005) "Mbeki leaves holes in new health law" *Business Day*, 20 April available online at http://allafrica.com/stories/200504200282.html accessed 21/3/2012.
[7] The relationship between policy and the law is of a complex nature. According to Carstens and Pearmain, policy is described in the following manner: "There is a distinct difference between policy and law. The former informs the latter. Policy informs legislation. However, the latter governs and overrides the former. In the context of the doctrine of the rule of law, policy that is contrary to law is itself illegal and unenforceable. Policy that is contrary to the Constitution is invalid since the conduct by means of which it was written is invalid. Policy must therefore be lawfully developed and implemented in order to maintain its legitimacy. Policy that is determined on the basis of empowering legislation does not itself become law unless it is converted into legislation that is approved by Parliament and signed into law by the President." See Carstens P & Pearmain D (2007) *Foundational principles of South African medical law*: 245-246.

charge of rendering health services.[8] On the 19th of August 2004 a briefing was delivered on the National Health Act, by the then Minister of Health, Manto Tshabalala-Msimang. During the briefing, the Minster stated that the NHA is "framework legislation"[9] which broadly provides for a legal and operational system and it also provides the framework for a structured and uniform health system in South Africa in order to unite the various elements of the system under one common goal: the improvement of universal access to quality health services.[10] The NHA is deemed to be the legislative document whereby all remaining traces of apartheid health policy are replaced and is greatly characterised by its transformative spirit.[11] The Preamble of the Act[12] serves as an example of this philosophy of reformation by *inter alia* recognising "the socio-economic injustices, imbalances and inequities of health services in the past; the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and the need to improve the quality of life of all citizens and to free the potential of each person."[13] The Preamble thus confirms that the NHA is designed to unify

[8] Kirby N (2005) *The National Health Act: A guide* available online at http://www.mondaq.com/article.asp?articleid=32307 accessed 24/2/2012.
[9] This means that the NHA must be "fleshed out" in Regulations. During the course of this chapter the Regulations which have been made in terms of the Act and which are relevant to this thesis will be discussed.
[10] Department of Health (2004) "Briefing by the Minster of Health on the National Health Act" available online at http://www.doh.gov.za/docs/pr/2004/pr0819.html accessed 12/3/2012.
[11] The Minister described the Health Act, Act 63 of 1977, which has now been replaced by the NHA, as "the last vestiges of apartheid in health policy" as the Health Act 1977 had largely determined the health infrastructure in South Africa since 1977. See footnote 14 *infra* for a list of health legislation which has been replaced by the NHA. See South African Society of Travel Medicine (2008) *A-Z of the National Health Act* available online at http://www.sastm.org.za/articles/AtoZofHealthAct.pdf accessed 12/3/2012. See also Kirby (2005) online.
[12] The **Preamble** of the NHA reads as follows: "Recognising-

- the socio-economic injustices, imbalances and inequities of health services of the past;
- the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights;
- the need to improve the quality of life of all citizens and to free the potential of each person;

Bearing In Mind That-

- the State must, in compliance with section 7(2) of the Constitution, respect, protect, promote and fulfil the rights enshrined in the Bill of Rights, which is a cornerstone of democracy in South Africa;
- in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures within its available resources to achieve the progressive realization of the right of the people of South Africa to have access to health care services, including reproductive health care;
- section 27(3) of the Constitution provides that no one may be refused emergency medical treatment;
- in terms of section 28(1)(c) of the Constitution every child has the right to basic health care services;
- in terms of section 24(a) of the Constitution everyone has the right to an environment that is not harmful to their health or well-being;

And In Order To-

- unite the various elements of the national health system in a common goal to actively promote and improve the national health system in South Africa;
- provide for a system of co-operative governance and management of health services, within national guidelines, norms and standards, in which each province, municipality and health district must address questions of health policy and delivery of quality health care services;
- establish a health system based on decentralised management, principles of equity, efficiency, sound governance, internationally recognised standards of research and a spirit of enquiry and advocacy which encourages participation;
- promote a spirit of co-operation and shared responsibility among public and private health professionals and providers and other relevant sectors within the context of national, provincial and district health plans."

[13] The Preamble is rather lengthy due to the inclusion of several of the principles mentioned in the 1997 White Paper for the Transformation of the Health System in South Africa. Some of the principles which were echoed are co-operative governance and management; national guidelines, norms and standards; decentralised management and a

the various components of the health system[14] and to provide internationally recognised, equitable and efficient health care to all South Africans.[15] The road of reform has however been a long one and the NHA suffered a very slow and tedious development. From 2003 to 2016, a mass of legal documents have been drafted and published under the umbrella of the Act. The following table illustrates this development and "lists" the relevant commencements, regulation and amendments which have formed part of the timeline of the NHA:

23 July 2004	The National Health Act, Act 61 of 2003	Government Gazette No.26595 of 23 July 2004
2 May 2005	Commencement of the Preamble, Definitions, Chapter 1, Chapter 2 with exception of section 11, Chapter 3, Chapter 4, Chapter 5, Chapter 7 with exception of sections 50 and 51, Chapter 9 with exception of section 71, Chapter 10 with exception of sections 77 to 79 and 83, Chapter 11 and Chapter 12 to a certain extent	Government Gazette No.27503 of 18 April 2005
5 January 2007	Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics	Government Gazette No.29526 of 5 January 2007
	Regulations regarding Artificial Fertilisation and Related Matters	Government Gazette No.29527 of 5 January 2007
23 February 2007	Regulations relating to Research on Human Subjects	Government Gazette No.29637 of 23 February 2007
	Regulations relating to the National Health Research Ethics Council	
	Regulations relating to the National Health Research Committee	
4 May 2007	Regulations relating to Human Stem Cells	Government Gazette No.29840 of 4 May 2007
30 June 2008	Commencement of section 53	Government Gazette No.31187 of 27 June 2008

spirit of co-operation and shared responsibility between private and public health professionals and providers. See National Department of Health (1997) *White Paper for the Transformation of the Health System in South Africa*.
[14] The NHA consolidates the following health legislation: the Health Act 1977; the Human Tissue Act, Act 65 of 1983; the National Policy for Health Act, Act 116 of 1990 and the Academic Health Centres Act, Act 86 of 1993.
[15] Kirby (2005) online.

14 May 2010	Regulations relating to Withdrawal of Blood from a Living Person for Testing	Government Gazette No.33188 of 14 May 2010
17 May 2010	Commencement of sections 55, 56, 68 and 93(1)	Government Gazette No.33187 of 14 May 2010
23 September 2010	Regulations relating to the National Health Research Ethics Council	Government Gazette No.33574 of 23 September 2010
	Regulations relating to the Establishment of the National Health Research Committee	Government Gazette No.33575 of 23 September 2010
24 January 2011	National Health Amendment Bill	Government Gazette No.33962 of 24 January 2011
1 April 2011	Regulations relating to Artificial Fertilisation of Persons	Government Gazette No.34159 of 1 April 2011
	Regulations relating to the Use of Human Biological Material	
	Regulations relating to Stem Cell Institutions or Organisations	
	Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Embryos, Zygotes and Gametes	
	Regulations relating to Tissue Banks	
	Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes	
	Regulations relating to Blood and Blood Products	
8 November 2011	National Health Amendment Bill	Government Gazette No.34739 of 8 November 2011
1 March 2012	Commencement of sections 11, 35, 41, 42, 43, 44, 45, 46, 50, 51, 54, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 71 and 93	Government Gazette No.35081 of 27 February 2012
2 March 2012	Regulations relating to Artificial Fertilisation of Persons	Government Gazette No.35099
	Regulations relating to the Use of Human Biological Material	
	Regulations relating to Blood and Blood Products	
	Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes	

	Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes	of 2 March 2012
	Regulations relating to Tissue Banks	
	Regulations relating to Stem Cell Banks	
29 May 2013	Regulations relating to Research on Human Subjects	Government Gazette No.36508 of 29 May 2013
2 September 2013	Commencement of National Health Amendment Act, Act 12 of 2013 with exception of sections 2 and 3	Government Gazette No.36787 of 30 August 2013
1 April 2014	Commencement of sections 36, 37, 38, 39 and 40	Government Gazette NO.37501 of 31 March 2014
1 September 2014	Commencement of sections 2 and 3 of the National Health Amendment Act, Act 12 of 2013	Government Gazette No.37730 of 10 June 2014
19 September 2014	Regulations relating to Research with Human Participants	Government Gazette No.38000 of 19 September 2014
11 May 2016	Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes: Amendment	Government Gazette No.39982 of 11May 2016
30 September 2016	Regulations relating to artificial Fertilisation of Persons	Government Gazette No.40312 of 30 September 2016

Figure H: NHA timeline

The NHA furthermore takes into account the State's obligations as mandated by the Constitution[16] and relies heavily thereon in that some 50 sections of the Constitution directly translate to the content of the NHA.[17] The inclusion of constitutional provisions is what makes the NHA "the most important piece of legislation in the health sector," and it further emphasises the transformative nature of the Act. This alignment with the Constitution may even be said to revolutionise the formulation of health care policy and treatment in South Africa.[18] Some

[16] The Minister stated: "In terms of section 27(2) of the Constitution, the State must take reasonable legislative and other measures to progressively achieve the right of access to health care services, and reproductive health care, within its available resources. The National Health Act is one of those legislative measures contemplated by the Constitution."
[17] These include the right to equality; the right to dignity; the right to life; the right to bodily and psychological integrity; the right to privacy; the right to freedom of conscience, religion, thought, belief and opinion and the right to freely choose one's trade, occupation or profession. See sections 9, 10, 11, 12, 14, 15 and 22 of the Constitution of the Republic of South Africa, 1996.
[18] Kirby (2005) online.

constitutional issues which are dealt with by the NHA include the right to emergency medical treatment, children's rights to basic health services and the right to an environment which is not harmful to the health or well-being of a person.[19]

The NHA consists of 12 chapters. Although chapters 2, 8 and 9 are most relevant to this thesis,[20] it is important to briefly discuss each of the other chapters as a global understanding of the Act is necessary to fully understand the legislative regulation of stem cell related activities and so also the role of informed consent in such activities. What follows is thus a summary of the chapters of the NHA.

Chapter 1 of the Act states the constitutional allocation of responsibility for health as lying with the national department as well as every provincial and municipal department.[21] It establishes the National Health System and places the Minister of Health in a supervisory role. As such the Minister is responsible for the protection, promotion and maintenance of health. Lastly, chapter 1 legislates what was previously done by policy directives only in that it consolidates the principle of free health care to certain groups who cannot afford such care,[22] specifically pregnant women, children[23] and persons with disabilities.[24] This is one of the novel and consumer-orientated concepts which have been formally introduced by the Act.

Chapters 3, 4 and 5 may be seen as completing the enactment of some design features of the national health system.[25] Chapter 3 contains and describes the functions of the Department of Health as well as the Director General. The highest policy body, called the National Health Council[26] is established and consists of the Minister, Members of the Executive Council for health and representatives of local government. The remit of the Council is that of policy making in that it advises the Minister on policy matters concerning the protection, improvement and maintenance of the health of the South African population. Chapter 3 further establishes a National Consultative Health Forum which must promote and facilitate communication and information sharing regarding national health matters.[27] Chapter 4 establishes provincial health services and outlines the functions of such provincial health departments. It thus provides for similar structures as chapter 3 but on a provincial level. This includes Provincial Health Councils

[19] See sections 27(3), 28(1) and 29 of the Constitution.
[20] These NHA chapters are discussed in detail in the course of this chapter. See paragraphs 4.1, 4.2 and 4.3 *infra*.
[21] Municipal responsibilities have in essence been limited to environmental health issues as opposed to personal health services or primary care. The term "municipal health services" is finalised and is to include water quality monitoring, food control, waste management, health surveillance of premises, surveillance and prevention of communicable diseases, vector control, environmental pollution control, disposal of the dead and chemical safety. The definition excludes port health, control of hazardous substances and malaria control.
[22] Persons who are members of medical schemes are thus excluded.
[23] Children under the age of 6 years.
[24] Department of Health (2004) online.
[25] Gray, Gengiah *et al.* (2005) 18.
[26] This body was previously known as "Health MinMec" and held its first meeting on the 6th of May 2005.
[27] South African Society of Travel Medicine (2008) online.

and consultative bodies. Chapter 3 and 4 both envision integrated health plans but provincial plans must comply with national plans and a hierarchy therefore exists. Chapter 5 establishes the District Health System. This system will be accountable to the community it serves and will be based on the principles of primary health care. It must further promote universal access to responsive, efficient, equitable and quality health care.[28]

Chapter 6 contains some of the more innovative elements of the Act but is rather controversial as it provides for the classification of health establishments; the certificate of need;[29] the establishment of hospital, clinic and community health centre boards and deals with the relationship between private and public health establishments.[30] The certificate of need or CoN, which will be required of all health establishments, will allow all private and public health establishments to be registered with the Department of Health. The controversy lies therein that the CoN is intended to ensure equal distribution of establishments.[31]

Chapter 7 provides for Human Resources Planning. The NHA mandates the development of a human resources policy and guidelines whereby adequate distribution of health personnel, training of staff at all levels of the health system and the effective utilisation of resources must be ensured by the national department. The Forum for Statutory Health Professional Councils is one of the co-ordinating mechanisms which are created by this chapter.[32] Chapter 7 further provides for the establishment of Academic Health Complexes.[33]

Chapter 10 deals with the inspection of health establishments and compliance with basic norms and standards.[34] This chapter of the NHA was, however, amended in the National Health Amendment Bills of 2011.[35]

Chapters 11 and 12 deal with the powers of the Minister and immediately came into effect. Chapter 11 empowers the Minister to make regulations in terms of the Act. Two provisions

[28] See in general, Gray, Gengiah *et al.* (2005) 19.
[29] According to the Minister the certificate of need should be seen as a licence and introduced factors into the licensing process which ensure that policy objectives such as a structurally unified and integrated health system, equity in health care, improved access to health services and optimal utilisation of resources are met. See South African Society of Travel Medicine (2008) online.
[30] See also Gray, Gengiah *et al.* (2005) 19.
[31] The constitutionality of a similar aspect of "need" as found in General regulation 18 of the Medicines and Related Substances Act was challenged in *The Affordable Medicines Trust v the Minister of Health and Others* 2004 (6) SA 387 (T) and 2005 JOL 13932 (CC) and was found to be *ultra vires*. What is interesting to note, however, is the statement by Ngcobo J at paragraph 13 wherein he explains that the purpose of need provisions is the enhancement of the scope of efficient utilisation of resources and that it allows the government to plan and implement the health plan more effectively.
[32] Gray, Gengiah *et al.* (2005) 19.
[33] The establishment of Academic Health Complexes will affect the Department of Education and the Treasury.
[34] The NHA as framework legislation does not regulate health professionals in their area of skill or competence as this falls to the statutory professional councils such as the Health Professions Council of South Africa. It can, however, regulate the premises from which the health professionals render their services.
[35] See *Figure H supra*.

deserve some attention. Firstly, the Minister is enabled to make regulations regarding the development of an essential drug list and medical as well as other assistive devices and secondly, the Minister may determine the processes whereby the Director-General must formulate certain reference price lists. This would have an indirect impact on the private sector providers as their prices will have to be compatible. Chapter 12 also came into effect immediately in order for the Minister to have the power to appoint advisory and technical committees and to delegate some powers, excluding the power to make regulations.

As a broad introduction to the NHA has now been provided, the purpose of this thesis chapter is a dissection and investigation of the pertinent provisions of the NHA which impact on stem cells and consent. It is not so much intended as a critical analysis wherein all the faults of the NHA are brought to light,[36] but as a discussion of the body of law pertaining to stem cells and related activities as it stands at the time of publication of this thesis.[37] The NHA may be seen as the skeleton of this body as it provides for the framework or structure and the Regulations made in terms of the Act are the muscles and organs which enable the body to function, literally "fleshing out" the NHA. The NHA and Regulations will thus be discussed in the course of this chapter. As the main focal point of this thesis relates to consent, special attention will be, paid to any provisions regarding this principle. Firstly however, a brief history of health legislation in South Africa is discussed. This is done in order to demonstrate not only some of the developments made in context of regulating health, but also in regulating consent and it further illustrates that revolutionary medical science such as stem cells requires revolutionary legislation.

3 PRECEDING LEGISLATION: THE HEALTH ACT, TISSUE ACT AND THE CHOICE OF TERMINATION OF PREGNANCY ACT

Shortly after the first democratic election in 1994, a process of legislative reform was implemented by the ANC in accordance with the party's declared policy of transformation of the South African health system. This transformation would make health care accessible to the entire South African population and would eliminate the inequities and discrimination of the past. The process of transformation was driven by amendments to reigning legislation in various areas as well as the creation of new legislation. In the first five years of the ANC

[36] For a critical discussion of the NHA, see Prinsen (2010) 228-260.
[37] October 2016.

government rule, new or amended legislation was thus formulated, debated, passed and implemented.[38]

The National Health Act is the product of this liberal transformative process of health policy reform and is seen as replacing the last vestiges of apartheid health policy. It repealed the Health Act, Act 63 of 1977 and Chapter 8 of the NHA repeals the Human Tissue Act, Act 65 of 1983. It is, however, not the only progressive legislation which has resulted from the transformation of the health system and the Choice on Termination of Pregnancy Act, Act 92 of 1996, which is relevant to this study as it relates to reproductive autonomy and rights,[39] was also created due to this reformative process. For the purpose of this study, only the Health Act, the Human Tissue Act and the Choice on Termination of Pregnancy Act, which was not repealed by the NHA, will be shortly discussed. This discussion follows a chronological order and specific mention is made of consent as found in these Acts. It is interesting to note how the requirement of consent developed. The Health Act made no mention thereof, the Tissue Act required consent but distinguished between adults and minors and the Termination of Pregnancy Act requires only the consent of the woman seeking a termination, regardless of her age. This demonstrates the move away from paternalism and towards patient autonomy.

3.1 THE HEALTH ACT OF 1977

The Health Act[40] has been rendered completely superfluous by the Constitution and the NHA.[41] The Health Act was assented to on the 17th of May 1977 and commenced on the 1st of September of that same year. Prior to the commencement of the Health Act, health matters in South Africa were regulated by the Public Health Act, Act 36 of 1919.[42] The Act was amended 13 times, *inter alia* by the Tissue Act, during its existence and was finally repealed by the NHA. The Preamble of the Act stated that the Act was to provide for measures for the promotion of health of the inhabitants of South Africa. This was to be done by the rendering of health services; by defining the duties, powers and responsibilities of certain authorities in rendering such health services;

[38] Albrecht S (2009) "Health Legislation in South Africa" available online at http://myfundi.co.za/e/Health_legislation_in_South_Africa#Consultion_on_health_legislation accessed 24/3/2012.
[39] For more on reproductive rights see Carstens & Pearmain (2007) 176-180. Aborted fetuses may be used in stem cell research as stem cells may be withdrawn or removed from cadaveric fetal tissue. See chapter 2 paragraph 3.1 *supra*. This source of stem cells is, however, fast becoming superfluous.
[40] Health Act 1977. Hereafter referred to as the Health Act.
[41] Carstens & Pearmain (2007) 245.
[42] Parliament passed this Act, which at the time was a pioneering measure, in June 1919 in the wake of the Spanish influenza epidemic of 1918. It was the first health-related legislation in South Africa and remained the basic health measure until 1977. For more see Phillips H (1990) "The origin of the Public Health Act of 1919" *South African Medical Journal* 77(10): 531-532. See also Coovadia H, Jewkes R, Barron P, Sanders D & McIntyre D (2009) "The health and health system of South Africa: Historical roots of current public health challenges" *The Lancet* 374(9692): 817-834.

by providing for coordination of health services; by repealing the Public Health Act and by providing for incidental matters.

In broad strokes, the Health Act dealt with the Health Matters Advisory Committee and National Health Policy Council;[43] the Department of Health and Welfare;[44] Provincial Administrations;[45] Local Authorities;[46] Regulations[47] and general provisions.[48] Nowhere, however, were any provisions made regarding informed consent.

3.2 THE HUMAN TISSUE ACT OF 1983

The Tissue Act[49] at the time of commencement repealed various Acts and was itself amended twice before being repealed completely by section 93(1) of the NHA.[50] The Tissue Act was enacted in order to provide for the donation and making available of human bodies and tissue for the purpose of medical or dental training, research or therapy, or for the advancement of medicine and dentistry in general; to provide for post-mortem examinations; the removal of tissue, blood and gametes from bodies of living persons and the use thereof; to make provision regarding the control of artificial fertilisation and also to regulate the import and export of human tissue, blood and gametes.[51]

The Act consisted of 5 parts dealing with specific issues. Firstly, the tissue and bodies of deceased persons was dealt with in Chapter 1 of the Act. This included providing for the donation of human bodies and tissue[52] and the institution to whom such donations may have been made[53] as well as the purposes of donation.[54] Matters surrounding removal of tissue during the post-mortem examination of a body as well as post-mortem provisions in general

[43] Chapter I of the Health Act.
[44] Chapter II of the Health Act.
[45] Chapter III of the Health Act.
[46] Chapter IV of the Health Act.
[47] Chapter V of the Health Act.
[48] Chapter VI of the Health Act.
[49] Human Tissue Act 1983. Assented to on the 20th of May 1983 and commended on the 12th of July 1985. Hereafter referred to as the Tissue Act.
[50] On commencement, the Tissue Act repealed the Anatomy Act, Act 20 of 1959; the Anatomy Amendment Act, Act 27 of 1961; the Anatomical Donations and Post-Mortem Examinations Act, Act 24 of 1970; the Anatomical and Post-Mortem Examinations Amendment Acts, Act 42 of 1972 and 59 of 1973; the Health Act 1977 and the Anatomical Donations and Post-Mortem Examinations Amendment Act, Act 39 of 1980. The Tissue Act was also amended by the Human Tissue Amendment Act, Act 106 of 1984 and the Human Tissue Amendment Act, Act 51 of 1989. Section 93(1) came into force on the 17th of May 2010 to the extent in which it repeals section 23(b) of the Human Tissue Act 1983. See Notice No.20 in Government Gazette No.33187 of 14 May 2010. Section 23(b) of the Human Tissue Act deals with the control of removal and use of tissue and blood and states that "no person, except a medical practitioner or dentist or a person acting under his supervision, may for the purpose of this chapter [*sic*] -withdraw any blood from the body of a living person or administer blood or a blood product to a living person."
[51] Preamble of the Tissue Act.
[52] Section 2 of the Tissue Act.
[53] Section 3 of the Tissue Act.
[54] Section 4 of the Tissue Act.

and disposal of a human body could also be found in this part of the Act.[55] This chapter of the Tissue Act also provided for the handing over of bodies to certain institutions,[56] the preserving of bodies for a period of time[57] and prohibitions on certain uses of gonads.[58]

Chapter 2 of the Tissue Act dealt with material from living persons. This material included tissue,[59] blood,[60] gametes[61] and blood products.[62] It stipulated the purposes for which the aforementioned material could be removed[63] and made specific and separate provision for the use of gonads[64] and the removal of tissue and blood.[65] Requirements with regard to tissue transplants were also provided for.[66] The issue of consent, which is addressed in the following paragraph, was dealt with in this chapter of the Tissue Act. Chapter 8 of the NHA is greatly based on Chapter 2 of the Tissue Act. Due to the development of science and medical technology, the provisions as found in the Tissue Act have unfortunately become outdated to the extent that new legislation was justified. It is, however suggested that the definitions as provided for by the Tissue Act, especially those relating to the terminology found in Chapter 2, are more scientifically and medically accurate and should have been directly transferred to the NHA.

The authorised institutions as well as importation and exportation of tissue, blood, blood products and gametes were provided for in that the authorisation of institutions, import and export permits, the disposal of material contrary to a permit and payment matters related to the import, acquisition or supply of material, were dealt with in Chapter 3 of the Act.[67] The provisions found here were greatly echoed in the NHA. The Tissue Act furthermore provided for the appointment and functions of inspectors of anatomy[68] and contained various general and supplementary provisions. These included *inter alia* the publication of certain facts, provisions for civil and criminal liabilities or the exclusion thereof as well as offences and penalties.[69]

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[55] Sections 7-10 of the Tissue Act.
[56] Section 12 of the Tissue Act.
[57] Section 13 of the Tissue Act.
[58] Section 16 of the Tissue Act.
[59] Section 1 of the Tissue Act defines tissue as "(a) any human tissue, including any flesh, bone, organ, gland or body fluid, but excluding any blood or gamete; and (b) any device or object implanted before the death of any person by a medical practitioner or dentist into the body of such person."
[60] Blood is human blood according to section 1 of the Tissue Act.
[61] A gamete, according to section 1 of the Tissue Act means "either of the two generative cells essential for human reproduction."
[62] Blood products are "any products derived or produced from blood," as stated in section 1 of the Tissue Act.
[63] Section 19 of the Tissue Act.
[64] Section 21 of the Tissue Act.
[65] Section 23 of the Tissue Act.
[66] Section 20 of the Tissue Act.
[67] Sections 24-28 of the Tissue Act.
[68] Sections 29-32 of the Tissue Act.
[69] Sections 33-41 of the Tissue Act.

3.2.1 Human Tissue And Consent

Consent was regulated by section 18 of the Tissue Act. Section 18 stated that no tissue, blood or gametes could be removed or withdrawn from the body of a living person for the purposes referred to in section 19 except where removal or withdrawal was done in accordance to the prescribed conditions and where consent had been granted therefore. Where the person was an adult, the person him/herself had to consent.[70]

Where the person from whom the tissue, blood or gametes were to be removed was a minor, additional consent was required. This additional consent was to be obtained from the minor's parents or guardian. Furthermore, where the tissue which was removed is replaceable by natural processes, or blood was withdrawn from the body of a competent witness,[71] the consent, written or oral, of that person was sufficient. Where tissue was removed with consent from a person in the interest of their health, such tissue could be used for any of the purposes listed in section 19.[72] This is clearly the foundation of the consent provisions found in the NHA but, as will be seen in the course of this discussion, the NHA provisions cover more ground and are more detailed.

3.3 THE CHOICE ON TERMINATION OF PREGNANCY ACT OF 1996

Prior to 1975, South African abortion law was governed by Roman-Dutch common law and abortion was a criminal offence except where continuation of the pregnancy threatened the woman's life.[73] The Abortion and Sterilisation Act came into operation in 1975 and legalised therapeutic abortion by way of statute for the first time in South Africa.[74] In order to qualify as legal, an abortion could only be undergone in certain prescribed circumstances, which were:[75]

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[70] Section 18(1)(b)(ii) refers to a "major" instead of an adult.
[71] According to section 1 of the Tissue Act, a competent witness is "a person of the age of 14 years or over who at the time when in terms of this Act anything is done in his presence or by him is not incompetent to give evidence in a court of law."
[72] Section 19 stipulated that tissue could be used for transplantation into the body of another living person, blood could be administered to another person or used in the production of a blood product and gametes could be used for artificial fertilisation. Artificial fertilisation of a person was defined as "the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction, including-(a) the bringing together outside the human body of a male and female gamete or gametes with a view to placing the product of a union of such gametes in the womb of a female persons; or (b) the placing of the product of the union of a male and female gamete or gametes which have been brought together outside the human body, in the womb of a female person, for such purpose."
[73] Van Oosten FFW & Ferreira M (1988) "Republic of South Africa" in Sachdev P (ed) *International Handbook on Abortion*: 416.
[74] Abortion and Sterilisation Act, Act 2 of 1975. Hereafter the Abortion Act.
[75] The conditions were summarized by Clarke B & Van Heerden B as found in Van Rooyen CAJ (1998) "Abortion: A study of final-year social work students' responses to abortion-related issues" *Social Work/Maatskaplike Werk* 34(3): 276.

1. Where continuation of the pregnancy would constitute a threat to the life of the woman;
2. Where the mental health of the woman was endangered by the continued pregnancy;
3. Where the child would suffer a serious physical or mental defect;
4. Where the pregnancy had resulted from rape or incest; or
5. Where the pregnancy was the result of intercourse with a mentally handicapped woman unable of comprehending the consequences of the pregnancy.

Furthermore, the Abortion Act prescribed by whom the abortion may have been performed and also who was involved in the making of decisions and recommendations regarding the abortion. The decision was thus made solely by medical practitioners and therefore constituted instances of extreme medical paternalism.[76]

This conservative approach and terrible violation of autonomy was corrected in 1997 by the commencement of the Choice on Termination of Pregnancy Act.[77] The Termination of Pregnancy Act is deemed one of the most liberal abortion laws in the world[78] and expressly demonstrates a "break away" from the restrictive Abortion Act in the Preamble which states that the Act repeals the restrictive and inaccessible Abortion and Sterilisation Act and promotes the reproductive rights and freedoms of women.[79]

The Termination of Pregnancy Act thus implements the ANC policy framework statement that "every woman must have the right to choose whether or not to have an early termination of

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[76] Medical paternalism is an ethical philosophy which believes that certain health decisions should be made by the persons providing health care. It thus stands in contrast to the principle of patient autonomy.

[77] Choice on Termination of Pregnancy Act, Act 92 of 1996. Hereafter referred to as the Termination of Pregnancy Act. The Act was assented to on the 12th of November 1996 and commenced on the 1st of February 1997. See Sekudu J (2002) *Abortion: A social work study* (DPhil thesis unpublished, University of Pretoria): 101-126 for a discussion of abortion legislation in general.

[78] Althaus FA (2000) "Work in progress: The expansion of access to abortion services in South Africa following legalization" *International Family Planning Perspectives* 26(2): 84.

[79] "**Preamble-**

- Recognising the values of human dignity, the achievement of equality, security of the person, non-racialism and non-sexism, and the advancement of human rights and freedoms which underlie a democratic South Africa;
- Recognising that the Constitution protects the right of persons to make decisions concerning reproduction and to security in and control over their bodies;
- Recognising that both women and men have the right to be informed of and to have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice, and that women have the right of access to appropriate health care services to ensure safe pregnancy and childbirth;
- Recognising that the decision to have children is fundamental to women's physical, psychological and social health and that universal access to reproductive health care services includes family planning and contraception, termination of pregnancy, as well as sexuality education and counselling programmes and services;
- Recognising that the State has the responsibility to provide reproductive health to all, and also to provide safe conditions under which the right of choice can be exercised without fear or harm;
- Believing that termination of pregnancy is not a form of contraception or population control;

This Act therefore repeals the restrictive and inaccessible provisions of the Abortion and Sterilization Act, 1975 (Act No.2 of 1975), and promotes reproductive rights and extends freedom of choice by affording every woman the right to choose whether to have an early, safe and legal termination of pregnancy according to her individual beliefs."

pregnancy according to her own beliefs"[80] and allows for "abortion on demand"[81] as the choice to terminate a pregnancy lies in the discretion of the woman rather than in the hands of medical practitioners and permits abortion until 22 weeks of pregnancy.[82]

Obviously, legislation as liberal as the Termination of Pregnancy Act evokes strong emotions and the Act was constitutionally challenged in the *Christian Lawyers' Association v Minister of Health* cases[83] wherein it was argued that the Act was invalid as it violated the right to life, as provided for by section 11 of the Constitution, of the unborn child. The case was, however, dismissed as it was found that an unborn fetus is not a bearer of rights. The second time the Christian Lawyers' Association challenged the Act it was argued that a person below that age of 18 should not be able to give consent to an abortion without the consent of her parents or guardians. Again, the case was dismissed as reproductive rights apply to all women and not only those over the age of 18 years.[84] The Act has furthermore been amended twice since commencement.[85]

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[80] Guttmacher S, Kapadia F, Te Water Naude J & de Pinho H (1998) "Abortion reform in South Africa: A case study of the 1996 Choice on Termination of Pregnancy Act" *International Family Planning Perspective* 24(4): 191.

[81] Albrecht (2009) online.

[82] Section 2 of the Termination of Pregnancy Act provides as follows: **"Circumstances in which and conditions under which pregnancy may be terminated-**

(1) A pregnancy may be terminated-

(a) upon request of a woman during the first 12 weeks of the gestation period of her pregnancy;

(b) from the 13th up to and including the 20th week of the gestation period if a medical practitioner, after consultation with the pregnant woman, is of the opinion that-

(i) the continued pregnancy would pose a risk of injury to the woman's physical or mental health; or

(ii) there exists a substantial risk that the fetus would suffer from a severe physical or mental abnormality; or

(iii) the pregnancy resulted from rape or incest; or

(iv) the continued pregnancy would significantly affect the social or economic circumstances of the woman; or

(c) after the 20th week of the gestation period if a medical practitioner, after consultation with another medical practitioner or a registered midwife is of the opinion that the continued pregnancy-

(i) would endanger the woman's life;

(ii) would result in a severe malformation of the fetus; or

(iii) would pose a risk of injury to the fetus.

(2) The termination of a pregnancy may only be carried out by a medical practitioner, except for a pregnancy referred to in subsection (1)(a), which may also be carried out by a registered midwife or registered nurse who has completed the prescribed training course."

[83] *Christian Lawyers' Association v Minister of Health* 1998 (4) SA 1113 (T) and *Christian Lawyers' Assoication v Minister of Health* 2005 (1) SA 509 (T). See Carstens & Pearmain (2007) 82-108 for discussions on these cases. See chapter 3 paragraph 5 *supra*.

[84] See in general, News24 (2004) "Teens given right to abortion" *News24*, 28 May available online at http://www.news24.com/SouthAfrica/News/Teens-given-right-to-abortion-20040528 accessed 7/5/2012. Consent is not bound to age but rather to the capacity to understand and make certain decisions in an autonomous manner. See chapter 3 paragraph 5.12 *supra*.

[85] The Termination of Pregnancy Act was amended by the Choice on Termination of Pregnancy Amendment Act, Act 38 of 2004 and the Choice on Termination of Pregnancy Amendment Act, Act 1 of 2008. The Act was also amended by the Criminal Law (Sexual Offences and Related Matters) Amendment Act, Act 32 of 2007 in that it changed the definitions of "rape" and "incest." See also *Doctors for Life International v Speaker of the National Assembly and Others* 2006 (12) BCLR 1399 (CC), News24 (2006) "Abortion Act declared invalid" *News24*, 17 August available online at http://www.news24.com/SouthAfrica/Politics/Abortion-Act-declared-invalid-20060817 accessed 7/5/2012 and News24 (2008) "Parliament relaxes abortion law" *News24*, 7 February available online at http://www.news24.com/SouthAfrica/Politics/Parliament-relaxes-abortion-law-20080207 accessed 7/5/2012 for more on the recent activities surrounding the Termination of Pregnancy Act.

3.3.1 Termination Of Pregnancy And Consent

Section 5 of the Termination of Pregnancy Act deals with the matter of consent. It provides therefore that the primary person to consent to an abortion is the woman herself, irrespective of her status as minor or adult. Without the consent of the woman no abortion may be performed[86] and no other person's consent to the termination of pregnancy is required.[87] Where the woman is a minor in terms of the Act,[88] a medical practitioner or a registered midwife or nurse must advise the minor to consult with other persons, such as her parents or family members or friends, but her refusal to do so may not justify refusal to perform the abortion.[89]

Certain circumstances are provided for wherein the consent of a person other than the woman herself may be obtained. Such circumstances are firstly, where the woman is completely incapable of understanding the consequences of termination of pregnancy due to severe mental disability[90] or secondly, where the woman is in a continuous state of unconsciousness without a reasonable prospect of regaining consciousness inside of the prescribed time to consent to the termination of pregnancy.[91] In such circumstances the pregnancy may be terminated for the reasons stipulated in section 2,[92] during the first 12 weeks or from the 13th to and including the 20th week of pregnancy on request of and with the consent of her natural or legal guardian or spouse.[93] Two medical practitioners, a registered midwife or nurse must, however, consent thereto.[94]

Termination of pregnancy after the 20th week will only be performed where the continuation of the pregnancy would endanger the woman's life, would result in a severe malformation of the fetus or would pose a risk of injury to the fetus. In such cases the consent of medical practitioners, a midwife or nurse is required.[95]

Section 6 of the Termination of Pregnancy Act provides therefore that a woman who requests a termination of pregnancy must be informed of her rights in terms of the Act. This sentiment is

[86] Sections 5(1) of the Termination of Pregnancy Act.
[87] Section 5(2) of the Termination of Pregnancy Act.
[88] According to section 1 of the Termination of Pregnancy Act, a minor is "any female person under the age of 18 years."
[89] Section 5(3) of the Termination of Pregnancy Act.
[90] Section 5(4)(a) of the Termination of Pregnancy Act.
[91] Section 5(4)(b) of the Termination of Pregnancy Act.
[92] Section 2 provides for termination on the grounds thereof that the pregnancy is a threat to the physical or mental health of the woman, there exists a possibility that the fetus will suffer from a mental or physical defect, where the pregnancy is the result of rape or incest or where the continuation of the pregnancy will seriously affect the social and economic position of the woman.
[93] Where no such person is available, termination may be performed on request of the woman's *curator personae*.
[94] Section 5(4) of the Termination of Pregnancy Act.
[95] Section 5(5) of the Termination of Pregnancy Act.

echoed in the NHA which also provides separately for the provision of information to the user of a medical service.[96]

As is evidenced by the previous discussion, the various legislative documents have led to and influenced the NHA. The NHA as focal point of this chapter is thus firmly rooted in well-established legal norms and standards in South Africa. It is, however, also novel legislation in that it provides for new technologies and as such, attention must now be turned towards these new and relevant provisions.

4 THE NATIONAL HEALTH ACT

As mentioned previously, the NHA is framework legislation and forms the skeleton of the body of law regulating stem cells and related activities. This thesis argues that stem cell therapy is as of yet so new and since the efficacy of such therapy has not yet been thoroughly tested, tantamount to research. Stem cell therapy is therefore stem cell research which involves human subjects. In context of this thesis the NHA is therefore of importance as it is the primary regulatory instrument by which stem cell therapy, or then stem cell research involving human participants, will be governed. The relevant provisions as found in the Act must thus be investigated. The following discussion is an examination of the three relevant chapters of the Act namely chapters 2, 8 and 9, which directly relate to this science and thesis subject.

4.1 CHAPTER 2: RIGHTS AND DUTIES OF USERS AND HEALTH CARE PERSONNEL

The general focus of study of this thesis is consent in context of stem cell therapy and research. This thesis chapter revolves around the NHA and the provisions thereof. It is thus clear that the provisions found in the NHA directly dealing with informed consent are of great importance to this study. Chapter 2 of the NHA is titled "the rights and duties of users and health care personnel" and includes the provisions regarding consent. It also introduces some of the transformative elements which attempt to protect the dignity of the health care users. Chapter 2 was set to be implemented immediately after promulgation of the Act with the exception of section 11(1).[97] This was done in order to allow the Department of Health the opportunity to develop and publish regulations and guidelines dealing with experimentation and research in

[96] Section 6 of the NHA provides for knowledge to be given to the user. See paragraph 4.1.1 *infra*.
[97] Section 11(1) of the NHA deals with health services for experimental or research purposes and requires that the health establishment must inform the user that the services are for research or experimental purposes or form part of such a project prior to the rendering of such services. Section 11(1) came into effect on the 1st of March 2012 as determined in Proclamation No.11 in Government Gazette No.35081 of 27 February 2012.

health.[98] The rights of patients, known as users, therefore changed immediately on the 2nd of May 2005 in that a user now has the following rights to:[99]

1. Emergency medical treatment;
2. Have full knowledge of one's condition;
3. Exercise one's informed consent;
4. Participate in decisions regarding one's health;
5. Be informed when one is participating in research;
6. Confidentiality and access to health records;
7. Lay complaints about the service; and
8. Health workers now have the right to be treated with respect.[100]

Section 1 of the NHA defines "user" as the person receiving treatment in a health establishment,[101] which includes receiving blood or blood products,[102] using a health service[103] or receiving treatment. Where a person below the age of 18 years[104] is receiving treatment or another health service, "user" must be understood as including such person's parent, guardian or authorised person acting on such person's behalf. It furthermore includes any person[105] acting on behalf of a person who is incapable of making decisions. "Health care personnel" means health care providers and health workers.[106] Health care providers are persons

[98] Department of Health (2004) online.
[99] Kirby (2005) online.
[100] This is "any person who is involved in the provision of health services to a user, but does not include a health care provider" according to section 1 of the NHA.
[101] According to section 1 of the NHA a health establishment is defined as "the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services."
[102] The definition of "blood product" may be considered broad enough to include stem cells according to Van Wyk. See Van Wyk C (2010) *Legal issues surrounding stem cell research including consent and ethics review* presented at the Transplantation Indaba, BMW Pavilion, Waterfront Cape Town, 2-3 August. Hereafter referred to as the Transplantation Indaba. Stem cells, however, are not blood products as they are not exclusively connected to blood. A separate definition for stem cells is necessary. Section 1 of the NHA provides for the following definition: "any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells." The medical definition thereof is, however, "the constituents of whole blood such as plasma or platelets that are used in replacement therapy." A blood product can thus not be removed from the human body. It must be removed from blood which may be withdrawn from a person's body and it is therefore submitted that separate provisions must be made for an institution where blood products may be generated. It is suggested that blood products should rather be defined as any processed or manufactured product derived from blood which is intended for therapeutic purposes, but excludes stem cells and genetic material. See Prinsen (2010) 238. See paragraph 5.10 *infra*.
[103] Health service is defined as "(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution, (b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution, (c) medical treatment contemplated in section 35(2)(e) of the Constitution and (d) municipal health services."
[104] According to section 39(4) of the Child Care Act, Act 74 of 1984 which was repealed by the Children's Act, Act 38 of 2005 this is the definition of a child. A child or minor may thus for the purposes of this thesis as well as any discussion surrounding the NHA, be understood as a person below the age of 18 years.
[105] This may be a spouse or partner, parent, grandparent, adult child, brother or sister or other person who is authorised by law to act on such a person's behalf according to section 1 of the NHA.
[106] Section 1 of the NHA.

providing health services in terms of a law. This includes the laws governing regulatory bodies in the health professions domain.[107]

The sections in Chapter 2 which are of most importance to this discussion, as they relate directly to consent and may thus have a bearing on stem cell research and treatment are sections 6, 7, 8, 9 and 11. Section 6 provides the user with the right to be informed of possible treatment options, the benefits and risks of each of the options and the costs thereof prior to the administration of such treatment. Section 7 requires the consent of the user while section 8 provides for the right to participate in decision making regarding treatment. Section 9 deals with health services without consent and section 11 regulates health services for experimental or research purposes. Chapter 2, however, also provides for emergency treatment,[108] discharge reports,[109] the duty to disseminate information,[110] confidentiality[111] and the laying of complaints.[112] Health records are given attention as well in the provision of an obligation to keep records,[113] access to health records[114] and access to health records by a health care provider[115] and also the protection of such records.[116] Lastly, the duties of the users and rights of the health care personnel are listed.[117] A detailed discussion of the most relevant sections will now be undertaken. This will be followed by a brief discussion, for the sake of completion, of the remaining sections of Chapter 2. These remaining sections, although not pertinent to the subject of this thesis chapter, are important in creating an understanding of the NHA as a whole and serve as an illustration of the current environment of health legislation in South Africa.

4.1.1 Section 6: User To Have Full Knowledge

As mentioned previously, the NHA contains consumer-orientated provisions and section 6 may be seen as such a provision. It not only lists topics of which the user must be informed, it also states that the user must, where possible, be informed thereof in a language which they understand and in a manner which takes cognisance of their level of literacy.[118] This might be

[107] These acts include the (a) Allied Health Professions Act, Act 63 of 1982; (b) Health Professions Act, Act 56 of 1974; (c) Nursing Act, Act 50 of 1978; (d) Pharmacy Act, Act 53 of 1974 and (e) Dental Technicians Act, Act 19 of 1979.
[108] Section 5.
[109] Section 10.
[110] Section 12.
[111] Section 14.
[112] Section18.
[113] Section 13.
[114] Section 15.
[115] Section 16.
[116] Section 17.
[117] Sections 19 and 20.
[118] Section 6(2) of the NHA. According to the Department of Health it is important to recognise and take into regard the patient or participant's background and states: "Participants' comprehension is addressed by laying out this information in a clear and simple style. In South Africa, this must be achieved via the use of culturally acceptable

linked with the idea that knowledge, appreciation and acquiescence form the foundation of lawful consent.[119] To truly have knowledge and appreciation one must thoroughly understand, and the best chance of understanding a subject lies in one's grasp of the language in which information on the subject is conveyed. The user must thus be informed, in such a manner which they will best understand, of the following:[120]

(a) The user's health status. This may be excluded in circumstances wherein substantial evidence exists which indicates that a disclosure of such information would not be in the best interests of the patient;[121]
(b) The available diagnostic and treatment options;
(c) The risks, benefits, consequences and costs of treatment options which have been discussed; and
(d) The user must be informed that they have the right to refuse any recommended or prescribed course of treatment. The user must also be informed of the implications, risks and obligations related to such a refusal.

The above is in concordance with the discussion of lawful consent in the previous chapters of this thesis.

The NHA does not define "health status" as mentioned in section 6(1)(a) and it is therefore submitted that it denotes a wider concept than HIV status, which is currently the most popular understanding of the term "status" in the health arena. It must be viewed as an encompassing term which includes all aspects of a person's physical and mental health. The health status of a person may be relevant in context of stem cell research, should a user be confronted with a diagnosis of a disease such as Alzheimer's, which could perhaps be treated by the application of stem cell therapy. Once a person becomes aware of their status they will be able to act accordingly. A person cannot pay attention to what they are unaware of.[122]

Section 6(1)(b) requires that the generally available diagnostic and treatment options should be explained to the user. Although stem cell technology is not "general," it has the potential to

practices including the use of the participant's language." See Department of Health (2006) *Guidelines for good practice in the conduct of clinical trials in human participants in South Africa.* See in general, Nienaber A (2010) "The regulation of informed consent to participation in clinical research by mentally ill persons in South Africa: An overview" *South African Journal of Psychiatry* 16(4): 122. Suggested further reading, Department of Health (2015) *Ethics in health research: Principles, processes and structures*.

[119] See chapter 3 *supra* for a more detailed discussion on knowledge, appreciation and acquiescence.
[120] Section 6(1)(a)-(d) of the NHA.
[121] See chapter 4 paragraph 2.3 *supra*.
[122] Prinsen (2010) 204.

someday be a commonplace medical treatment.[123] It is suggested that as the efficacy of stem cell treatment is still untested and it therefore borders on research, stem cell treatment might be better provided for under section 11 of the NHA, health services for research or experimental purposes, which is discussed in the course of this chapter.[124] Stem cell therapy does, however, have numerous potential applications and thus the range of treatments which is available and applicable to the specified disease should be explained to the user. It is submitted that the treatment processes, such as the method and side effects, should also be explained to the user.[125]

Users must be also informed of the benefits and risks as well as the costs and consequences of a treatment, and, where the user refuses treatment, the risks involved therein must be explained, according to sections 6(1)(c) and (d). The case of *Castell v De Greef*[126] may be mentioned here as it dealt with the subject of risks in medical procedures, being informed of treatment options as well as that of refusal to medical treatment.[127] In this case, the court confirmed that a patient has the right to provide consent but also to refuse any medical treatment. This may be seen as patient autonomy and self-determination in context of South African medical law.[128] This entails that the correct and accurate diagnosis is given to the user by the treating physician, alternative methods of treatment are discussed as well as the effects of the treatment and that the user must have knowledge and appreciation to provide informed consent. A patient must therefore be informed and advised of the inherent risks involved in the proposed treatment. *In casu*, it was stated that a physician is obliged to warn a patient of the relevant and inherent risks of a proposed treatment, procedure or surgery.[129]

Stem cells may cure diseases which have been regarded as incurable[130] or difficult to cure.[131] Certain diseases which could potentially be treated by stem cell therapy, such as diabetes, are incurable and are only managed by the available medical treatments. Stem cell therapy could thus be beneficial in that it may be a cure to an illness and may further improve the quality of life of the person receiving treatment. Conversely, however, is the existence of certain risks which are involved in such treatments. The formation of cancerous cells for example, is a

[123] An exception to this is the use of stem cell therapy to alleviate the symptoms of chemotherapy in cancer patients. See in general, EuroStemCell (2016) "Leukaemia: How can stem cells help?" available online at http://www.eurostemcell.org/factsheet/leukaemia-how-can-stem-cells-help accessed 15/6/2016.
[124] See paragraph 4.1.5 *infra*.
[125] Prinsen (2010) 204.
[126] *Castell v De Greef* 1994 (4) SA 408 (C). See chapter 3 paragraph 5.10 *supra*.
[127] Refusal to medical treatment may, in its most common form, relates to advance medical directives. An example of this is a "Do Not Resuscitate" order. For more on this see Jordaan L (2011) "The legal validity of an advance refusal of medical treatment in South African law (part 1)" *De Jure* 44(1): 32-48.
[128] Van der Walt A (2012) "Informed consent" available online at http://www.medicallaw.co.za/news-informed-consent.html accessed 10/4/2012.
[129] See chapter 3 paragraph 5.10 *supra* for a detailed discussion on informing a patient of risks.
[130] Such as spinal cord injury.
[131] Such as cancer.

concern. The user should therefore be informed of the risk that stem cell therapy may potentially lead to the formation of cancerous growths. Also of importance is to guard against fostering the false hope of a miraculous recovery. It is submitted that not only the risks and benefits but also the expected side effects and potential change in quality of life form the basis of the requirement to inform a user of the consequences of a treatment or procedure. Lastly, the related costs of the proposed treatment or procedure must be discussed with the user.[132] This provision also emphasises the spirit of consumer protection found in the NHA.

In closing, it is recommended that section 6 be used in conjunction with regulation 6 of the Human Subjects Regulations[133] as the Regulation provides for more detailed and precise requirements in context of obtaining consent. Regulation 6, which is discussed in the course of this chapter,[134] provides for a guideline in the drafting of a specified consent document. Obtaining informed consent for the purpose of any stem cell related activity, medical treatment or scientific research, is fraught with many complex issues which may only be overcome by making use of a detailed consent process. Generic consent will thus not be sufficient and should not be deemed valid and lawful. This aspect has been addressed and will be discussed in greater detail throughout the course of this thesis.

4.1.2 Section 7: Consent Of User

According to section 7, which is subject to section 8, a user may not receive any health service without informed consent.[135] Informed consent is therefore a prerequisite for the rendering of any health service and thus administrative procedures must be completed before any such service may be rendered. There are, however, exceptions as provided for by section 7 of the NHA. These include circumstances where:[136]

1. The patient is unable to give consent but it may be obtained from a person who is mandated in writing by the patient or authorised to do so in terms of a court order;
2. The spouse or partner of the patient is able to give consent or the parent, grandparent, an adult child or a brother or a sister of the patient may alternatively provide consent to the treatment;

[132] Stem cell therapy is expensive and the University of California at Berkeley stated that stem cell therapies would likely be costly due to high development expenses and potential high use. See California Stem Cell Report (2010) "High cost of stem cell therapy: Will stem cell firms share more risk?" available online at http://californiastemcellreport.blogspot.com/2010/03/high-costs-of-stem-cell-therapy-will.html accessed 18/3/2012.
[133] See paragraph 5.5 *infra* for a discussion hereof.
[134] See paragraph 5.5 *infra*.
[135] See in general, Nienaber (2010) 122.
[136] Section 7(1)(a)-(e).

3. Consent need not be obtained from the patient where the provision of the health service is authorised by law or is court ordered;
4. Failure to treat the patient will cause a serious risk to public health; or
5. Any delay in treatment may result in death or cause irreversible damage to the patient's health and the service or treatment has not been expressly, implicitly or by conduct refused.

Sections 7(1)(a) and (b) basically restate the definition of a user regarding the person who may, by proxy, give consent in circumstances where the user is incapable thereof. Regarding the subsection (1)(c) order, the draft Regulations regarding Communicable Diseases[137] should be noted as they provide for certain proposed prerequisites to be met before such an order may be obtained, which compel a person to be forcibly treated.[138] It must be shown that:[139]

1. The disease or health risk was previously determined as being hazardous to the public health;
2. Other measures, besides forced isolation and treatment, have been attempted by the State;
3. Forced isolation and treatment must be determined to be the most justifiable course of action in preventing the spread of the disease; and
4. It must be shown that the disease will spread in the absence of an intervention.

A scenario envisioned by subsection (1)(d), where a user must be treated regardless of consent due to public interest may occur where, for example, persons are quarantined due to drug resistant tuberculosis,[140] ebola or the H1N1 virus.[141] Section 7(1)(e), which refers to emergency medical treatment, must be read in conjunction with section 5.[142]

Sections 7(2) and 7(3) are of importance to this thesis. Section 7(2) states that a health care provider must take all reasonable steps to obtain the user's informed consent. It is somewhat

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[137] Communicable disease is defined in section 1 of the NHA as "a disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host."
[138] Regulations regarding Communicable Diseases of 25 January 2008. See also the Regulations relating to Communicable Diseases of 13 April 2010.
[139] Regulation 10(3) of the Regulations regarding Communicable Diseases. See also *Minister of Health of the Province of the Western Cape v Goliath and others* 2009 (2) SA 248 (C).
140 This was the situation in the *Goliath* case *supra*. For further reading, on this, see Nienaber A (2009) "The involuntary isolation of patients with XDR-TB: Is the term 'health service' in section 7 of Act 61 of 2003 interpreted too broadly? Minister of Health, Western Cape v Goliath and Others 2009 (2) SA 248 (C)" *SA Publiekreg/SA Public Law: States of Statelessness: Politicide and Constitution in the African Post-colony* 24(2): 659-667 and Legal Brief (2009) "Advance Notification-SA Law Reports and SA Criminal Law Reports" available online at http://www.legalbrief.co.za/article.php?story=20090228112712408 accessed 10/4/2012.
[141] Commonly known as "Swine Flu."
[142] See paragraph 4.16 *infra* for a brief discussion of section 5. See also *Soobramoney v Minister of Health, KwaZulu-Natal* 1997 12 BCLR 1696 (CC) where the meaning of emergency medical treatment in terms of section 27(3) of the Constitution was clarified to some extent. See in general, the Emergency Medical Services Regulations of 8 May 2015.

uncertain what constitutes reasonable steps. The South African cases, both of which were discussed previously, of *Stoffberg v Elliott*[143] as confirmed by *Louwrens v Oldwage*[144] may, however, offer some clarity in this regard. For a patient to give their informed consent they must know and understand the form of health service which will be provided and they must further know and understand the risks of such a service. The physician or attending nurse does not, however, have to inform the patient of every possible risk if such a risk is unlikely, or if it is only minimal harm. The reasonable steps which must be taken in order to obtain consent thus consist of an understandable and knowledgeable explanation of the relevant benefits, risks, costs and implications or consequences of a proposed medical procedure or treatment.[145] Consent in context of medical interventions must be understood as informed consent. Section 7(3) contributes greatly to this discussion as it provides the definition of informed consent and states that informed consent is "consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6." Since the efficacy of stem cell therapy is untested, it cannot be said to be certain and therefore it is not a specified health service. As such, support is given to the thesis argument that informed consent is not the proper format of consent in instances of stem cell therapy.

It is also helpful to note one of the further first definitions of informed consent provided specifically in context of stem cells, which at least foresees research activities, as found in the Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics which are discussed in greater detail in the course of this chapter.[146] The Regulations define informed consent as "an agreement by which a participant, donor or health care user voluntarily confirms his or her willingness to participate in research, donation or treatment, after understanding all aspects of such research, donation or treatment that are relevant to his or her decision." It is emphasised in both these aforementioned definitions that the person participating, in whatever capacity, must have knowledge and understanding of all aspects related to their participation. In context of stem cell therapy-research, this is an immense concern as this thesis argues that stem cell related activities are still too novel to have any certainty regarding these aspects. This therefore has great consequences on the lawfulness or validity of consent.

[143] *Stoffberg v Elliott* 1923 CPD 148. See chapter 3 paragraph 5.1 *supra*.
[144] *Louwrens v Oldwage* 2006 (2) SA 161 (SCA). See chapter 3 paragraph 5.11 *supra* for a discussion of the case as it was heard by the court *a quo*.
[145] Prinsen (2010) 207.
[146] See paragraph 5.1 *infra*.

4.1.3 Section 8: Participation In Decisions

A user has the right to participate in a decision which will affect their personal health and treatment.[147] After consent has therefore been obtained, a person must be informed that they are entitled to participate in the decision making process surrounding their treatment. This participation, as provided for by section 8, includes giving consent where consent has been given by a different person. Where a person, other than the user, gives consent for a treatment to be administered, the user must be consulted where possible and if the user is capable of understanding, but lacks legal capacity to consent themselves, the user must be informed according to the section 6 requirements.[148] In other words, where a procedure has been performed with the consent of a person other than the user, the user must still give their consent after the procedure has been performed or treatment has been administered.[149] Where a user is unable to participate in the decision making process, as in emergency treatment, the user must be informed of the treatment after it has been provided. Only where a disclosure of this nature would be against the best interests of the user, will an exception be made.[150]

Section 8 demonstrates consumer protection tendencies and strongly indicates that a user should be involved in medical decision making procedures regarding their personal health and treatment.[151] This constitutes a departure from paternalism, which was prevalent in earlier health legislation, and a move towards autonomous medical decision making on the part of the patient. It also indicates a respect for the patient's treatment preferences. Lastly, it is also noteworthy that section 8 is indicative of participation as a process. This lends itself to the concept of a dynamic consent format as will be introduced in the course of this thesis as a contribution to the field of law.

4.1.4 Section 9: Health Service Without Consent

Section 9 deals with situations where a health service is rendered without the consent of the user and thus recognises that circumstances exist where a person may be forcibly admitted to a health establishment. Although this section directly deals with issues of consent, it need only be mentioned and is it is not pertinent to this discussion as it merely states procedures to be followed. It provides that where a user is admitted to a health establishment without their or

[147] Section 8(1) of the NHA.
[148] Section 8(2)(a) and (b) of the NHA.
[149] Section 12(2)(c) of the Constitution.
[150] Section 8(3) of the NHA.
[151] Section 8 may be interpreted as alluding to a model of shared medical decision making. See Prinsen (2010) 208-214 for a discussion hereof.

another's consent, the establishment must notify the head of the provincial department within 48 hours after the user was admitted.[152] The aim of this is to enable the provincial department to monitor the user's treatment and ensure that his or her rights are respected or where the rights are restricted, that this is justifiable. This is, however, not necessary where the user does give their consent to the provision of a health service within 24 hours of admission.[153] This may perhaps be relevant in cases of emergency medical treatment. Further situations wherein section 9 may find application include where a person poses a threat to themselves or the public. A person may also be forced to undergo medical testing, such as an HIV test, without consent in terms of the Criminal Law (Sexual Offences and Related Matters) Amendment Act,[154] where such a person is accused of committing a sexual offence.[155]

4.1.5 Section 11: Health Services For Experimental Or Research Purposes[156]

Prior to providing a user with any health service for experimental or research purposes, the user must be informed in accordance with the section 6 prescribed manner, that the specific health service is partly or wholly intended for experimental or research purposes or projects.[157] A health establishment may, however, not provide any health service to a user unless the user as well as the health care provider primarily responsible for the user's treatment, the head of the health establishment and the relevant health research ethics committee have given prior written authorisation for the provision of the specific health service.[158]

The NHA does not define "authorisation" which means that the normal grammatical meaning of the word may be ascribed thereto. Generally, this indicates a process of granting permission or consent. Also, in the United Kingdom, a distinction may be drawn between English and Scottish legislation for the purposes of stem cell regulation and in the Scottish Human Tissue Act the term "authorisation" is used rather than "consent" but it has a corresponding meaning.[159] It is suggested that the failure to specify either "informed" or "broad" consent in these instances where health services are provided for research or experimental purposes may be interpreted in support of the argument that untested treatments such as stem cell therapy which is

[152] Section 9(1) of the NHA.
[153] Section 9(3) of the NHA.
[154] Criminal Law (Sexual Offences and Related Matters) Amendment Act 2007.
[155] Involuntary mental health care services are also related to health services without consent. See chapter 4 paragraph 5.2 *supra*.
[156] Section 11 is closely related to section 71 of the NHA which deals with informed consent for research or experimentation involving human subjects. See paragraph 4.3.2 *infra* for a discussion of section 71. Section 11 came into force on 1 March 2012 as enacted by Notice No.11 in Government Gazette No.35081 of 27 February 2012.
[157] Section 11(1) of the NHA.
[158] Section 11(2) of the NHA.
[159] See chapter 8 paragraph 2.5 and 3.5 *infra*.

tantamount to research involving human subjects requires a novel consent format such as the dynamic format introduced in the course of this thesis.

Although the NHA defines "health research"[160] it does not provide a definition of "experimental or research purposes" and it could thus be assumed to mean experimentation and research regarding health and health care.[161] The definition provided for by the NHA for health research states that it includes any research which contributes to the knowledge of:[162]

(a) Human biological, clinical, psychological or social processes;
(b) Improved methods of providing health services;
(c) Human pathology;
(d) The causes of disease;
(e) Environmental effects on the human body;
(f) The development or new application of pharmaceuticals, medicines and related substances; and
(g) The development of new applications of health technology.

Section 11 may therefore be perceived to provide for a particular type of health research as it only refers to experimental health services.[163] This means that in order to qualify as a section 11 intervention, a health research study must investigate an experimental health service. It therefore excludes studies of proven health services. The requirements of the generally applicable obligations due in health research, prior authorisation and informing the user of the experimental nature of the service, must then also be met.[164] Stem cell research should thus qualify as health research in terms of the NHA. Where a person therefore wishes to participate in a research study which is intended to further knowledge regarding health or medicine,[165] such a person must be informed of all relevant section 6 and 11 information.

Section 11 thus emphasises the requirement of and statutorily mandates prior consent. Not only does it establish consent as an imperative requirement to an intervention for experimental or research purposes, it also explicitly requires that a user be informed that the health service they

[160] According to section 1 of the NHA, this is "any research which contributes to knowledge of-(a) the biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision of health services; (c) human pathology; (d) causes of disease; (e) the effects of the environment on the human body; (f) the development or new application of pharmaceuticals, medicines and related substances; and (g) the development of new applications of health technology."
[161] Prinsen (2010) 215.
[162] Section 1 of the NHA.
[163] See footnote 103 *supra* for the definition of a "health service" as provided for by section 1 of the NHA.
[164] Strode AE (2013) "The parameters of the current legal framework for health research: Forms of health research which are regulated and obligations imposed on researchers" *South African Journal of Bioethics and Law* 6(2): 70-71.
[165] "Medicine" must be understood as a broad concept which encompasses the elements of health research: the biological, clinical, psychological or social processes in human beings; improved methods for the provision of health services; human pathology; the causes of disease; the development or new application of pharmaceuticals, medicines and related substances and the development of new applications of health technology.

are receiving is for such purposes. In other words, a user must be made aware of the research or experimental nature of the intervention and must understand that a health service is thus more than a traditional or mere medical intervention where therapy is administered. Should this reasoning be extrapolated to the hypothesis of this thesis, a patient-participant must thus be informed that the stem cell therapy they are to receive is experimental in nature and is for research purposes. Although it may not seem like research participation, any involvement in an untested and uncertain treatment such as stem cell therapy is experimental in a sense and thus research-orientated.

The Regulations Relating to Research on Human Subjects are supplementary to section 11. The Human Subjects Regulations provide for general research principles including the principles of health research, the obligations of researchers, participation of special groups of people and research which requires additional consideration and consent. These Regulations are discussed in greater detail in the course of this chapter.[166]

This concludes the discussion pertaining to the relevant sections of Chapter 2 of the NHA. For the sake of completion, however, some miscellaneous sections also found in Chapter 2 must also be mentioned.

4.1.6 Miscellaneous: Sections 5, 10, 12, 13 To 17, 18, 19 and 20[167]

Legislation must always be read and interpreted as a whole and this brief discussion of the remainder of the sections found in Chapter 2 is therefore aimed at providing an overall view of the aspects which are now statutorily arranged for by the NHA. Although these sections do not directly influence stem cell activities, they do form part of the greater environment of health regulation in South Africa.

4.1.6.1 Section 5: Emergency treatment

Section 5 of the NHA echoes the Constitution,[168] and states that no person may be refused emergency medical treatment. As mentioned in the above discussion of Chapter 1 of the NHA, the Act introduces consumer-orientated ideas into the realm of health legislation in South Africa. For example, section 5 requires a health care worker or health establishment to provide

[166] These Regulations also supplementary section 71 of the NHA.
[167] Suggested further reading, Hassim A, Heywood M & Honermann B (2008) *The National Health Act: A guide*.
[168] Section 27(3) of the Constitution states that no person may be refused emergency medical treatment.

any person who requires emergency treatment with such treatment. Although "emergency medical condition" is not defined in the NHA, the General Regulations made in terms of the 1998 Medical Schemes Act as amended,[169] provide the following definition: "the sudden and, at the time, unexpected onset of a health condition that requires immediate medical or surgical treatment, where failure to provide medical or surgical treatment would result in serious impairment to bodily functions or serious dysfunction of a bodily organ[170] or part, or would place the person's health in serious jeopardy."[171] This means that health establishments must treat a person in such a condition if they are able to. Private hospitals do, however, sometimes insist on payment, even in emergency situations and individual health facilities may have differing or their own interpretation of what constitutes emergency medical treatment.[172]

4.1.6.2 Section 10: Discharge reports

A health care provider must provide a user with a discharge report, verbally or written,[173] at the time of the user's discharge from the health establishment with which the health care provider is affiliated. This report must contain the information which may be prescribed by the Minister.[174] The Minister must, however, when prescribing such information, have regard to the nature of the rendered health service, the user's prognosis and the need for follow-up treatment.

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[169] Medical Schemes Act, Act 131 of 1998.
[170] An organ is defined as "any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete" according to section 1 of the NHA.
[171] In *Soobramoney v Minister of Health, Kwa-Zulu Natal* 1998 1 SA 765 (CC), the meaning of this term was tested. The appellant claimed that dialysis was emergency medical treatment as envisioned in section 27(3) of the Constitution which states that no person may be refused such treatment. It was, however, found that dialysis did not constitute such treatment. In paragraph 51, Sachs J stated the following: "the special attention given by section 27(3) to non-refusal of emergency medical treatment relates to the particular sense of shock to our notions of human solidarity occasioned by the turning away from hospital of people battered and bleeding or those who fall victim to sudden and unexpected collapse. It provides reassurance to all members of society that accident and emergency departments will be able to deal with the unforeseeable catastrophes which could befall any person, anywhere at any time. The values protected by section 27(3) would, accordingly, be undetermined rather than reinforced by any unwarranted conflation or emergency and non-emergency treatment such as that argued by the appellant."
[172] In practice, private hospitals will stabilise a person in critical condition and when such a person is in a stable condition, have them transferred to a public institution. See in general, the 2015 Emergency Medical Services Regulations. See also McQuoid-Mason D (2013) "Emergency medical treatment and 'do not resuscitate' orders: When can they be used?" *South African Medical Journal* 103(4): 223-225.
[173] A verbal report is sufficient in the case of an outpatient but a written report is required for an inpatient. "Inpatient" means that the procedure which the user underwent required the user to be admitted to a health establishment such as a hospital with the primary goal of closely monitoring the user during and after the procedure. "Outpatient" means that the procedure did not require the user to be admitted and that the procedure or treatment may also be administered outside of a hospital.
[174] The Cabinet member in charge of Health.

1.1.6.3 Section 12: Duty to disseminate information

This section provides for the sharing of health information by requiring that the national department and each provincial department, district health council and municipality must disseminate appropriate, adequate and comprehensive information on the health services which they are responsible for. This includes:

(a) The types and availability of health services;
(b) The organisation of health services;
(c) Visiting timetables and operating schedules;
(d) Procedures for access to health services;
(e) Other aspects of health services which may be of use to the public;
(f) Procedures for laying complaints; and
(g) The rights and duties of users and health care providers.

It is assumed that this is connected to the establishment of a National Health Information System.

4.1.6.4 Sections 13 to 17: Health records

As was mentioned above, the NHA introduces a number of protective elements into the health system. Confidentiality, and specifically patient records, is now heavily protected under sections 12 to 17.[175] Section 13 mandates that the person in charge of a health establishment must

[175] Sections 12 to 17 must be read together with the definition of "personal information" as provided for by section 1 of the Promotion of Access to Information Act, Act 2 of 2000. This definition reads as follows: "information about an identifiable individual, including, but not limited to-
(a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the individual;
(b) information relating to the education or the medical, criminal or employment history of the individual or information relating to financial transactions in which the individual has been involved;
(c) any identifying number, symbol or other particular assigned to the individual;
(d) the address, fingerprints or blood type of the individual;
(e) the personal opinions, views or preferences of the individual, except where they are about another individual or about a proposal for a grant, an award or a prize to be made to another individual;
(f) correspondence sent by the individual that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence;
(g) the views or opinions of another individual about the individual;
(h) the views or opinions of another individual about a proposal for a grant, an award or a prize to be made to the individual, but excluding the name of the other individual where it appears with the views or opinions of the other individual; and
(i) the name of the individual where it appears with other personal information relating to the individual or where the disclosure of the name itself would reveal information about the individual,
but excludes information about an individual who has been dead for more than 20 years."

ensure that a health record containing the prescribed information must be created and maintained.[176]

The general principles regarding disclosure of information are found in sections 14 and 15. All information concerning a user is confidential and this includes information on the user's health status, treatment or stay in a health establishment. Disclosure to a third party is provided for by section 15, but only in circumstances where the user consents to such disclosure, where a court order mandates such disclosure, where non-disclosure constitutes a risk to public health[177] or where a disclosure is made from one health care provider or worker to another for a legitimate cause in the ordinary course and scope of their duties or if such a disclosure is in the user's interest.[178]

A health care provider may examine a user's health record for the purpose of treatment or for study, teaching or research. For treatment purposes only the user's authorisation is required but in the case of study, teaching or research, the user as well as the head of the health establishment and the relevant ethics committee must give their authorisation.[179]

Severe penalties are imposed by section 17 for any limitation of a user's right to privacy or any infringement of confidentiality.

4.1.6.5 Section 18: Laying of complaints

A user has the right, in terms of section 18 of the NHA, to lay complaints regarding treatment received at a health facility. Health establishments must clearly display the procedure to follow in laying complaints and it must be communicated to users on a regular basis. A user may be allowed to complain to the head of the establishment where the establishment is a private facility.

[176] This is subject to the National Archives of South Africa Act, Act 43 of 1996 and the Promotion of Access to Information Act 2000.
[177] As provided for by section 14(2)(a)-(c) of the NHA. According to *Tshabalala-Msimang and Another v Makhanya and Others* 2008 (6) SA 102 (W) the details of a public figure's private medical records may be published in the media where the publication is in the public interest. This may still constitute a punishable offence in terms of section 17 of the NHA though. A non-public figure's medical records are not a matter of public interest at all.
[178] Section 15(1) of the NHA.
[179] The user's authorisation is not required where the identity of the user is not reflected.

4.1.6.6 Section 19: Duties of users

Although the NHA provides for a number of protective measures, it also imposes certain obligations on users. Any refusal or failure to adhere to such obligations would make the user guilty of an offence in terms of section 89.[180] A user is required to:

(a) Adhere to the rules of an establishment wherein they are admitted;
(b) Provide accurate information regarding their condition to the health care provider rendering their services and co-operate with such care provider;[181]
(c) Treat all health care providers and workers with respect and dignity; and
(d) Sign a discharge certificate where they refuse the recommended treatment which serves as a means of indemnification.[182]

4.1.6.7 Section 20: Rights of Health Care Personnel

Section 20 provides for the rights of health care personnel. They are protected from unfair discrimination on the grounds of their healthcare status.[183] Furthermore, a health establishment must implement measures to minimise injury or damage to the person or property of the health care personnel and also the transmission of disease. A health care provider may refuse to treat a user if the user is verbally or physically abusive towards them or sexually harasses the health care provider.[184]

This then concludes the discussion of Chapter 2 of the NHA which is important in context of consent and is therefore relevant to this thesis in a broad sense. Chapter 8 of the NHA, however, focuses more specifically on certain materials which include stem cells and their regulation and attention must now be turned to an investigation of the relevant provisions found in this chapter of the Act.

[180] It must be noted that section 89 falls within Chapter 10 of the NHA which was amended by the National Health Amendment Act, Act 12 of 2013. See *Figure H supra*.
[181] This is subject to section 14 of the NHA.
[182] See in general, Aids Law Project (2014) *Health and democracy*: 316-347.
[183] See Kirby (2005 online.
[184] Suggested further reading, Aids Law Project (2014) 316-347.

4.2 CHAPTER 8: CONTROL OF USE OF BLOOD, BLOOD PRODUCTS, TISSUE AND GAMETES IN HUMANS

Chapter 8 deals with the complex issue of control over blood, blood products, tissue[185] and gametes[186] and is titled "Control of Use of Blood, Blood Products, Tissue and Gametes in Humans."[187] During the briefing by the Minister of Health, the Minister emphasised the importance of this chapter and stated that the human body must not be exploited as a commodity as this would be a violation of human dignity. Dignity must therefore be protected while the importance of human tissue is acknowledged.[188] Many provisions found in Chapter 8 have been directly drawn from the Human Tissue Act which was completely repealed when Chapter 8 come into force.[189] Unfortunately the larger part of this chapter has not yet come into force, resulting in a legislative vacuum, with the exception of the sections 53, 56, 68 and 93(1) which are operational.[190]

Chapter 8 is rather controversial as may be expected of any legislation dealing with stem cells. There are, however, legal reasons for the dissatisfaction with this chapter of the NHA. Chapter 8 is, aside from greatly lacking legislative clout, low quality legislation and does not reflect international trends in stem cell regulation and is thus weighing down the development of this technology in South Africa. Scientists as well as ethicists have pointed out factual errors contained in this chapter on various occasions. In fact, in 2009 a working group was established in an attempt to rectify this situation by drafting an amendment to this chapter.[191] A previous analysis of this chapter of the NHA has been analysed and recommendations regarding aspects which must be amended have been made and will not be repeated in detail.[192] For the purposes of this discussion, Chapter 8 will merely be discussed as it has been published and amended and

[185] Tissue is defined as "human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete" according to section 1 of the NHA.
[186] Section 1 of the NHA defines this as "either of the two generative cells essential for human reproduction."
[187] If this chapter remains the primary regulatory tool of stem cell research and treatment in South Africa, it is submitted that the title be amended to expressly include stem cells, either by direct use of the term or by use of an umbrella term.
[188] Department of Health (2004) online.
[189] An example of this is the provision for blood transfusion services. See Gray, Gengiah *et al.* (2005) 20.
[190] Section 53 was proclaimed into force by the President in Notice No.22 in Government Gazette No.31187 of 27 June 2008. Sections 56, 68 and 93(1) were proclaimed in Notice 20 of 2010 in Government Gazette No.33187 of 14 May 2010.
[191] This working group was established under mandate of the Department of Health on the 14th of July 2009. It is comprised of seven expert groups which are each dedicated to a specific issue. The seven groups are: blood transfusion; assisted reproductive technology; cell-based therapy; transplantation; genetic services; tissue banks; and examination, allocation and disposal of human bodies and tissues. These groups consulted with stakeholders and their representatives and considered the policy documents of such entities in order to amend or rewrite chapter 8. To name two, some documents which were taken into account were the *World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation* and the *Istanbul Declaration of 2008*.
[192] For an in-depth discussion of the recommendations which have been made regarding Chapter 8 see Prinsen L (2010) 233-250.

thus currently stands, in order to sketch a picture of the legislative environment of stem cell technologies and to establish the background to the subject of this thesis.

4.2.1 Section 53: The Establishment Of A National Blood Transfusion Service[193]

Section 53 was the first section of Chapter 8 to come into force as it was proclaimed on the 30th of June 2008.[194] From 2008 to 2010 this was the only enacted section of Chapter 8.[195] Section 53 mandates the Minister to establish a blood transfusion service for the Republic of South Africa by granting non-profit organisations a licence. These organisations must be capable of providing this service throughout the South African territory.[196] Such a licensed organisation must comply with the norms and standards as may be prescribed in regulations made in terms of section 90 of the NHA and must further provide the prescribed blood transfusion and related services.[197] This may include establishing regional units.[198] The holder of such a licence has the sole right to provide blood transfusion services in South Africa. Any person other than the licence holder who provides a blood transfusion service is therefore guilty of an offence and liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.[199]

4.2.2 Section 54: Designation Of Authorised Institution[200]

According to section 54, the Minister may designate any institution, other than an institution contemplated in section 63 of the NHA,[201] as an authorised institution by notice in the Government Gazette.[202] Section 54(2) states that such an institution may then:[203]

(a) Acquire, use or supply the body of a deceased person for any of the section 64 purposes;[204]

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[193] "Blood transfusion service" is not defined in the NHA. The Regulations relating to Blood and Blood Products, however, provide such a definition. See paragraph 5.10 *infra*.
[194] Section 53 was enacted by the President of South Africa in Notice No.22 of 27 June 2008.
[195] See *Figure H supra*.
[196] Section 53(1).
[197] Section 53(2)(a).
[198] Section 53(2)(b).
[199] Section 53(3).
[200] An authorised institution is "any institution designated as an authorised institution in terms of section 54" according to section 1. Section 54 only came into force on the 1st of March 2012 by way of Notice No.11 of 27 February 2012.
[201] See paragraph 4.2.10 *infra*.
[202] Section 54(1).
[203] Section 54(2)(a)-(d). Sections referenced in the course of section 54 are discussed in the course of this chapter.

(b) Acquire or use any tissue[205] lawfully imported or removed from the body of a living or deceased person for any of the purposes referred to in either section 56 or section 64, whatever the case may be;

(c) Supply any tissue preserved by it to an institution or person contemplated in section 63 for any of the purposes referred to in sections 58 or 64;[206] and/or

(d) Acquire, use and supply blood products for any of the purposes referred to in sections 56 or 64.[207]

At this juncture it may be submitted that perhaps, in drafting any amendments to this chapter of the NHA or in drafting new legislation in this regard, the ambit of the Act must be broadened in order to enable the Act to accommodate and/or absorb new developments such as bioprinting and scaffolding for example. Section 54(3) states that the Minister may impose conditions in respect of the exercise of a section 54(2) power.

4.2.3 Section 55: Removal Of Tissue, Blood, Blood Products Or Gametes From Living Persons[208]

Section 55 states that no person may remove tissue, blood, a blood product or gametes from another living person's body, for any purpose referred to in section 56, unless the person from whom the tissue, blood, blood product or gametes is removed has granted permission, in the form of consent, in the prescribed manner[209] and such removal is practised in accordance with prescribed conditions.[210] Unfortunately, the NHA does not provide for a clear description of what requirements constitute "prescribed conditions." This issue will have to be addressed in any amendments to the Act or in regulations dealing with the removal of material from humans.

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[204] See paragraph 4.2.9 *infra* for a discussion of the provisions regarding issues surrounding deceased persons. The Human Tissue Authority in the United Kingdom may present a model to aspire to as it is a central institution which regulates all activities related to the body of a deceased. It is thus recommended that subsection (2)(a) be broadened to permit such institutions to store, process and analyse the body of a deceased as well. See chapter 8 *infra*.
[205] Section 1 defines tissue as "human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or gametes." It is recommended that a new definition should be drafted which includes gametes and cells, particularly stem cells, as falling under tissue. The NHA does not provide for a definition of stem cells, embryonic or adult, and it is further recommended, perhaps in the alternative, that at the very least an umbrella term must be provided under which stem cells may be brought under the field of application of the NHA in a direct manner. Such an umbrella term may then perhaps also include DNA and RNA as well as other genetic materials.
[206] This section must also include cells and gametes or the umbrella term as recommended in footnote 187 *supra*.
[207] As previously mentioned, it is submitted that the storage, processing and analysis of such materials should be included. The recommendations made here would lead to a more comprehensive and inclusive regulatory regime for human biological materials.
[208] Section 55 came into force on 17 May 2010 as enacted by Notice No.20 of 14 May 2010.
[209] Section 55(1)(a).
[210] Section 55(1)(b).

A further issue is the lack of a finer grained definition or description of consent. It is this issue which this thesis endeavours to address.

4.2.4 Section 56: Use Of Tissue, Blood, Blood Products Or Gametes Removed Or Withdrawn From Living Persons[211]

Section 56 has some bearing on this thesis as it is the prescriptive section regarding what actions involving material from living persons are permissible. This section deserves attention in any attempted regulation of stem cell related technologies in South Africa and will in all probability require some amendment. Due to the importance of this section, the text of the Act is directly quoted here. Subsections (1) and (2) are then discussed separately.

Section 56(1) reads "a person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed." Section 56(1) only provides for the use of tissue, gametes, blood or blood products and then only for medical or dental purposes as prescribed. This is interesting as stem cells may be withdrawn from tissue as well as from gametes. Stem cell therapy may therefore qualify as permissible under section 56. Stem cell research would, however, not qualify. As previously recommended, section 56(1) should be considered for amendment.[212] In context of the thesis, and by making use of some gymnastic reasoning, it could be argued that, since stem cells may be withdrawn from tissues and gametes and then applied in stem cell therapies which are tantamount to research, section 56 may be applicable to both stem cell therapy and research.

Where subsection (1) names material which is permissible to remove or withdraw, subsection (2) provides for certain circumstances where and the human materials which may not, even for the activities prescribed in subsection (1), be removed or withdrawn. The Minister may, however, permit such removals or withdrawals under prescribed conditions. This subsection states:[213]

> "(2)(a) Subject to paragraph (b), the following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purpose contemplated in subsection (1):

[211] Section 56 came into force on the 17th of May 2010 as enacted by Notice No.20 of 14 May 2010.
[212] As suggested by Prinsen, section 56 should be amended by expansion as well as contraction. The addition should be made of research as permissible use of material. Furthermore, stem cells or at least an umbrella term must be added to the usable material named in this section. The scope of this section must then be narrowed by the removal of "blood products." A blood product cannot be removed from the human body and the inclusion thereof is thus indicative of the legislator's lack of technical knowledge pertaining to stem cell technology. Such amendment may constitute a massive development in stem cell regulation. See Prinsen (2010) 238.
[213] It should be noted that the first reference to stem cells in the NHA is contained within this section. Stem cells are not defined and it is submitted that a definition should be provided within the Act itself and that reliance on Regulations to provide such a definition is unsatisfactory.

> (i) tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Care Act, 2002 (Act No. 17 of 2002);
> (ii) tissue which is not replaceable by natural processes from a person younger than 18 years;
> (iii) a gamete from a person younger than 18 years; or
> (iv) placenta, embryonic or fetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.
>
> (b) The Minister may authorise the removal or withdrawal of tissue, blood, a blood product or gametes contemplated in paragraph (a) and may impose any condition which may be necessary in respect of such removal or withdrawal."

Concerning subsections (ii) and (iii) it may be argued that the removal or withdrawal of stem cells from a minor should be permitted as stem cells do not technically constitute gametes. This is especially true in the case of adult stem cells. Furthermore, stem cells are replaceable by natural processes as they proliferate indefinitely. This removal or withdrawal would, however, be subject to the required consent being obtained.[214]

Subsection (2)(iv) is rather confusing as it in fact prohibits stem cell removal or withdrawal. Chapter 8 is the proposed regulatory tool for stem cells and related activities in South Africa and yet here we find the explicit prohibition of an activity which is, by nature, essential to stem cell research and treatment. The Minister may only approve the removal or withdrawal of tissue, blood and blood product or gametes. Ministerial approval is, however, not ideal as the Minister, or a delegated person acting on behalf of the Minister, often lacks the knowledge regarding stem cell research and related matters. This may inhibit their decision making and ultimately result in a blow to the development of this technology in South Africa.[215] Also, Ministers are appointed by political parties and as such must promote the agenda of the party. Where an issue is not supported by or a priority of the party, the proper amount of needed resources and attention will not be given to the issue. Stem cell related activities are not a national health priority and as such they may hardly be expected to receive sufficient notice in these circumstances.

This section serves as an excellent example of the issues surrounding the NHA. It creates more uncertainty than clarity. Also, this section may be deemed an internal limitation to Chapter 8 of the NHA due to the prohibition on removal or withdrawal of certain materials from certain persons and furthermore due to the provision of additional ministerial regulatory powers.

[214] This is indicative of a fundamental lack of the necessary technical scientific knowledge on the part of the legislator.
[215] An independent authority must be established to deal with such matters as based on the United Kingdom model which will be discussed in the course of this thesis. See chapter 8 *infra*. See also Prinsen (2010) 239-241 for further recommendations regarding section 56.

4.2.5 Section 57: Prohibition Of Reproductive Cloning Of Human Beings[216]

Section 57 is contentious and deals with reproductive cloning of human beings. Specifically, it deals with the prohibition thereof. This section provides therefore that no person may manipulate genetic material such as gametes, zygotes[217] or embryos[218] and also that no person may participate in any activity with the purpose of reproductive cloning. This then includes nuclear transfer and embryo splitting.[219] Reproductive cloning of human beings is, however, internationally and nationally prohibited. It has been argued that this subsection is to some extent superfluous.[220]

The issue which, however, is most vexing is the fact that section 57 is self-contradictory as subsection (2) allows for therapeutic cloning which makes use of adult or umbilical cord cells. This concern is that therapeutic cloning and reproductive cloning follow exactly the same process, namely nuclear transfer.[221] Subsection (1) prohibits this very activity. Clearly this lack of knowledge on the part of the legislator indicates that governmental control of this field of technology would be a grave mistake and thus an independent authority must be established to deal with these matters. Section 57 further mandates ministerial approval for the importation or exportation[222] of human zygotes or embryos.[223] Any contravention of the section 57 provisions could result in a fine or imprisonment.[224] A further anomaly exists in that research on stem cells and zygotes not older than 14 days is permitted by section 57(4).[225] Stem cells are seen as immortal and it is thus proposed that this must be interpreted as relating to the "age" of the zygote and not of the stem cells.

Lastly, section 57 provides for the definitions of reproductive and therapeutic cloning. Section 57(6) states that reproductive cloning of a human being means "the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose"[226] and therapeutic cloning is "the manipulation of genetic

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[216] Section 57 came into force on 1 March 2012 by enactment in Notice No.11 27 February 2012.
[217] A zygote is defined as "the product of the union of a male and female gamete" by section 1 of the NHA.
[218] An embryo is "a human offspring in the first eight weeks from conception" according to section 1 of the NHA. See section 57(1)(a).
[219] Section 57(1)(b).
[220] Prinsen (2010) 241.
[221] See chapter 2 paragraph 3.6.1.2 *supra*.
[222] See the Regulations relating to Import and Export in paragraph 5.7 *infra*.
[223] Section 57(3).
[224] Section 57(5).
[225] Section 57(4) reads "the Minister may permit research on stem cells and zygotes which are not more than 14 days old on a written application and if (a) the applicant undertakes to document the research for record purposes and (b) prior consent is obtained from the donor of such stem cells or zygotes."
[226] Section 57(6)(a).

material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues."[227]

4.2.6 Section 58: Removal And Transplantation Of Human Tissue In Hospital Or Authorised Institution[228]

Section 58 reads "a person may not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except (a) in a hospital[229] or an authorised institution and (b) on the written authority of (i) the medical practitioner in charge of clinical services in that hospital or authorised institution, or any other medical practitioner authorised by him or her or (ii) in the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner authorised thereto by the person in charge of the hospital or authorised institution." Subsection (2) then requires that a medical practitioner as contemplated in subsection (1)(b) may not participate in any transplant procedure wherefore they themselves have granted authorisation. Section 56(1) must be read together with section 58.[230]

Section 58 strongly demonstrates the spirit of consumer protection as any such procedure must be executed in a prescribed location which must adhere to certain standards.[231] Furthermore, a knowledgeable person is placed in a position of authority from where the rights of the user may be protected.

4.2.7 Section 59: Removal, Use Or Transplantation Of Tissue, And Administering Of Blood And Blood Products By Medical Practitioner Or Dentist[232]

Section 59 provides for persons who may undertake the permitted activities. Only a registered medical practitioner or dentist may remove tissue from a living person, use the tissue or transplant it into another living person.[233] Also, only a medical practitioner or dentist or a person under their instruction or supervision may administer blood or a blood product to a

[227] Section 57(6)(b).
[228] Section 58 came into force on 1 March 2012 in terms of Notice No.11 of 27 February 2012.
[229] For purposes of this chapter a hospital is "a health establishment which is classified as a hospital by the Minister in terms of section 35" as defined by section 1 of the NHA.
[230] Section 56(1) reads "A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed."
[231] Which includes *inter alia* standards of treatment and hygiene.
[232] Section 59 only came into force on 1 March 2012 by enactment in Notice No.11 of 27 February 2012.
[233] Section 59(1).

living person.[234] It is concerning that no provision has been made for a person not in a medical practitioner's position, such as a researcher. Researchers must therefore be added to the understanding of competent persons able to work with stem cells. This rings especially true in context of the hypothesis posited throughout this thesis.

4.2.8 Section 60: Payment In Connection With The Importation, Acquisition Or Supply Of Tissue, Blood, Blood Products Or Gametes[235]

According to section 60(1) of the NHA, only the following entities are entitled to payment in connection with tissue, blood, blood products or gametes used for the purposes stipulated in sections 56 and 64:

1. A hospital or person as contemplated in section 58(1);[236]
2. A person or institution as contemplated in section 63;[237] and
3. The importer or exporter of tissue or gametes.

Hospitals should, however, it is suggested, have no part in the "trade" aspect of human materials and must only apply or use such material as appropriate.[238] Such a ban on trade activities would ensure that there are fewer conflicts of interest in the treatment of users.

Payment must not exceed the amount reasonably required to cover the costs involved in the importation, export, acquisition or supply of the tissue, blood, blood products or gametes.[239] This, however, does not prevent the health care provider from receiving remuneration for the professional service rendered by him according to section 60(3).[240]

It is an offence, according to section 60(4) for a person who has donated any of the named material to receive any other financial reward except for the reimbursement of reasonable costs. It is also an offence or to sell or trade these human materials in contravention of any of the provisions made elsewhere in Chapter 8.[241] Any contravention of the provisions of this section are punishable according to subsection (5) which states that any person convicted of an

[234] Section 59(2).
[235] Section 60 also only came into force on the 1st of March 2012 by publication of Notice No.11 of 27 February 2012.
[236] This would then be in connection with transplantations of human tissue in a hospital.
[237] This relates to human material which is donated to a prescribed institution or person. Where blood or blood products are imported, exported, acquired or supplied the persons or institutions contemplated in section 63 are entitled to payment.
[238] This is connected to the discussion of who should obtain consent. It is suggested that ideally the attending physician, employed by the hospital, should obtain consent and only where no conflicts of interests exist.
[239] Section 60(2).
[240] Section 60(3).
[241] This concurs with the ethical position on the matter of payment.

offence is liable on conviction to a fine and/or imprisonment for a period no longer than five years.[242]

4.2.9 Sections 61, 62 and 64 to 67: Deceased Persons[243]

The focus of this thesis falls on stem cells which, as previously stated may be removed or withdrawn from cadaveric fetal tissue.[244] The development of technology utilising adult stem cells is, however, making this redundant to a great extent. The provisions which place more focus on organs,[245] tissue and other materials from human bodies are thus not pertinent. For the sake of completion, however, the provisions regarding these materials as relating to deceased persons must be briefly discussed and for the sake of convenience, these sections as found in Chapter 8 have been grouped together here.

Section 61[246] deals with the allocation and use of human organs. Stem cells may be obtained by removing or withdrawing them from the body of a deceased person. Section 61, however, makes no reference to stem cells and it is uncertain whether or not this would be permitted. Any material removed or withdrawn from a deceased person must be used in the prescribed manner. This may then be for transplantation, treatment, education or research purposes.[247]

Section 62 allows, in effect, for the donation of human bodies and tissues.[248] Donations may be made for purposes of education,[249] health research,[250] the advancement of health sciences,[251]

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[242] See paragraph 5.7 *infra*.
[243] Sections 61, 62 and 64-67 came into force on the 1st of March 2012 in Notice No.11 in Government Gazette No.35081 of 27 February 2012.
[244] See paragraph 2 in chapter 3.1 *supra*.
[245] An organ is "any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete" according to section 1 of the NHA. This definition has been described as "boorish" and should perhaps be considered for amendment to be brought closer along the lines that an organ is various tissues which are joined in a structural unit and adapted to perform specific functions. See Prinsen (2010) 245.
[246] Section 61: **"Allocation and use of human organs-**
(1) Human organs obtained from deceased persons for the purpose of transplantation or treatment, or medical or dental training or research, may only be used in the prescribed manner.
(2) Human organs obtained in terms of subsection (1) must be allocated in accordance with the prescribed procedures.
(3) An organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing.
(4) The Minister must prescribe—
(a) criteria for the approval of organ transplant facilities; and
(b) procedural measures to be applied for such approval.
(5)(a) A person who contravenes a provision of this section or fails to comply therewith or who charges a fee for a human organ is guilty of an offence.
(b) Any person convicted of an offence in terms of paragraph (a) is liable on conviction to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment."
[247] Section 61(2).
[248] Section 62: "**Donation of Human Bodies and Tissue of Deceased Persons-**
(1)(a) A person who is competent to make a will may—
(i) in the will;

therapeutic purposes[252] or for the production of therapeutic or diagnostic or prophylactic substances.[253]

A donation may be revoked prior to the transplantation of the relevant organ. This must be done in the same manner wherein the donation was originally made. Where a donation was made by way of a will, the donation may be revoked by another document or by the intentional destruction of the will.[254] Section 65 only provides therefore that revocation must be done prior to transplantation. A difference does, however, exist between revoking a donation a week prior and revocation at a time where the donee is already on the operating table. Some certainty must therefore be provided regarding the "cut-off" time for revocation.

Post-mortem examination of human bodies is dealt with in section 66 and section 67 with the removal of tissue at such a post mortem examination. It also deals with obtaining tissue from persons or institutions.[255]

4.2.10 Section 63: Human Bodies, Tissue, Blood, Blood Products Or Gametes May Be Donated To Prescribed Institutions Or Persons[256]

Section 63 states that a human body, tissue, blood, blood products or gametes may be donated to a prescribed institution or person.[257] This means that currently only the body of a deceased

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(ii) in a document signed by him or her and at least two competent witnesses; or
(iii) in an oral statement made in the presence of at least two competent witnesses, donate his or her body or any specified tissue thereof to be used after his or her death, or give consent to the post mortem examination of his or her body, for any purpose provided for in this Act.
(b) A person who makes a donation as contemplated in paragraph (a) must nominate an institution or a person contemplated in section 63 as donee.
(c) If no donee is nominated in terms of paragraph (b), the donation is null and void.
(d) Paragraph (b) does not apply in respect of an organ donated for the purposes contemplated in section 61 (1) and the donee of such organ must be determined in terms of section 61 (2).
(2) In the absence of a donation under subsection (1)(a) or of a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may, after that person's death, donate the body or any specific tissue of that person to an institution or a person contemplated in section 63.
(3) (a) The Director-General may, after the death of a person and if none of the persons contemplated in subsection (2) can be located, donate any specific tissue of that person to an institution or a person contemplated in section 63.
(b) The Director-General may only donate the specific tissue if all the prescribed steps have been taken to locate the persons contemplated in subsection (2)."

[249] The training of students in health sciences according to section 64(1)(a).
[250] Section 64(1)(b). "Health research includes any research which contributes to knowledge of (a) the biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision of health services; (c) human pathology; (d) causes of disease; (e) the effects of the environment on the human body; (f) the development or new application of pharmaceuticals, medicines and related substances; and (g) the development of new applications of health technology" as stated in section 1 of the NHA.
[251] Section 64(1)(c).
[252] Section 64(1)(d). This includes the use thereof in living persons.
[253] Section 64(1)(e).
[254] Section 65.
[255] See chapter 8 paragraph 5.1.4 *infra*.
[256] Section 63 became operational on the 1st of March 2012 by publication in Notice No.11 of 27 February 2012.

person, tissue, blood or blood products and gametes may be donated to the prescribed persons or institution. As Chapter 8 is the proposed regulatory tool for stem cells in South Africa, this is obviously insufficient regulation as no mention is made of stem cells. This may create the impression that stem cell donation is not permitted as it could be argued that had the legislator intended to permit it, it would be provided for in this section of the Act. It is furthermore not advisable to simply interpret blood products as a broad enough term to include stem cells as suggested by Van Wyk,[258] as blood products are also misunderstood by the legislator.

4.2.11 Section 68: Regulations Relating To Tissue, Cells, Organs, Blood, Blood Products And Gametes

Section 68 provides therefore that the Minister may make Regulations regarding various matters.[259] In the course of the discussion above, certain Regulations have already been mentioned as supplementing certain provisions. Some of the matters which may potentially and it is suggested hopefully, be addressed and supplemented in Ministerial Regulations created under section 68 of the NHA might include:

1. Definitions;
2. Removal, withdrawal and donation;
3. Storage and control;
4. Compensation;
5. Establishment of data banks;
6. Restrictions;
7. Prerequisites such as consent;
8. Files, records, registers and reporting;
9. Use, which includes: testing, health research, training and archaeological, medical or heritage studies;
10. Therapeutic cloning;

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[257] The donor is a person as contemplated in sections 55(a) or 62. The purpose of such donation must fall within the ambit of sections 56 or 64(1).
[258] Van Wyk C (2010) Transplantation Indaba.
[259] See section 68(1)(a)-(r). The issues which may be further regulated by Regulations made in terms of this section, which are relevant to this study are: (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post-mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons; (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue; (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes; (g) the importation and exportation of tissue, human cells, blood, blood products or gametes; (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes; (l) the artificial fertilisation of persons; (n) the records and registers to be kept by persons and institutions; and (p) the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose.

11. Authorisation by the Director-General as well as withdrawal of such authorisation;
12. Data protection and traceability as well as confidentiality;
13. Quality and safety as well as stem cell reception;
14. Stem cell processing;
15. Labelling, documentation and packaging;
16. Distribution; and
17. Third party relationships.

This then concludes the discussion pertaining to Chapter 8 of the NHA and the relevant Regulations are discussed in the course of this thesis chapter. As the argument posed in the course of this thesis states that treatments of which the efficacy has not been tested borders on or may qualify as research, the specific provisions related to research, involving human subjects, are of importance. To this end Chapter 9 of the NHA must be investigated.

4.3 CHAPTER 9: NATIONAL HEALTH RESEARCH AND INFORMATION

Research should be subject to review by a South African ethics committee in order to measure the scientific and ethical rigor thereof. According to the HPSCA's *General ethical guidelines for biotechnology research*, the objects of a research ethics committee are to maintain ethical standards of practice in research, to protect the participants from any harm or exploitation, to preserve the rights of the research participant[260] and to provide the public with the assurance that research is being conducted ethically.[261] Chapter 9 of the Act contains the provisions related to issues of national health research and information and it is important as it provides for the establishment of the National Health Research Committee,[262] National Health Research Ethics Council[263] and national health research ethics committees.[264] The committees are tasked with setting national health research priorities and the Council is the highest over-arching body to set research standards and norms. Research must be done in accordance to the health priorities of the country[265] and since massive advances have been made in medical science due to the use of new technology, it becomes imperative to have access thereto. Progress must, however, still be achieved in a responsible manner and must be of benefit to society. Research wherein human subjects partake can therefore, under no circumstances ever be uncontrolled. In

[260] The rights of the research participant therefore take precedence over the rights of society.
[261] Health Professions Council of South Africa (2008) "General ethical guidelines for biotechnology research" *Guidelines for good practice in the health care professions: Booklet 7*: 9.
[262] Section 69 of the NHA.
[263] Section 72 of the NHA.
[264] Section 73 of the NHA.
[265] Section 70 of the NHA deals with the identification of health research priorities. See footnote 272 *infra* for more on section 70.

context of this thesis this therefore means that stem cell therapy which is tantamount to research involving human subjects, or then patient-participants must be strictly regulated and controlled. The importance of chapter 9 is emphasised when one is reminded that the NHA is the legislative tool whereby stem cells will be regulated. In context of this thesis, the legislative codification of ethical approval is noteworthy as the doctrine of informed consent finds its roots in ethical principles.[266] Stem cell technologies, therapy or research, will be dependent on approval by ethics bodies such as the National Health Research Committee. In order to obtain approval, certain consent requirements will have to be met. No discussion on the legislative regulation of stem cells and related activities can therefore be complete without a discussion of chapter 9 of the NHA. What follows is an examination of the relevant provisions in Chapter 9 of the Act.

4.3.1 Section 69: The National Health Research Committee[267]

Research ethics committees play an important role in the control and regulation of research involving humans or animals since the researcher himself must never be the only adjudicator of whether or not a project conforms to ethical norms and standards.[268] As mentioned previously, research ethics committees must maintain ethical standards of practice in research, preserve the rights of and protect research participants from exploitation or other harm and appease the public as to the ethical validity of the manner wherein research is conducted. This therefore explains the need for an independent body such as the National Health Research Committee. [269] Conversely, however, research ethics committees must be mindful that research is of benefit to society and should not be hindered unnecessarily.[270]

Sections 69(1) and (2) mandates the Minister to establish the National Health Research Committee, consisting of no more than 15 persons. These persons are to be appointed by the Minister only after consultation with the National Health Council as established by section 22(1) of the NHA. A member of the Committee may then serve for a period of three years and may be

[266] Although chapter 9 creates a platform for the development of norms for research on human subjects, no age for independent consent to medical research is provided for. This is an aspect which will have to be clarified and has evoked criticism, specifically levelled at the quality of the legal drafting. See the discussion of section 71 in paragraph 4.3.2 *infra*.
[267] It is important to note that article 19 of the *Bioethics Declaration* also requires the establishment of independent, multidisciplinary and pluralist ethics committees which are tasked with (a) assessing the relevant ethical, legal, scientific and social issues related to research projects involving humans; (b) providing advice on ethical issues in clinical settings; (c) assessing scientific and technological developments, formulating recommendations and contributing to the preparation of guidelines on any issues; and (d) fostering debate, education and public awareness of, and engagement in bioethics. See chapter 6 paragraph 3.2.8 *infra*.
[268] Medical Research Council of South Africa (2003) *Guidelines of ethics for medical research: General principles (Book 1)* paragraph 9.5.2.
[269] Hereafter referred to as the Committee.
[270] MRC SA (2003) paragraph 9.6.1.

reappointed at the end of such a term. Should a person, however resign, voluntarily or on request of the Minister, the vacancy may be filled for the unexpired period of time that the resigned person still had to serve. The Committee must carry out the following duties:[271]

(a) Determine the health research which must be carried out by the public health authorities;
(b) Ensure that health research agendas and research resources are focused on priority health problems in South Africa;[272]
(c) Develop and advise the Minister on the implementation and application of an integrated national strategy for health research; and
(d) Coordinate the public health authorities' research activities.

The Minister may prescribe the manner in which the Committee conducts its affairs as well as the procedures, such as the procedure for decision making, to be followed.[273] Section 69 thus outlines the nature and functions of the Committee. The Minister exercises a high degree of control over the Committee and some concern has been raised in this regard.[274] The functioning of the Committee is, however, additionally regulated by the Regulations relating to the National Health Research Committee of 23 February 2007 which supplement section 69 of the Act.[275]

4.3.2 Section 71: Research On Or Experimentation With Human Subjects[276]

The NHA contains three sections which provide for different categories of health research of which section 71 is one and which relates specifically to research or experimentation on living persons. The other sections are section 1 which provides for health research and section 11 which provides for health services for research or experimental purposes.[277]

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[271] Section 69(3)(a)-(d) of the NHA.
[272] Read together, sections 69(3)(a) and (b)therefore require the Committee to determine and prioritise health and research issues and must further ensure health priorities receive the necessary attention and resources. It is, however, necessary to know what the priority health issues are and in this regard section 70 provides some clarification in the identification of health research priorities. Section 70(1) states that the Committee is tasked with identifying health priorities and advising the Minister of such priorities. In identifying the priorities, the Committee must have regard to (a) the burden of disease; (b) the cost-effectiveness of interventions aimed at reducing this burden; (c) the availability of human and institutional resources for the implementation of an intervention; (d) the health needs of vulnerable groups such as women, older persons, children and people with disabilities and (e) the communities' health needs. According to the HPCSA, research should be responsive to the health care needs of the community and must also be in line with the health priorities identified in the NHA. See Health Professions Council of South Africa (2008) "General ethical guidelines for health researchers" *Guidelines for good practice in the health care professions: Booklet 6*: 3.
[273] Section 69(4) of the NHA.
[274] The Minister may appoint members to the Committee who are sympathetic to his or her own ideology. There are thus no explicit safeguards to protect against ideology driven, rather than scientifically based, decision making.
[275] See paragraph 5.4 *infra* for a discussion of the Regulations.
[276] Section 71 only became operational on 1 March 2012 by enactment in Notice No.11 of 27 February 2012.
[277] Strode (2013) 69.

Section 71 was excluded in the 2005 promulgation notice and only became operational on the 1st of March 2012.[278] Section 71(1) states that research or experimentation on living persons may only be conducted in the prescribed manner and once consent has been obtained. It is suggested that the omission of the legislature to specify a particular format of obtaining consent opens the door to the dynamic model of consent introduced in the course of this thesis. Research or experimentation involving minors,[279] therapeutic and non-therapeutic, is briefly dealt with by sections 71(2) and 71(3). According to section 71(2), a minor may only partake in research or experimentation for therapeutic purposes where it is in the best interests of the minor,[280] in the manner and under the conditions which may have been prescribed,[281] with consent of the parent or guardian of the minor[282] and the consent of the minor themselves in circumstances where the minor is capable of understanding.[283] Non-therapeutic research or experimentation is dealt with in section 71(3) which states the same requirements but has the additional and stricter requirement of ministerial consent in terms of section 71(3)(a)(ii).[284] Some criticism has been levelled at section 71 due to the amount of power the Minister may exercise in terms of the NHA.[285] Although this is a valid concern, it is recommended that section 71(3)(b) should rather be interpreted as a protective provision which prevents a minor from being subjected to research or experimentation unnecessarily. The Minister may withhold consent for non-therapeutic research or experimentation, therefore making any continued research or experimentation unlawful, in the following circumstances:[286]

(i) Research or experimentation with adult participants may just as easily achieve the research objects;
(ii) The research or experimentation is unlikely to significantly benefit or improve understanding of the condition, disease or disorder;

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[278] As proclaimed in the Government Gazette No.35081 of 27 February 2012.
[279] The Act uses the terms "minor" and "child" interchangeably. This is problematic as no definitions for these terms are provided for by the Act. These terms are defined differently in various pieces of South African legislation. The Children's Act offers the following definition: "a person under the age of 18 years."
[280] Section 71(2)(a) of the NHA.
[281] Section 71(2)(b) of the NHA.
[282] Section 71(2(c) of the NHA.
[283] Section 71(2)(d) of the NHA. It is nowhere specified what the minor must understand. This is an issue which will require further attention as lawful consent requires that the person giving consent must possess capacity; must give consent voluntarily; must have knowledge and appreciation of what is being consented to; and there must be acquiescence on the part of the patient. See in general, Nienaber A (2013) "Consent to research by mentally ill children and adolescents: The implications of Chapter 9 of the National Health Act" *South African Journal of Psychiatry* 19(1): 20-22.
[284] *Ibid*.
[285] Unfortunately, the NHA does not allow minors to autonomously participate in therapeutic and non-therapeutic research. Furthermore, ministerial and parental consent is mandated for non-therapeutic research. This is short-sighted, conservative and potentially in conflict with the interests of the minor. An example of this conflict could be where research is done regarding child abuse or teenage pregnancy. The NHA does, however, also have some positive points. Section 71(1) which deals with human research echoes section 12(2) of the Constitution in that it reaffirms the right to bodily and psychological integrity, specifically the right to security in and control over one's body and not to be subjected to medical or scientific research without consenting thereto. See Gray, Gengiah *et al.* (2005) 20.
[286] Section 71(3)(b)(i)-(v) of the NHA.

(iii) In situations where the consent which was given by the minor, the parents or guardian of the minor are *contra boni mores*;
(iv) The research or experimentation could pose a serious risk to the health of the minor; and
(v) Where there does exist some risk to the health and well-being of the minor which outweighs the potential benefit of such research or experimentation.

As will be shown below, the separation of therapeutic and non-therapeutic research is regarded as a weakness of section 71. Also, in the previous chapter it was argued that the distinction between therapeutic and non-therapeutic research is blurred, especially so in context of stem cell related activities.[287] This argument is reiterated here and it is suggested that in the context of stem cells, therapeutic and non-therapeutic research is one and the same.

Human research and experimentation are controversial topics and it is clear that the provisions provided by section 71, although a much needed point of departure, are not sufficient in themselves to regulate this matter. At this juncture, it is interesting to note some of section 71's strengths and weaknesses as identified by scholars as it illustrates the above statement that section 71 is a needed point of departure but is in itself not sufficient regulation of human subject research and experimentation. Strode *et al.*[288] state that section 71 contains the strengths of establishing a platform which enables the Minister to develop wide-ranging human research participant protection regulations; it supplements and strengthens the existing and general consent laws; it introduces the concept of the "best interests of the child" in instances of research for therapeutic purposes[289] and lastly it creates additional procedural safeguards for children participating in research for non-therapeutic purposes.[290] However, the weaknesses or limitations of section 71 are that it neglects to provide an age for independent consent to medical research; consent is posed as the primary protective measure while ignoring dignity and confidentiality for example; it may be contrary to existing or draft consent legislation and ethical guidelines; the much contested distinction between therapeutic and non-therapeutic interventions is retained;[291] the NHA fails to describe the process of obtaining Ministerial consent for non-therapeutic research and interpretation is impeded by poor drafting and inconsistencies.[292]

As was mentioned above, human subject research is greatly controversial and in need of proper regulation. Taking the above strengths and weaknesses into account, it becomes clear why it is

[287] See chapter 4 paragraph 4 *supra*.
[288] Strode A, Grant C, Slack C & Mushariwa M (2005) "How well does South Africa's National Health Act regulate research involving children?" *South African Medical Journal* 95(4): 266.
[289] Section 71(2) of the NHA.
[290] Section 71(3)(a)(ii) of the NHA.
[291] See chapter 4 paragraph 4 *supra*.
[292] Strode, Grant *et al.* (2005) 266-267.

necessary to build on the framework established by the NHA in general and section 71 in particular by way of Regulations. The Regulations relating to Research on Human Subjects therefore offer valuable supplementation to section 71 and are discussed in the course of this chapter.[293] Section 71 and the supplementary Regulations are, however, of immense importance in context of this thesis as it is argued throughout that stem cell therapy is tantamount to research involving human subjects and as such these provisions will play an important role in any regulatory process.

4.3.3 Section 72: The National Health Research Ethics Council

Section 72 establishes the National Health Research Ethics Council[294] which will be composed of members appointed by the Minister.[295] The Ethics Council is tasked with the following duties:[296]

(a) The determination of guidelines for the functioning of health research committees;
(b) The registration and auditing of health research ethics committees;
(c) Setting of norms and standards whereby research on humans and animals are to be conducted. The norms and standards of clinical trials[297] must also be established by the Ethics Council;[298]
(d) The adjudication of complaints regarding the functioning of health research ethics committees;
(e) Violations or potential violations of ethical or professional rules must be referred to the relevant statutory health professions council;
(f) Instituting any necessary prescribed disciplinary action; and
(g) Advising the national department and the provincial departments on ethical issues regarding research.

As with the Committee established by section 69, which is supplemented by the Research Committee Regulations, section 72 is supplemented by the Regulations relating to the National Health Research Ethics Council.[299]

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[293] See paragraph 5.5 *infra* for this discussion.
[294] Hereafter referred to as the Ethics Council.
[295] According to sections 72(2)-(5) the Minister must appoint no more than 15 persons. This is done only after the Minister has consulted the National Health Council and interested parties have made nominations of persons on invitation of the Minister. A list of such nominees must be published in the Government Gazette. A person may then be appointed for a term of three years which may be renewed. A member may resign or be requested to resign by the Minister for a good cause and the vacancy may then be filled for the remainder of their term.
[296] Section 72(6)(a)-(g).
[297] Clinical trials means "a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medical method or treatment" according to section 72(7) of the NHA. "Efficacy" is the ability of an intervention or treatment to produce the desired beneficial effect. Additionally, it may be stated that this should occur in expert hands and under ideal circumstances.
[298] "Clinical trials" is defined in section 72(7). See paragraph 4.3.3 *supra*.

4.3.4 Section 73: Health Research Ethics Committees

Section 73 is closely related to section 72 as it elaborates to some extent on the provisions of section 72. It may be said that section 73, in a manner, illustrates the importance of section 72 in that it requires every health agency, institution or establishment at which research is conducted to establish or have access to an ethics committee registered with the Ethics Council. These research ethic committees must review research proposals and protocols[300] in order to ensure that any proposed research will promote health; contribute to the prevention of communicable and non-communicable diseases or disability and result in cures for diseases.[301] Where the research proposal and protocol meet all ethical standard requirements as set by the research ethics committee, the committee must approve of the research. [302]

4.3.5 Sections 74, 75 And 76: National Health Information Systems

Sections 74, 75 and 76 deal with the establishment of a National Health Information Systems (NHIS).[303] A NHIS plays an important role in ensuring that reliable and timely information on health is available for operational and strategic decision making. A NHIS may be seen as an essential component in sustained health development and improved health outcomes as it strengthens the health system of a country as a whole.[304] For the purpose of this thesis, these provisions are of less importance but must still be briefly discussed as they facilitate a global understanding of the NHA and Chapter 9 of the Act.[305]

The Department of Health must facilitate and coordinate the establishment, implementation and maintenance of health information systems; on national, provincial and local levels; by the provincial departments, district health councils, the municipalities and by the private health

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[299] See paragraph 5.3 *infra* for more on these Regulations.
[300] The NHA requires all protocol to be approved by a research ethics committee prior to research commencing. Health research ethics committees use a protocol review procedure which ensures that ethical standards are met and to consider all questions regarding research. See HPCSA (2008) *Booklet 6*: 1.
[301] Section 73(2)(a) of the NHA.
[302] Section 73(2)(b) of the NHA.
[303] Hereafter referred to as HNIS.
[304] Stansfield S, Orobaton N, Lubinski D, Uggowitzer S & Mwanyika H (2009) "The case for a National Health Information System architecture: A missing link to guiding national development and implementation" *Social Science & Medicine*: 1.
[305] For more on the National Health Information System (NHIS) see Department of Health (1997) "Towards a National Health Information System for South Africa: Report of a seminar held at Broederstroom" *White Paper for the Transformation of the Health System in South Africa* available online at http://www.hst.org.za/publications/towards-national-health-information-system-south-africa-report-seminar-held-broederstro accessed 6/4/2012. See also Muschel J (1999) "District health information systems" *South African Health Review*: 147-160.

sector.[306] Categories of data for submission and collection as well as the person responsible therefore, the manner whereby and the format thereof may be prescribed by the Minister.[307]

Provincial systems are the responsibility of the relevant member of the Executive Council as the responsible MEC must create a committee to establish, facilitate and implement the health system at a provincial and local level.[308] District health councils and every municipality providing health services will then also be responsible for the establishment and maintenance of an information system as part of the NHIS.[309]

The analysis and discussion of the relevant provisions of the NHA now draw to a close. In the course of this discussion, numerous references were made to certain sections being supplemented by Regulations. In order to fully grasp the legislative environment of stem cell related activities in South Africa, it therefore becomes essential also to evaluate these Regulations. The following section of this chapter thus offers such an evaluation and discussion.

5 REGULATIONS

Regulations as subordinate or delegated legislation play an important role in the creation of a legislative or regulatory environment, as an Act of Parliament and other forms of original legislation are not capable of providing for each and every aspect in need of regulation: not in an ever-changing world and society and especially not in a fast-developing field of science such as stem cells. Original legislation is thus drafted in broad strokes and subordinate legislation is then required to provide for the details.[310] One could say that Regulations therefore "flesh out" the skeleton of legislation which is essential in instances of framework legislation such as the NHA.[311] Since the Act as original legislation is lacking as the primary regulatory tool of stem cells and related matters,[312] the Regulations form a very important part of the regulatory framework. Regulations may be drafted in a manner which is able to keep up with the fast development of this science and may further inform policy documents and decision making. The Regulations also provide insight into interpreting and understanding the content of the Act. It falls outside the scope of this thesis to discuss all of the Regulations which have been made in terms of the

[306] Section 74(1) of the NHA.
[307] Section 74(2) of the NHA.
[308] Section 75 of the NHA.
[309] Section 76 of the NHA.
[310] Hahlo HR & Kahn E (1973) *The South African legal system and its background*: 163. See also Botha C (2005) *Wetsuitleg: 'n Inleiding vir studente*: 16-18.
[311] See paragraph 2 *supra*.
[312] This is due to the fact that Chapter 8 of the NHA is slow in development and in content, is riddled with *lacuna* and there is little or no understanding of the science. See Prinsen (2013) 522-532 for a detailed discussion of these short comings.

NHA. However, what follows is a discussion of the various relevant Regulations which have been made in terms of the NHA and have some bearing on the issue addressed in this thesis.[313] It is interesting to note the process of "fine tuning" and perfecting which is illustrated by the changes in the Regulations through the years. Special attention is given to the provisions dealing with consent, stem cells, treatment, research and human subject experimentation. The Regulations have been put together into ten groups according to the commonality of the subject matter of the Regulations. This is also done to illustrate the constant "fine tuning" of the regulatory framework.

5.1 REGULATIONS REGARDING USE OF BIOLOGICAL MATERIAL

The first group of Regulations to be discussed share the common subject of the use of human material. The Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics;[314] the 2011 Regulations relating to the Use of Human Biological Material[315] and the 2012 Regulations relating to the Use of Human Biological Material[316] will therefore be discussed here.

The 2007 Regulations regarding Use supplemented the NHA from the "get go" as it provided for valuable definitions of terms not previously defined in the NHA. The definition of "informed consent" is obviously of importance to this study and should be taken note of. The Regulations provided for the following 21 new definitions:[317]

1. Biological material: "any material from a human being including blood, cells, tissue, DNA, RNA, polar bodies, blastomeres, embryos and gametes;"
2. Blastocyst: "a pre-implantation embryo consisting of an outer layer, which forms the placenta and a 30-200-cell inner cell mass, which develops into the fetus;"[318]
3. Blastomere: "also called a 'blastocyte' means an undifferentiated embryonic cell, derived from a blastocyst;"

[313] In accordance to sections 68 and 90 of the NHA.
[314] Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics of 5 January 2007. Hereafter referred to as the 2007 Regulations regarding Use.
[315] Regulations relating to the Use of Human Biological Material in of 1 April 2011. Hereafter referred to as the 2011 Use of Human Biological Material Regulations.
[316] Regulations relating to the Use of Human Biological Material of 2 March 2012. Hereafter referred to as the 2012 Use of Human Biological Material Regulations.
[317] Regulation 1 of the 2007 Regulations regarding Use.
[318] See chapter 2 *supra* for the medical definition of a blastocyst.

4. Cell: "the basic structural and functional unit in people and all living things. Each cell is a small container of chemical and water wrapped in a membrane;"[319]
5. Chromosome: "a thread-like structure made up of DNA found in the nucleus of all cells with the nuclei of human cells normally contain[ing] 46 chromosomes, arranged in 23 pairs;"
6. Cultured cells: "cells that have been grown outside the body;"[320]
7. Differentiation: "the process whereby an embryonic cell becomes specialised;"
8. DNA: "the abbreviation for deoxyribonucleic acid, which is a nucleic acid composed of building blocks called nucleotides;"
9. Embryonic stem cell: "any cell from the 30-200 inner cell mass of the blastocyst;"
10. Embryonic tissue: "tissue from an embryo;"
11. Export: "export from South Africa by any means;"
12. Fetal tissue: "tissue from a fetus;"
13. Fetus:[321] "a human offspring from eight weeks after conception until birth;"
14. Import: "import into South Africa by any means;"
15. *In vitro* fertilisation: "the process whereby an ovum (egg) is fertilised with a sperm outside the body. Embryos thus produced could be introduced into the womb of a woman for reproductive purposes or by permission; excess embryos may be used to derive embryonic stem cells;"
16. Informed consent: "an agreement by which a participant, donor or health care user voluntarily confirms his or her willingness to participate in research, donation or treatment, after understanding all aspects of such research, donation or treatment that are relevant to his or her decision;"[322]
17. Medical practitioner: "a person registered with the Health Professions Council of South Africa;"
18. Medical scientist: "a person registered as a medical scientist with the Health Professions Council of South Africa;"
19. Prescribed institution: "an institution such as university, private laboratory or assisted reproductive facility, accredited by the South African Accreditation System (SANAS) to perform stem cell research and related technologies;"[323]

[319] This definition was not obtained from as reliable a source as a person would expect from the legislator to make use of. It is, in fact, available online. See ExpertGlossary (2012) "Cell" available online at http://www.expertglossary.com/definition/cell accessed 21/8/2012.
[320] See chapter 2 paragraph 3.5 *supra* for a discussion of the process of cell culturing.
[321] The Regulations make use of the spelling "foetus" rather than "fetus."
[322] Here, once again, the importance of information is illustrated.
[323] It is suggested that this is a clarifying definition and elaborates on the definition of "authorised institution" as provided for by section 1 of the NHA.

20. Primordial germ cell: "stem cells found in the gonad of a fetus capable of becoming ova or sperm;" and
21. Stem cell: "any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, hematopoietic cell[324] or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell."[325]

The 2007 Regulations regarding Use supplement section 56 of the NHA and are divided into three chapters. The first chapter deals with harvesting and use of human material.[326] Only a registered medical practitioner or dentist[327] may harvest human biological material for genetic testing, health research or therapeutic purposes and such material may only be harvested in a hospital or authorised or prescribed institution or at a research institution in the case of ancestry analysis.[328] The removal or withdrawal of biological material is then subject to the condition of informed consent being obtained for the removal or withdrawal.[329]

The person from whom the material is to be removed must provide informed consent. Where a person is younger than 18 years of age the position is slightly more complex. If the person is older than 12 years of age and has the mental capacity and level of maturity to understand the benefits, risks and social or other implications, the minor may provide consent.[330] Where the minor is younger than 12 years of age or does not have the capacity to understand or the level of maturity, a parent, guardian or caregiver must provide consent.[331] The head of the health establishment or the Minister may consent in certain circumstances.[332]

[324]This is spelt as "haemopoietic" in the Regulations.
[325] This is the first legal definition provided for stem cells. It is suggested that "one of the body's master cells with the ability to become any of the body's over 200 cell types" may be a more user-friendly definition. See chapter 2 *supra* above for a medical definition of stem cells.
[326] This material includes: DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies intended for genetic testing, health research and therapeutics.
[327] Hereafter the term "registered person" will be used and is meant as including both a registered medical practitioner as well as a registered dentist. "Registered" means that the person is registered with the Health Professions Council of South Africa. Specific reference will be made to an additional person where the regulations provide therefore.
[328] Regulation 2 of the 2007 Regulations regarding Use. It should be noted that no genetic research may be carried out unless it has been approved by a registered health research ethics committee as referred to in section 73(1) of the NHA according to regulation 3(2) of the 2007 Regulations regarding Use.
[329] Regulation 3 of the 2007 Regulations regarding Use.
[330] Regulation 3(b)(i) of the 2007 Regulations regarding Use.
[331] Regulation 3(b)(ii) of the 2007 Regulations regarding Use.
[332] According to regulations 3(b)(iii) and (iv) of the 2007 Regulations regarding Use, the head of a health establishment may consent in the case of an emergency and the Minister may consent where the parent, guardian or caregiver (*aa*) unreasonably refuse to give consent, (*bb*) are incapable of consenting, (*cc*) are not readily traceable or (*dd*) are deceased.

Where a person is mentally ill[333] they may consent if they are able to do so. Where they are unable a curator, spouse, next-of-kin, adult child or sibling may consent. In the case of an emergency, the head of the heath establishment may consent.[334]

Chapter 1 of the Regulations regarding Use furthermore provides a list of purposes for which certain materials may be used.[335] These purposes include *inter alia* DNA, RNA and chromosome-based genetic testing;[336] health research as referred to in section 69(3) of the NHA and studies of archaeological, medical or heritage value.[337] All the information gathered regarding human biological material must then be entered into a central data bank which must be established by the Director General.[338]

Chapter 2 provides for regulatory measures concerning research relating to the use of gametes, embryos, fetuses, cultured cells and stem cells. This chapter deals *inter alia* with the contentious and important aspect of ownership of human material, specifically stem cells, and distinguishes between two different scenarios. Firstly, it provides for ownership matters prior to harvesting stem cells and states that the ownership of excess *in vitro* fertilised embryos, umbilical cord blood for the purpose of research and aborted fetal tissue vests in the donor thereof. Ownership, however, vests in the parents of a child where stem cells are derived from umbilical cord blood for the treatment of a child.[339] The second scenario deals with ownership after consent has been given by a donor to harvest stem cells. Here, ownership vests in the State[340] except where umbilical cord blood is used to derive stem cells from for the treatment of a child in which case the parents retain ownership.[341] It almost appears that consent transfer's ownership from the donor to the State.

As is seen from the above, consent plays an important role in research relating to human material and specifically to stem cells. Not only does it seemingly vest ownership of stem cells in

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[333] As defined in section 1 of the Mental Health Care Act, Act 17 of 2002.
[334] Regulation 3(c) of the 2007 Regulations regarding Use.
[335] These materials are: human DNA, RNA, cultured cells, blastomeres including single cells from a developing blastocysts, amniocytes, polar bodies, stem cells and small tissue biopsies. See also the discussion of the Regulations relating to the Use of Human Biological Material in paragraph 5.1 *infra*.
[336] This includes: (i) diagnostic tests; (ii) testing for genetic carrier status; (iii) antenatal testing; (iv) voluntary presymptomatic, predictive or susceptibility testing, screening tests, drug response or toxicity tests, identity or paternity tests; (v) test that are performed postnatally and (vi) and (vii) provide for pre-implantation tests to be carried out on a ovum.
[337] Regulation 4 of the 2007 Regulations regarding Use. This regulation deals with material withdrawn or removed from a living person. For the provisions regarding tissue removed or withdrawn from a deceased person, see regulation 6 of these Regulations.
[338] Regulation 7 of the 2007 Regulations regarding Use.
[339] Regulation 9 of the 2007 Regulations regarding Use.
[340] The State thus has ownership of the stem cells derived from excess embryos, umbilical cord blood intended for research purposes, aborted fetuses and from adult progenitor cells.
[341] See in general, Martin-Rendon E & Blake DJ (2007) "Patenting human genes and stem cells" *Recent Patents on DNA Gene Sequences* 1(1): 25-34 and Copely News Service (2006) "Does legal ownership of genes, stem cells go beyond the pale?" available online at http://www.thenhf.com/article.php?id=345 accessed 20/5/2012.

the State but it is also a prerequisite in cases where adult, fetal or umbilical cord stem cells are used for therapeutic cloning purposes;[342] in research utilizing embryonic stem cells[343] and in research using primordial germ cells.[344]

A further interesting aspect which is dealt with in this chapter of the Regulations regarding Use is that it stipulates that a person who donates, by way of removal, the various biological materials mentioned may only be reimbursed for reasonable expenses incurred by that person in order to effect the donation. Thus, a person may not "sell" biological material and the donor is removed from any trade aspect of stem cells. This further supports the notion that informed consent transfers ownership of material. Although this is in line with the ethical stance that there should be no financial incentives in donation in order to protect persons from exploitative practices, it seems exploitative nonetheless as stem cell research has definite monetary implications and gains and the beneficiaries thereof are then the stem cell institutions and hospitals, stem cell banks and the persons involved therein. It seems that those who enable this research or therapy must thus be satisfied with only the knowledge that they have contributed to the greater knowledge pool or to humanity as such. This discussion however falls outside the scope of this thesis. It is recommended that this aspect of transfer of ownership deserves further investigation and should be reconsidered as this thesis argues that a person who donates material maintains an interest in such material and should therefore still have a measure of say in the uses thereof.

Lastly, Chapter 3 of the Regulations regarding Use deals with genetic and stem cell registers, the intellectual property rights of research findings;[345] the storage and control of genetic information and offences.

The 2011 Use of Human Biological Material Regulations were a modified version of the 2007 Regulations regarding Use and further supplement section 56 of the NHA.[346] They must therefore be read together with the 2007 Regulations regarding Use, as well as section 56 of the NHA. Interestingly, in addition to new definitions, some of the definitions have been amended.[347] This means that the 2011 Use of Human Biological Material Regulations provides for a total of 16 "new" definitions. These definitions are:[348]

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[342] Regulation 10 of the 2007 Regulations regarding Use.
[343] Regulation 11 of the 2007 Regulations regarding Use.
[344] Regulation 13 of the 2007 Regulations regarding Use.
[345] Regulation 16 states that "all stem cells and information derived from their research, together with any diagnostic, prophylactic or therapeutic substances emanating from this research shall not be subject to intellectual property rights." Intellectual property rights, however, apply to other, appropriate, forms of genetic research.
[346] See paragraph 4.2.4 *supra*.
[347] The definitions as they originally appeared are provided in the footnotes *infra*.
[348] Regulation 1 of the 2011 Use of Human Biological Material Regulations.

1. Biological material: "material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor cells and small tissue biopsies;"[349]
2. Cell: "the smallest structural and functional unit of an organism, consisting of cytoplasm and a nucleus enclosed in a membrane in living things;"[350]
3. Chromosome: "a thread-like structure made up of DNA found in the nucleus of all cells;"[351]
4. DNA: "deoxyribonucleic acid, which is a nucleic acid, composed of building blocks called nucleotides;"[352]
5. Donation: "donation of human biological material for genetic testing, genetic training, genetic health research for therapeutic purposes;"
6. Donor: "a person from whose body human biological material has been removed or withdrawn for the purpose of genetic testing, genetic training, genetic health research and therapeutics;"
7. Embryonic stem cell: "any cell from the 30-200 [cell] inner cell mass of the blastocyst;"[353]
8. *In vitro* fertilisation: "the process whereby a female gamete is fertilised with a male gamete outside the body of the female person;"[354]
9. Mutation: "a permanent change and a structural alteration in the DNA;"
10. Polar bodies: "a product that is formed during the development of the female gamete (during meiosis), which contains little cytoplasm and a haploid number of chromosomes;"[355]
11. Progenitor cells: "cells which give rise to a distinct stem cell line;"
12. RNA: "ribonucleic acid molecule similar to DNA but containing ribose rather than deoxyribose;"
13. Serious genetic condition: "a condition which compromises the functional, physical or mental ability of a person and which can sometimes be lethal;" and

[349] "Any material from a human being including blood, cells, tissue, DNA, RNA, polar bodies, blastomeres, embryos and gametes."
[350] "The basic structural and functional unit in people and all living things. Each cell is a small container of chemical and water wrapped in a membrane."
[351] "A thread-like structure made up of DNA found in the nucleus of all cells with the nuclei of human cells normally contain[ing] 46 chromosomes, arranged in 23 pairs." Males carry a "xy" chromosome and females carry an "xx" chromosome.
[352] "The abbreviation for deoxyribonucleic acid, which is a nucleic acid composed of building blocks called nucleotides."
[353] "Any cell from the 30-200 inner cell mass of the blastocyst."
[354] "The process whereby an ovum (egg) is fertilised with a sperm outside the body. Embryos thus produced could be introduced into the womb of a woman for reproductive purposes or by permission; excess embryos may be used to derive embryonic stem cells."
[355] Haploid is defined as "1. having half the number of chromosomes characteristically found in the somatic (diploid) cells of an organism; typical of the gametes of a species whose union restores the diploid number or 2. an individual or cell having only one member of each pair of homologous chromosomes." See the Free Dictionary (2012) "Haploid available online at http://medical-dictionary.thefreedictionary.com/haploid accessed 28/5/2012.

14. Stem cell: "any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell."[356]

A further new definition is that of "competent person." The definition of a competent person differs from Regulation to Regulation as each deals with a different and separate aspect of stem cells and therefore different persons are competent. This should not be seen as an amendment. For the purpose of the 2011 Use of Human Biological Material Regulations, and in context of this thesis, a competent person means "appropriately trained and qualified person and- … (d) in the case of developing blastocyst, a person trained in basic or clinical embryology as well as tissue culture techniques; … (h) in the case of research, a medical technologist or scientist registered as such under the Health Professions Act 1974 (Act No. 56 of 1974)."

The 2011 Use of Human Biological Material Regulations is then, similar to the 2007 Regulations regarding Use, divided into three chapters. The first chapter is entitled "Removal of human biological material for genetic testing, genetic training, genetic research and therapeutics." The title therefore states an umbrella term, namely "biological material,"[357] rather than listing each individual material. This chapter provides for removal of human biological material;[358] consent requirements;[359] removal of biological material from deceased persons;[360] use of human biological material[361] and pre-implantation and prenatal testing for sex selection.[362]

Chapter 2 of the Use of Human Biological Material Regulations 2011 deals with research relating to the use of human biological material. It provides for therapeutic cloning using adult, fetal or

[356] "Any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, hematopoietic cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell." It is suggested that the new definition as provided for here is a better and more scientifically correct definition as it is broad enough to include adult or somatic stem cells.
[357] "Biological material" includes blastomeres but not stem cells.
[358] Regulation 2 of the 2011 Use of Human Biological Material Regulations.
[359] Contained in regulation 3 "Removal or withdrawal of human biological material from living persons" of the 2011 Use of Human Biological Material Regulations. Regulation 3 requires that prior written consent be obtained for the removal of biological material for the purposes of genetic testing, genetic training, genetic health research and therapeutics. Separate provision is made for persons younger than 18 and persons with mental illness.
[360] Regulation 4 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 6 of the 2007 Regulations regarding Use.
[361] Regulation 5 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 4 of the 2007 Regulations regarding Use. The new regulations are less detailed but contain the same provisions.
[362] Regulation 6 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 5 of the 2007 Regulations regarding Use. Sex testing is prohibited except in the case of serious sex linked or sex limited genetic conditions. For more on gender testing and the role it plays in determining sex-linked genetic diseases see, Lippman A (1991) "Prenatal genetic testing and screening: Constructing needs and reinforcing inequities" *American Journal of Law & Medicine* 17: 15; McKinnon WC, Baty BJ, Bennett RL, Magee M, Neufeld-Kaiser WA, Peters KF, Sawyer JC & Schneider KA (1997) "Predisposition genetic testing for late-onset disorders in adults: A position paper of the National Society of Genetic Counsellors" *Journal of the American Medical Association* 278(15): 1217; Wachbroit R (1987) "Making the grade: Testing for genetic disorders" *Hofstra Law Review* 16: 583; Lapham EV, Kozma C & Weiss JO (1996) "Genetic discrimination: Perspectives of consumers" *Science Genome Issue* 274(5287): 621 and World Health Organisation (2012) "Gender and genetics" available online at http://www.who.int/genomics/gender/en/index1.html accessed 28/5/2012.

umbilical cord stem cells;[363] research using embryonic stem cells;[364] research utilizing primordial germ cells[365] and for compensation in respect of removal or withdrawal of material.[366] Lastly, chapter 3 provides for human biological material registers.[367] This includes provisions regarding storage and control of the flow of genetic information[368] and offences in terms of the Regulations.[369] The provisions, except for differing terminology, remain the same in content. The 2011 Use of Human Biological Material Regulations, however, omits any regulations dealing with ownership matters.[370]

A year after the 2011 Regulations were published, another set of Regulations were published in the Government Gazette, including new Regulations relating to the Use of Human Biological. The 2012 Use of Human Biological Material Regulations provide for new and altered definitions but also omitted some definitions provided for in previous Regulations. The newly-added definitions are the following:[371]

1. Stem cell therapy: "the use of stem cells for therapeutic purposes;"
2. Transgenic cells: "cells derived for species other than human;"
3. Umbilical cord blood stem cells: "stem cells found in umbilical cord blood;" and
4. Validation: "the process of establishing documented evidence that provides a high degree of assurance that specific process [*sic*] will consistently produce the predetermined outcome."

Although not new, the definitions of "biological material" and "stem cell" as provided for in the 2012 Regulations must be noted as these definitions have been amended. The 2012 definition of biological material reads that it means "material from a human being including DNA, RNA, blastomeres, polar bodies, cultured cells, embryos, gametes, progenitor stem cells,[372] small tissue biopsies and growth factors from the same."[373] The 2012 definition of stem cell states that

[363] Regulation 7 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 11 of the 2007 Regulations regarding Use.
[364] Regulation 8 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 12 of the 2007 Regulations regarding Use.
[365] Regulation 9 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 13 of the 2007 Regulations regarding Use.
[366] Regulation 10 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 14 of the 2007 Regulations regarding Use.
[367] Regulation 11 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 15 of the 2007 Regulations regarding Use.
[368] Regulation 12 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 17 of the 2007 Regulations regarding Use.
[369] Regulation 13 of the 2011 Use of Human Biological Material Regulations. Previously provided for by regulation 18 of the 2007 Regulations regarding Use.
[370] Ownership is dealt with in regulations 9 and 10 of the 2007 Regulations regarding Use.
[371] Regulation 1 of the 2012 Use of Human Biological Material Regulations.
[372] The 2011 Use of Human Biological Material Regulations merely made mention of "progenitor cells" and not progenitor stem cells.
[373] "Growth factors" is therefore also a new addition to the definition of biological material.

it means "a cell that has both the capacity to self-renew as well as to differentiate into mature, specialised cells."

The 2012 Use of Human Biological Material Regulations are not divided into chapters as the previous Regulations were and provide largely for the same subject matter as the 2011 Use of Human Biological Material Regulations save for a few alterations in phrasing and omissions of certain provisions. Two new regulations were, however, added to the 2012 Use of Human Biological Material Regulations and will be examined in the course of this discussion. The 2012 Regulations therefore make provision for the removal of human biological material;[374] removal or withdrawal of biological samples from living persons;[375] removal of biological material from deceased persons;[376] use of human biological material;[377] pre-implantation and prenatal testing for sex selection;[378] research utilising embryonic stem cells and umbilical cord stem cells;[379] research utilising primordial germ cells;[380] stem cell therapy utilising adult, embryonic and umbilical cord blood cells;[381] use of transgenic cells for stem cell therapy;[382] compensation in respect of withdrawal of human biological material;[383] human biological material registers;[384] storage and control of flow of genetic information;[385] and offences.[386]

Two new regulations found in the 2012 Use of Human Biological Material Regulations relate to stem cell therapy which makes use of adult, embryonic and umbilical cord blood cells and the use of transgenic cells for stem cell therapy. The 2012 Regulations require that the written informed consent of the donor of the adult, embryonic or cord blood stem cells must be obtained prior to them being used in stem cell therapy.[387] In regards to the use of nonhuman

[374] Regulation 2 of the 2012 Use of Human Biological Material Regulations.
[375] Regulation 3 of the 2012 Use of Human Biological Material Regulations. Previously the wording read "material" and not "samples."
[376] Regulation 4 of the 2012 Use of Human Biological Material Regulations.
[377] Regulation 5 of the 2012 Use of Human Biological Material Regulations.
[378] Regulation 6 of the 2012 Use of Human Biological Material Regulations.
[379] Regulation 7 of the 2012 Use of Human Biological Material Regulations. Previously provided for by regulation 8 of the 2011 Use of Human Biological Material Regulations which only provided for embryonic stem cells and no mention was made of umbilical cord blood stem cells. Also, ministerial approval and an undertaking by the competent person to document the research are no longer required as previously provided for by regulation 8 of the 2011 Use of Human Biological Material Regulations and have been omitted.
[380] Regulation 8 of the 2012 Use of Human Biological Material Regulations. It is interesting to note that here too the requirement of Ministerial approval and the undertaking by the competent person are no longer required as previously provided for by regulation 9 of the 2011 Use of Human Biological Material Regulations and have been omitted.
[381] Regulation 9 of the 2012 Use of Human Biological Material Regulations. This regulation is new and is discussed in more detail in the course of this chapter.
[382] Regulation 10 of the 2012 Use of Human Biological Material Regulations. This regulation is also new and is discussed further in the course of this chapter.
[383] Regulation 11 of the 2012 Use of Human Biological Material Regulations.
[384] Regulation 12 of the 2012 Use of Human Biological Material Regulations. Previously provided for by regulation 11 of the 2011 Use of Biological Material Regulations which stated that only the Ethics Council would have access to such registers. This is hugely alarming in context of privacy concerns.
[385] Regulation 13 of the 2012 Use of Human Biological Material Regulations.
[386] Regulation 14 of the 2012 Use of Human Biological Material Regulations.
[387] Regulation 9 of the 2012 Use of Human Biological Material Regulations.

transgenic cells in stem cell therapy, the 2012 Use of Human Biological Material Regulations states that such cells may only be used in human stem cell therapy where the clinical validity and utility of these cells have been demonstrated and prior permission has been obtained from the Research Ethics Council.[388] It is also noteworthy that the 2012 Regulations make no mention of therapeutic cloning which was previously expressly provided.[389]

5.2 REGULATIONS REGARDING ARTIFICIAL FERTILISATION

The second group of Regulations to be discussed relates to Artificial Fertilisation. It must be mentioned that the relevance of these Regulations in context of stem cell research and therapy is declining due to the fact that the use of embryonic stem cells is being phased out and replaced by new technologies such as induced pluripotent stem cells which utilize adult stem cells. Keeping this in mind, the Regulations to be discussed here are the Regulations regarding Artificial Fertilisation and Related Matters;[390] the 2011 Regulations relating to Artificial Fertilisation of Persons,[391] the 2012 Regulations relating to Artificial Fertilisation of Persons[392] and the 2016 Regulations relating to Artificial fertilisation of Persons.[393]

The 2007 Artificial Fertilisation Regulations are of some importance but only to the extent that embryonic stem cells are still relevant. The definitions which must be taken note of are as follows:[394]

1. Artificial fertilisation: "conception resulting from artificial insemination or *in vitro* fertilisation of a woman;"
2. Artificial insemination: "the placing of male gametes (sperm) into the female reproductive tract by means other than copulation;"
3. Competent person: "for an artificial fertilisation program means a medical practitioner, clinical technologist, medical technologist or medical scientist registered with the Health Professions Council of South Africa (HPCSA) with expertise as follows-(a) a gynaecologist with training in reproductive endocrinology, particularly in the use of ovulation-inducing

[388] Regulation 10 of the 2012 Use of Human Biological Material Regulations. For more on the Council see paragraph 5.3 *infra*.
[389] Regulation 7 of the 2011 Use of Human Biological Material Regulations.
[390] Regulations regarding Artificial Fertilisation and Related Matters of 5 January 2007. Hereafter referred to as the 2007 Artificial Fertilisation Regulations.
[391] Regulations relating to Artificial Fertilisation of Persons of 1 April 2011. Hereafter referred to as the 2011 Artificial Fertilisation of Persons Regulations.
[392] Regulations relating to Artificial Fertilisation of Persons of 2 March 2012. Hereafter referred to as the 2012 Artificial Fertilisation of Persons Regulations.
[393] Regulations relating to Artificial Fertilisation of Persons of 30 September 2016. Hereafter referred to as the 2016 Artificial Fertilisation of Persons Regulations.
[394] Regulation 1 of the 2007 Artificial Fertilisation Regulations.

agents and the hormonal control of the menstrual cycle; (b) a gynaecologist with training in pelvic reparative (infertility) surgery and laparoscopic and ultrasound-guided oocyte retrieval techniques; (c) an ultrasonographer with specialised training in gynaecologic sonography who provides the monitoring of follicular development; (d) an expert in male reproduction (andrology) with special training in semenology; (e) an expert in male reproductive surgery; (f) an expert in the organization and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques; (g) an expert in gamete and embryo cryopreservation techniques; or (h) an expert in gamete biology and experience in microoperative techniques."

4. Embryo transfer: "the placing of the embryo into the uterus or fallopian tube of the recipient and zygote transfer has a corresponding meaning;"
5. *In vitro* fertilisation: "the process of fertilising an ovum (egg) with a male sperm outside the body of a recipient;" and
6. Recipient: "a female person in whose reproductive organs a male gamete or gametes are to be introduced by other than natural means; or in whose uterus/womb or fallopian tube a zygote/zygotes or embryo/embryos is/are to be placed for the purpose of human reproduction."

The 2007 Artificial Fertilisation Regulations is then divided into three chapters. The first regulates matters concerning the removal or withdrawal of gametes and related matters. It should be noted that the 2007 Artificial Fertilisation Regulations only apply to the withdrawal of gametes from living persons[395] and such removal may only be effected by a competent person.[396] Removal is then also subject to informed consent of the donor to a physical examination and questioning by a competent person,[397] to the removal or withdrawal[398] and to the submission of certain data to certain persons.[399] Additionally, matters concerning the establishment of a central data bank;[400] restriction on donations;[401] gamete donor files; availability of information and the destruction of gametes[402] are provided for in Chapter 1 of the 2007 Artificial Fertilisation Regulations. The provisions affecting destruction are relevant to stem cell technologies as will be explained in the following paragraph.

Chapter 2 contains provisions regarding artificial fertilisation, embryo transfer and related matters. According to the 2007 Artificial Fertilisation Regulations a competent person must

[395] Regulation 2 of the 2007 Artificial Fertilisation Regulations.
[396] Regulation 3(1) of the 2007 Artificial Fertilisation Regulations.
[397] Regulation 7(e)(i) of the 2007 Artificial Fertilisation Regulations.
[398] Regulation 7(e)(ii) of the 2007 Artificial Fertilisation Regulations.
[399] Regulation 7(e)(iii)-(v) of the 2007 Artificial Fertilisation Regulations.
[400] Regulation 5 of the 2007 Artificial Fertilisation Regulations.
[401] Regulation 6 of the 2007 Artificial Fertilisation Regulations.
[402] Regulation 8 of the 2007 Artificial Fertilisation Regulations.

destroy a zygote or embryo which they have in storage unless the Minister consents thereto that it is used for a purpose other than embryo transfer.[403] This means that where excess fertilised embryos exist, which will not be used in fertilizing the donor of the embryo and no other recipient will receive the donation, such an embryo may, with Ministerial permission be used to derive embryonic stem cells. Requisites for artificial fertilisation and embryo transfer,[404] recipient files and the availability of information[405] and registers containing the names of competent persons and authorised institutions as well as deletions and provisional deletions are further provided for by chapter 2.[406] Chapter 3 deals with the remaining general provisions.[407]

The 2011 Artificial Fertilisation of Persons Regulations is a modified version of the Artificial Fertilisation Regulations of 2007. Apart from the addition of a few new definitions and the amendment of certain others, this Regulation does not differ greatly from the original. In fact, this Regulation at most rephrases certain regulations and rearranges the order of the provisions. For this reason, it is also only relevant to this thesis in as far as it concerns embryonic stem cells derived from excess embryos originally fertilised in order to fertilise a person for reproductive purposes. The definitions are provided here:[408]

1. Artificial fertilisation: "the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction and includes artificial insemination, *in vitro* fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection;"[409]
2. Central data bank: "an electronic bank into which all information regarding artificial fertilisation treatment outcome is stored and managed;"
3. Competent person: "in relation to artificial fertilisation means a person registered as such in terms of the Health Professions Act, 1974 (Act No. 56 of 1974); who is-(a) a medical practitioner specialising in gynaecology with training in reproductive medicine; (b) a

[403] Regulation 10(4)(c)(ii)(*bb*) of the 2007 Artificial Fertilisation Regulations.
[404] Regulation 11 of the 2007 Artificial Fertilisation Regulations.
[405] Regulation 13 of the 2007 Artificial Fertilisation Regulations.
[406] Regulation 14 of the 2007 Artificial Fertilisation Regulations.
[407] Regulations 15-22 therefore provide for reporting of births as well as disorders and mental illness; the ownership of gametes, zygotes and embryos; prohibition of disclosure of certain facts; appeals; offences and penalties; delegation of powers and savings and withdrawals.
[408] Regulation 1 of the 2011 Artificial Fertilisation of Persons Regulations. The definitions as provided for by the Artificial Fertilisation Regulations of 2007 are provided in the footnotes *infra* where alterations have been made.
[409] "Conception resulting from artificial insemination or *in vitro* fertilisation of a woman."

medical scientist, medical technologist, clinical technologist, with training in reproductive biology and related laboratory procedures;"[410]

4. Freezing or cryopreservation: "freezing or cryopreserving genetic material including ova, sperm, embryos, ovarian tissue or stem cells by an authorised institution;"
5. *In vitro* fertilisation: "the process of spontaneous fertilisation of an ovum with a male sperm outside the body in an authorised institution;"
6. Oocyte: "the female gamete;"[411]
7. Sperm: "the male gamete;" and
8. Surrogate: "a voluntary recipient of an embryo who will carry such embryo to birth for contractual parents."

The 2012 Artificial Fertilisation of Persons Regulations, are very similar to the 2011 Regulations and also only contain minor amendments and additions of a few words. These minor alterations will be discussed very briefly. The 2012 Artificial Fertilisation of Persons Regulations does, however, provide for one new definition, namely that of "freezing or cryopreservation." In terms of regulation 1 of the 2012 Regulations this may be understood as "freezing or cryopreserving genetic material including ova, sperm, embryos, ovarian tissue or stem cells by an authorised institution."

The division of the regulations into chapters as was done in the 2011 Regulations was removed in the 2012 Artificial Fertilisation of Persons Regulations. As was mentioned, only minor amendments were made in the 2012 Regulations which will be mentioned here briefly.

According to regulation 3 of the 2012 Artificial Fertilisation of Persons Regulations, no person other than a competent person may remove or withdraw a gamete from a donor for the purpose of artificial fertilisation. Once a gamete has been removed by such a person it must be stored in a frozen state or cryopreserved.[412] A new regulation was added to the 2012 Regulations relating to pre-implantation and prenatal testing for sex selection.[413] The prohibition of such practices is similarly provided for in the Regulations relating to Use of Human Biological Material 2011 and

[410] "For an artificial fertilisation program means a medical practitioner, clinical technologist, medical technologist or medical scientist registered with the Health Professions Council of South Africa (HPCSA) with expertise as follows - (a) a gynaecologist with training in reproductive endocrinology, particularly in the use of ovulation-inducing agents and the hormonal control of the menstrual cycle; (b) a gynaecologist with training in pelvic reparative (infertility) surgery and laparoscopic and ultrasound-guided oocyte retrieval techniques; (c) an ultrasonographer with specialised training in gynaecologic sonography who provides the monitoring of follicular development; (d) an expert in male reproduction (andrology) with special training in semenology; (e) an expert in male reproductive surgery; (f) an expert in the organization and maintenance of a basic or clinical embryology laboratory as well as tissue culture techniques; (g) an expert in gamete and embryo cryopreservation techniques; or (h) an expert in gamete biology and experience in microoperative techniques."
[411] "The process of fertilising an ovum (egg) with a male sperm outside the body of a recipient."
[412] Previously provided for by regulation 3 of the 2011 Artificial Fertilisation of Persons Regulations which only made mention of storing the gamete in a frozen state.
[413] Regulation 13 of the 2012 Artificial Fertilisation of Persons Regulations.

2012 as previously discussed.[414] The last new addition to the 2012 Artificial Fertilisation of Persons Regulations is found in regulation 19 which prohibits the disclosure of certain facts. Here, the disclosure of the identity of a donor of gametes is prohibited except where such disclosure is mandated by law or a court order to the effect.[415] As was mentioned previously, the relevance of the Artificial Fertilisation regulations will become less as stem cell science moves away from the use of embryonic and related materials towards adult and induced stem cells.

The 2016 Regulations did not bring about any significant provisions and contributes mostly in providing for altered definitions, which is indicative of a process of fine-tuning legislative documents. The definitions for "artificial insemination," "cell," "central data bank," "competent person," and "deceased" were all moderately changed and a new definition for database was added to the Regulations. It may, with a slight sigh of relief, be noted that the new definition for "cell" no longer refers to a cell as being a small "container of chemical [*sic*] and water," and illustrates somewhat more scientifically found drafting on the legislature's side. On the other hand, however, aspects of the drafting style and structuring of the 2016 Regulations hark back to the earlier Regulations.[416] This back-and-forth method of drafting is unsatisfactory and confusing and will have to be eliminated in future.

5.3 REGULATIONS RELATING TO THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

The following is a brief discussion of the Regulations relating to the National Health Research Ethics Council[417] and the Regulations relating to the National Health Research Ethics Council.[418] As is the case with the Research Committee Regulations, these Regulations will not be discussed in fine detail and should simply be taken note of as they are relevant but not of great importance to this thesis.

The 2007 Ethics Council Regulations supplement section 72 of the NHA. The main role of these Regulations is providing for detailed provisions on the functioning of the Ethics Council.[419] The

[414] See paragraph 5.1 *supra*.
[415] Previously provided for by regulation 18 of the 2011 Artificial Fertilisation of Persons Regulations which made no provision for any exceptions to this prohibition.
[416] The 2016 Regulations, for example, contain a heading for chapter 3 but no other earlier chapters are distinguished in the Regulation itself. Chapter 3 thus seems to come from nowhere. The 2007 and 2011 Artificial Fertilisation Regulations, however, were divided into chapters.
[417] Regulations relating to the National Health Research Ethics Council of 23 February 2007. Hereafter referred to as the 2007 Ethics Council Regulations.
[418] Regulations relating to the National Health Research Ethics Council of 23 September 2010. Hereafter referred to as the 2010 Ethics Council Regulations.
[419] "Council" is defined as "the National Health Research Ethics Council established in terms of section 72(1) of the Act" according to regulation 1 of the 2007 Ethics Council Regulations.

2007 Ethics Council Regulations therefore determine the constitution of the Ethics Council;[420] the powers of the Council;[421] matters concerning the members such as the nomination and appointment of members[422] as well as their remuneration.[423] Also, the duties of the chairperson[424] and the secretariat[425] are determined. The 2007 Ethics Council Regulations provide for council meetings[426] and the required quorum and decision making procedure to be followed;[427] the procedure to follow where an appeal is brought against a decision of the Ethics Council[428] and lastly offences and penalties are provided for.[429]

The 2010 Ethics Council Regulations, in a manner of speaking, reordered the 2007 Regulations. Although no major amendments were brought about by these Regulations, it is still of some importance to discuss them as the Council will ultimately have some input into any proposed stem cell related research and therapy.[430] The 2010 Ethics Council Regulations provide for a definition not previously given namely "animal research." According to regulation 1 of the 2010 Ethics Council Regulations this means "the conducting of research on animals for human health research benefit."[431]

The 2010 Ethics Council Regulations then further provides for the constitution of the council;[432] nomination and appointment of Council members;[433] appointment of the chairperson and the vice-chairperson;[434] council meetings;[435] the quorum, procedure and decision making at

[420] Regulation 2 of the 2007 Ethics Council Regulations.
[421] Regulation 3 of the 2007 Ethics Council Regulations. The Council may, in order to perform their functions as stipulated in section 72(6) of the NHA, conduct inspections to ensure that there is compliance with council directives and may further instruct any person to modify protocols or cease research which is in contravention to the directives of the Council. "Council" is defined as "the National Health Research Ethics Council established in terms of section 72(1) of the Act" according to regulation 1 of the 2007 Ethics Council Regulations.
[422] Regulation 4 of the 2007 Ethics Council Regulations.
[423] Regulation 10 of the 2007 Ethics Council Regulations.
[424] Regulation 5 of the 2007 Ethics Council Regulations. The chairperson is the chairperson of the Council.
[425] Regulation 11 of the 2007 Ethics Council Regulations. The secretariat is the directorate who is responsible for research in the National Department as defined by regulation 1.
[426] Regulation 6 of the 2007 Ethics Council Regulations.
[427] Regulation 7 of the 2007 Ethics Council Regulations.
[428] Regulation 8 of the 2007 Ethics Council Regulations.
[429] Regulation 9 of the 2007 Ethics Council Regulations.
[430] Where new regulations are provided for it is, however, indicated in the footnotes.
[431] It is suggested that research includes experimentation in context of the 2010 Ethics Council Regulations. Previously provided for by regulation 2 of the 2007 Ethics Council Regulations. The new regulation merely requires that nine members of the Council must have extensive experience and knowledge of health research ethics. Previously this was more specific and required 5 members with knowledge of ethics and four who worked in an ethics-related discipline. The new regulation 2 of the 2010 Ethics Council Regulations, however, in sub-regulation 2(f) expressly requires that one member of the Council must have extensive knowledge in animal health research ethics.
[432] Regulation 2 of the 2010 Ethics Council Regulations.
[433] Regulation 3 of the 2010 Ethics Council Regulations. Previously provided for by regulation 4 of the 2007 Ethics Council Regulations.
[434] Regulation 4 of the 2010 Ethics Council Regulations. Previously provided for by regulation 4 of the 2007 Ethics Council Regulations.
[435] Regulation 5 of the 2010 Ethics Council Regulations. Previously provided for by regulation 6 of the 2007 Ethics Council Regulations.

meetings;[436] working of the Council;[437] the secretariat;[438] appeals[439] and remuneration of Council members.[440] The 2010 Ethics Council Regulations do not, as the 2007 Ethics Council Regulations did, make separate provision for the powers of the Council or offences and penalties. The prescribed form for nominating members is provided for by the Annexure to the Regulations.

5.4 REGULATIONS RELATING TO THE NATIONAL HEALTH RESEARCH COMMITTEE

For the purpose of this thesis, these Regulations will not be discussed in much detail and should simply be taken note of. The Committee and the Council as discussed previously will, however, have a certain role to play in stem cell research and therapy.[441] The following is therefore a brief discussion of the 2007 Regulations relating to the National Health Research Committee[442] and the 2010 Regulations relating to the Establishment of the National Health Research Committee.[443]

The 2007 Research Committee Regulations supplement section 69 of the Act[444] by providing for the constitution of the Committee;[445] nomination and appointment of committee members;[446] remuneration;[447] the duties of the chairperson[448] as well as the secretariat.[449] Committee

[436] Regulation 6 of the 2010 Ethics Council Regulations. The new sub-regulation 6(3) states that Council matters are to be treated as confidential and members must refrain from unreasonable disclosures of such information. A further new sub-regulation 6(7) requires members to recuse themselves from deliberations in which they have a conflict of interest. Previously provision was made for these matters in regulation 7 of the 2007 Ethics Council Regulations.
[437] Regulation 7 of the 2010 Ethics Council Regulations. This is a new regulation and makes provision for working groups to advise the Council.
[438] Regulation 8 of the 2010 Ethics Council Regulations. Previously provided for by regulation 11 of the 2007 Ethics Council Regulations.
[439] Regulation 9 of the 2010 Ethics Council Regulations. Previously provided for by regulation 8 of the 2007 Ethics Council Regulations. The 2010 Regulations provide for more specific procedural steps to be taken in the event of an appeal.
[440] Regulation 10 of the 2010 Ethics Council Regulations.
[441] See MRC SA (2003) paragraph 9.8 for more on the functions of a research ethics committee.
[442] Regulations relating to the National Health Research Committee of 23 February 2007. Hereafter referred to as the 2007 Research Committee Regulations.
[443] Regulations relating to the Establishment of the National Health Research Committee of 23 September 2010. Hereafter referred to as the 2010 Research Committee Regulations.
[444] See paragraph 4.3.1 *supra* for a discussion of the section 69.
[445] Regulation 2 of the 2007 Research Committee Regulations. "Committee" is defined as "the National Health Research Committee established in terms of section 69(1) of the Act" according to regulation 1 of the 2007 Research Committee Regulations.
[446] Regulation 3 of the 2007 Research Committee Regulations. Membership of such a committee must be influenced by two principles. First, committees must possess the technical competence and judgment to reconcile the consequences of participation with the research objects. Second, committees must respect the opinion of lay persons. See in general, Häyry H (1998) "Should the decisions of ethics committees be based on community values?" *Medicine, Healthcare and Philosophy* 1: 57-60.
[447] Regulation 9 of the 2007 Research Committee Regulations.
[448] Regulation 4 of the 2007 Research Committee Regulations. Regulation 1 defines the chairperson as "chairperson of the Committee."
[449] Regulation 10 of the 2007 Research Committee Regulations. The secretariat is defined as "the directorate responsible for research in the national [*sic*] Department" by regulation 1.

meetings[450] and the quorum and procedures to be adopted at such meetings or during decision making[451] are provided for as well as the procedure of appeal against any decisions made by the Committee.[452] Lastly, the offences and penalties for contravention of these regulations are provided for.[453]

The 2010 Research Committee Regulations is very similar to the 2007 Research Committee Regulations and follows the same format as the Ethics Council Regulations.[454] The 2010 Regulations provide for establishment of the Committee;[455] constitution of the Committee;[456] nomination and appointment of members;[457] appointment of the chairperson and vice-chairperson;[458] meetings of the Committee;[459] the quorum and procedures of decision making at meetings;[460] working groups of the Committee;[461] the secretariat[462] and appeals.[463] The 2010 Research Committee Regulations make no separate provision for remuneration of Committee members of offences and penalties for contravention of the Regulations as was the case with the 2007 Research Committee Regulations. The Annexure to the 2010 Regulations provides for the nomination of members form.

5.5 REGULATIONS RELATING TO RESEARCH ON HUMAN SUBJECTS AND PARTICIPANTS

This thesis ventures to introduce a new and dynamic format of obtaining consent and as such posits that stem cell therapy borders on stem cell research and that this is research involving human subjects. For this reason, the 2007 Regulations relating to Research on Human

[450] Regulation 5 of the 2007 Research Committee Regulations.
[451] Regulation 6 of the 2007 Research Committee Regulations.
[452] Regulation 7 of the 2007 Research Committee Regulations.
[453] Regulation 8 of the 2007 Research Committee Regulations.
[454] See paragraph 5.3 *supra*. As was done in the discussion of the 2010 Ethics Council Regulations, new provisions will be indicated in the footnotes.
[455] Regulation 2 of the 2010 Research Committee Regulations. This is a new provision.
[456] Regulation 3 of the 2010 Research Committee Regulations. Previously provided for by regulation 2 of the 2007 Research Committee Regulations.
[457] Regulation 4 of the 2010 Research Committee Regulations. Previously provided for by regulation 3 of the 2007 Research Committee Regulations.
[458] Regulation 5 of the 2010 Research Committee Regulations. This is also a new provision. Matters related to the duties of the chairperson were previously provided for by regulation 4 of the 2007 Research Committee Regulations.
[459] Regulation 6 of the 2010 Research Committee Regulations. Previously provided for by regulation 5 of the 2007 Research Committee Regulations.
[460] Regulation 7 of the 2010 Research Committee Regulations. Previously provided for by regulation 6 of the 2007 Research Committee Regulations.
[461] Regulation 8 of the 2010 Research Committee Regulations. This is also a new provision such as the provision for working groups in the Ethics Council Regulations. See paragraph 5.3 *supra*.
[462] Regulation 9 of the 2010 Research Committee Regulations. Previously provided for by regulation 10 of the 2010 Research Committee Regulations.
[463] Regulation 10 of the 2010 Research Committee Regulations. Previously provided for by regulation 7 of the 2007 Research Committee Regulations.

Subjects;[464] the 2013 Regulations relating to Research on Human Subjects;[465] and the 2014 Regulations relating to Research with Human Participants[466] are of importance and must be examined in some detail. This discussion then also illustrates the "fine tuning" of the regulatory instruments pertaining to stem cells and related matters.

The 2007 Human Subjects Regulations are divided into three chapters. For the purpose of this thesis, chapters 1 and 2 are of most importance. The Regulations also provide the following new definitions:

1. Minimal risk: "the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life;"
2. Non-therapeutic research: "any research not directed towards the benefit of the individual but rather towards improving scientific knowledge or technical application;" and
3. Vulnerable persons: "those whose willingness to volunteer in a research study may be unduly influenced by the expectation of benefits associated with participation."

Chapter 3 deals with research involving animals and may be of relevance in the regulation of the use of chimeric mice.[467]

Chapter 1 deals with general principles regarding research. The principles of health research[468] lay out, in general terms, certain requirements which should be met in any research which involves the participation of human subjects. Some of the noteworthy requirements include that the health research must be relevant to the overall developmental needs of the South African community.[469] It may therefore be assumed that the South African health care priorities must be kept in mind.[470] Research which involves human subjects must be conducted in accordance with valid scientific methodology and possess a high probability of finding an answer to the proposed research question.[471] Furthermore, the research must be practised by a suitably

[464] Regulations relating to Research on Human Subjects of 23 February 2007. Hereafter referred to as the 2007 Human Subjects Regulations.
[465] Regulations relating to Research on Human Subjects of 29 May 2013. Hereafter referred to as the 2013 Human Subjects Regulations.
[466] Regulations relating to Research with Human Participants of 19 September 2014. Hereafter referred to as the 2014 Human Participants Regulations.
[467] Chapter 3 reads as follows: "**Research involving animals-**
Where animals are used for research that will benefit humans, the following must be adhered to:
(a) the research proposal must also be submitted to an animal research ethics committee; and
(b) the researchers must consult and comply with the regulations and guidelines prescribed by the National Department of Agriculture."
See chapter 2 paragraph 3.3 *supra* for a discussion on the use of animals in stem cell research and therapy.
[468] Regulation 2 of the 2007 Human Subjects Regulations.
[469] Regulation 2(1)(a) of the 2007 Human Subjects Regulations.
[470] Prinsen (2010) 216.
[471] Regulation 2(1)(b) of the 2007 Human Subjects Regulations.

qualified principal investigator. This investigator must be a South African resident and must possess extensive experience in health research.[472] Provisions are also made regarding the participants and it is required that the research participants must be well informed and make informed decisions[473] and that the privacy and confidentiality of all participants is well protected.[474] Further protective measures are found in that it is required that the selection and recruitment of participants must be just and fair.[475] The risks and benefits of the research must be analysed prior to any research being undertaken[476] and any research undertaken must be subjected to independent review by a health research ethics committee.[477] Lastly, any clinical research must be registered on the South African National Clinical Trials Register.[478] Regulation 3 establishes some additional obligations which are placed on researchers.[479]

The provisions regarding participation of special groups of people are directly supplementary to the provisions found in section 71(2) and 71(3) as they stipulate the requirements for the participation of children as well as persons who are mentally impaired. Regulation 4(1) states that children may only participate in research where:[480]

(a) The research poses only a minimal risk to the child;[481]
(b) Where the research poses a greater than minimal risk but may be beneficial to the child;
(c) The research cannot be undertaken with adults as subjects; and
(d) The parent or legal guardian of the child consents thereto that the child may participate. A child's refusal to participate must always precede the consent of a parent or guardian.

Regulation 4(2) is of equal importance as it protects the interests of mentally and/or intellectually impaired persons. Research involving such persons must strictly involve mental disability so that it necessitates the involvement of such impaired persons; be sufficiently justified for involving such persons who may be institutionalised; have proper procedures for evaluating and confirming that the participant is truly incapable of giving informed consent; it

[472] Regulation 2(1)(c) of the 2007 Human Subjects Regulations.
[473] Regulation 2(1)(d) of the 2007 Human Subjects Regulations.
[474] Regulation 2(1)(e) of the 2007 Human Subjects Regulations.
[475] Regulation 2(1)(f) of the 2007 Human Subjects Regulations.
[476] Regulation 2(1)(g) of the 2007 Human Subjects Regulations.
[477] Regulation 2(1)(h) of the 2007 Human Subjects Regulations.
[478] Regulation 2(1)(i) of the 2007 Human Subjects Regulations.
[479] These obligations are (a) adherence to the requirements of regulation 2; (b) researchers must submit their research proposals for approval to an accredited Research Ethics Committee and to the Medicines Control Council or the Council where necessary; (c) disseminate positive as well as negative research results in a timely and competent manner; (d) disclose the sources and extent of funding for research to both the participants and Research Ethics Committee; (e) ensure monitoring of safety on activities; and (f) refer participants for professional assistance where necessary.
[480] As a note on the drafting of the 2007 Human Subjects Regulations, it must be mentioned that a mistake was made in the numbering of regulation 4(1). As published, it reads (a), (a), (b), (c). This has no effect on the power of the regulation but may lead to confusion.
[481] Regulation 1 defines "minimal risk" as "the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than ordinarily encountered in daily life."

must be ensured that the consent which was given by the person responsible for the impaired person was free from coercion; and to ensure that no or minimal risk is involved, and where minimal risk is involved, the anticipated benefits outweigh such risks.[482] Regulation 4(3) deals with vulnerable persons who are in dependent relationships and 4(4) gives special attention to research involving women. Regulation 5 broadly provides for research which requires additional consideration.[483]

Regulation 6 is of immense importance to this thesis as it may be seen as the framework whereby recommendations could be made for the proper procedure to be followed in or format of obtaining consent. Not only is it the first provision which hints at the complexity of informed consent in research such as stem cell research, it also provides, what may best be described as a checklist of inalienable requirements, for the lawfulness of informed consent. According to regulation 6, a person on whom the research is to be conducted has the right to be informed of the following:

(a) The purpose of the research;
(b) Treatments and the possibility of random assignment of each treatment where the research involves treatment;
(c) The methods and procedures to be followed or used in the course of the research;
(d) Alternatives other than participating in the research;
(e) The potential or real harm and risks involved in participation;
(f) Expected benefits to the participant and others as a result of the research;
(g) The extent to which confidentiality and privacy will be protected;
(h) Any available insurance in the event of injury or damage caused by participation;
(i) Details of a contact person in the event of such a research related injury;
(j) Incentives which were given for participation as well as any differences in incentives;
(k) In cases of clinical trials, the participant must be informed of the availability of treatment beyond the duration of the trial;
(l) Details of the sponsors of research, if any, and any potential conflict of interests; and
(m) Proof of ethics committee approval.

In context of this thesis and the proposed dynamic consent format, it is submitted that these prescriptions must be included in any format whereby consent may be obtained.

Chapter 2 of the 2007 Human Subjects Regulations is also of importance as it provides for genetic, stem cell research and reproductive health. It provides some regulatory

[482] Regulation 4(2)(a)-(e) of the 2007 Human Subjects Regulations.
[483] This includes research involving: indigenous medical systems, emergency medical treatment, innovative therapy and research involving prisoners.

supplementation to the NHA especially regarding stem cell research. Regulation 7(1) mandates that informed consent[484] must be obtained from a stem cell donor before the stem cell research or therapeutic cloning may be conducted. The findings which emanate from such research are not subject to intellectual property rights.[485] Lastly, the reimbursement of the donor, for any reasonable expenses which they incurred in making such donation,[486] is provided for. Furthermore, all health research studies involving human participants must be reviewed by a registered health research ethics committee as well as satisfy the requirements made by such a committee. Should the committee then make any recommendations, these recommendations must be adhered to.[487]

The 2013 Human Subjects Regulations which came into operation on the date of their publication[488] provided for a few altered as well as a slew of new definitions which had not appeared in the 2007 Regulations. The definitions for "minimal risk," "non-therapeutic research" and "vulnerable persons" was altered.[489] The newly added definitions which are of relevance include the following:[490]

1. Best interests: "significant decisions affecting a minor's life should aim to promote amongst others the minor's physical, mental, moral and emotional welfare;"[491]
2. Human subject: "a living person about whom an investigator obtains data or specimens or identifiable private information through investigation or interaction with that person;"
3. Significant risk: "substantial risk or serious harm;" and
4. Therapeutic research: "research that holds out the prospect of direct benefit to the participant."

The 2013 Human Subjects Regulations no longer divide the regulations into chapters and simply continues with provisions regarding the principles of health research. According to the 2013 Regulations any health research conducted in South Africa which involves human subjects must be undertaken with the informed consent of the subject or their legally authorised

[484] In terms of regulation 7(4) of the 2007 Human Subjects Regulations, consent must be obtained from a gamete donor prior to artificial insemination and the gamete donor is entitled to reimbursement.
[485] Regulation 7(2) of the 2007 Human Subjects Regulations.
[486] Regulation 7(3) of the 2007 Human Subjects Regulations.
[487] Regulation 8 of the 2007 Human Subjects Regulations.
[488] Regulation 9 of the 2013 Human Subjects Regulations.
[489] According to regulation 1 of the 2013 Human Subjects Regulations minimal risk is "the probability or magnitude of the harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life including routine medical, dental or psychological tests or examinations." Non-therapeutic research is "research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalizable [*sic*] knowledge." Vulnerable persons are "those persons whose context exposes them to conditions that increase their risk of harm, or limits their freedom to make choices."
[490] Regulation 1 of the 2013 Human Subjects Regulations.
[491] This is in concurrence with section 28(2) of the Constitution which states that the best interests are of paramount importance in every matter concerning the child.

representative.[492] Also, where the 2007 Regulations merely stated that the rights of the subject had to be respected, the 2013 Regulation explicitly requires that the right to dignity, privacy, bodily integrity and equality be respected. This is in line with the Constitution as section 12(2)(c) expressly protects the right to bodily integrity and also protects the right to consent to medical and scientific experimentation.[493]

The 2007 and the 2013 Human Subjects Regulations provide for the obligations of the researchers. An aspect which has been greatly refined in the 2013 Regulations, however, is that of participation of special classes of persons. The 2013 Human Subjects Regulations distinguish between different classes of persons[494] but also the degrees of risk involved in the research study. Minors may only participate in research where the participation of the minor is indispensable to the study and it poses a minimal risk; a more than minimal risk but holds the prospect of direct benefit to the minor or a minor increase over minimal risk and holds not benefit to the minor but will yield generalisable knowledge.[495] No mention is made of the minor's consent.[496]

The mentally impaired may only be research subjects where their participation is necessitated due to the strict focus on mental disability in the study, suitable evaluation procedures are in place to establish whether such a person is capable of giving their consent and where possible their free consent has been obtained. The same degrees of risk as those identified in instances concerning a minor also apply to persons who suffer from mental illness. The 2013 Human Subjects Regulations also provides for persons in dependent relationships,[497] women and particularly pregnant women[498] and other types of research which require additional consideration.[499]

A small but significant "fine tuning" of the 2013 Human Subjects Regulations provisions may be found in the regulations related to consent as they now also include the consent of a legally authorised representative of the research subject.[500] Lastly, Ministerial consent for non-therapeutic research as provided for by section 71 of the NHA is provided for.[501] It is interesting

[492] Regulation 2(e) of the 2013 Human Subjects Regulations. Sub-regulation (d) also states that research subjects must be well informed and able to make appropriate decisions.
[493] See chapter 3 paragraph 6.1.1 *supra*.
[494] These include minors, intellectually or mentally impaired persons, persons who are in dependent relationships, women, and other types of persons such as prisoners or persons involved in indigenous medical systems.
[495] Regulation 4(1) of the 2013 Human Subjects Regulations.
[496] It is strongly suggested that definitions or clarification be provided regarding the meaning of "more than minimal risk" and "minor increase over minimal risk."
[497] Regulation 4(3) of the 2013 Human Subjects Regulations.
[498] Regulation 4(4) of the 2013 Human Subjects Regulations.
[499] Regulation 5 of the 2013 Human Subjects Regulations.
[500] Regulation 6 of the 2013 Human Subjects Regulations. Also, the subject must now be informed of reimbursement as well as incentives for participation according to sub-regulation 6(j) of the 2013 Human Subjects Regulations.
[501] Regulation 8 of the 2013 Human Subjects Regulations.

to note that the 2007 Regulations' provisions regarding genetic, stem cell and reproductive health and those regarding research involving animals have been omitted.[502]

The process of "fine tuning" as mentioned previously is well illustrated in the 2014 Human Participants Regulations which will now be discussed.[503] Firstly, the use of the word "subject" was replaced by the word "participant." It is suggested that this is a more humane phrasing and is indicative of the shifting view of the role and status of human subjects or then, participants in research studies. The definition of "human subject" was thus changed to "human participant" and this wording is used throughout the 2014 Human Participants Regulations. The definitions of "minimal risk" and "vulnerable persons" have also been slightly amended.[504] Only the provisions which are new to the 2014 Human Participants Regulations will be discussed in detail here as the other provisions are similar to the 2013 Human Subjects Regulations.

Health research involving human participants may only be undertaken with the appropriate consent in terms of regulation 2(f) of the 2014 Human Participants Regulations. Researchers also have certain obligations in conducting research involving human participants. These obligations include consultation with representatives from the participating community and other stakeholders; assessing the ongoing welfare of participants and registering clinical trials in the South African National Clinical Trials Register.[505]

Research involving vulnerable persons must only include vulnerable persons where it would be inappropriate to involve non-vulnerable persons; not systematically exclude vulnerable persons as this might constitute discriminatory practices;[506] be responsive to South Africa's health needs and priorities and be especially ethically reviewed.[507] The 2014 Regulations also provide for research where persons involved in hierarchical relationships are involved and states that such research would be appropriate where the related risks have been minimised and appropriate consent procedures followed.[508]

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[502] Previously provided for by regulation 7 and 3 of the 2007 Human Subjects Regulations respectively.
[503] See paragraph 4 *supra*.
[504] Regulation 1 of the 2014 Human Participants Regulations. Minimal risk is now defined as "the probability or magnitude of the harm or discomfort anticipated in the research is not greater than that ordinarily encountered in daily life in a stable society or in routine medical, dental, educational or psychological tests or examinations." Vulnerable persons are now defined as "those persons in increased risk of research-related harm, or who are limited in their freedom to make choices, or relatively incapable of protecting their own interests."
[505] Regulation 3 of the 2014 Human Participants Regulations.
[506] See chapter 4 paragraphs 5.1.2.2 and 5.1.2.3 *supra*.
[507] Regulation 4 of the 2014 Human Participants Regulations.
[508] Regulation 4.4(b) of the 2014 Human Participants Regulations.

A new and important addition was made in regard to the provisions regarding consent for research in that the freedom to choose to participate or not and to be able to withdraw from research without penalty or reason is now provided for.[509]

The last novel provision of the 2014 Human Participants Regulations which is of relevance to this thesis pertains to the review of proposals for research with human participants. Such proposals must be registered with an ethics committee; at least minimally satisfy the National Department of Health's ethical guideline for research with human participants and must adhere to decisions of the relevant committee.[510]

5.6 REGULATIONS RELATING TO HUMAN STEM CELLS

The Regulations relating to Human Stem Cells[511] and the Regulations relating to Stem Cell Institutions or Organisations[512] must be read together even though these Regulations seem to address different issues on the face of it. In reality, however, these two Regulations provide for identical issues regarding stem cells as well as related institutions and organisations save for a few amendments, additions and omissions.

The 2007 Stem Cell Regulations are of great importance as they provide for various regulatory measures not previously provided for, or not provided for in such precise terms. It may further be mentioned that until the further Regulations were made, this Regulation may have been viewed as the pivotal regulatory document to supplement Chapter 8 of the NHA. The Regulations provide the following new definitions:[513]

1. Clone: "an organism that is a genetic copy of an existing organism;"[514]
2. Competent person: "(a) in the case of stem cells retrieval from a deceased person, a medical practitioner or person who by qualification is competent to remove the specific cells; or (b) in the case of stem cells retrieval from a living person, a medical practitioner who by qualification is a competent person to remove the specific stem cells;"
3. Distribution: "transportation and delivery of tissue and cells intended for human application;"[515]

[509] Regulation 5(f) of the 2014 Human Participants Regulations.
[510] Regulation 6 of the 2014 Human Participants Regulations.
[511] Regulations relating to Human Stem Cells of 4 May 2007. Hereafter referred to as the 2007 Stem Cell Regulations.
[512] Regulations relating to Stem Cell Institutions or Organisations of 1 April 2011. Hereafter referred to as the 2011 Institution and Organisation Regulations.
[513] Regulation 1 of the 2007 Stem Cell Regulations.
[514] It is unfortunate that this only refers to "clone" as a noun and not as a verb. It is suggested that a description or definition of the action is also required.

4. Embryonic stem cells: "specialised or undifferentiated cells that can divide indefinitely in culture and can develop into specialised or undifferentiated cells;"
5. Human application: "the use of tissues or cells on or in a human recipient and extracorporeal applications;"[516]
6. Multipotent: "a cell that is specialised for specific tissue;"[517]
7. Pluripotent: "a cell that is able to develop into most tissues and organisms;"
8. Preservation: "the use of chemical agents, alterations in environment conditions or other means during processing, to prevent or retard biological or physical deterioration of cells or tissue;"
9. Processing: "all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;"
10. Procurement: "a process by which tissue or cells are made available;"[518]
11. Responsible person: "any person registered in terms of the Health Professions Act, 1974 (No 56 of 1974) and who is in charge of the activities referred to in regulation 2(1)(a), (b) and (c);"
12. Serious adverse event: "an untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, death or life threatening, disabling or incapacitating condition for patients or which might result in, or prolong, hospitalisation or morbidity;"
13. Storage: "maintaining the product under appropriate controlled conditions until distributed;" and
14. Totipotent: "a cell that is able to form an entire organism."

The 2007 Stem Cell Regulations further contain 22 regulations dealing with various matters. For the sake of convenience, some of the issues as regulated by different regulations have been grouped together. Only the pertinent regulations will be discussed in greater detail. The other regulations will, however, briefly be mentioned.

The use of stem cells; which may include acquiring, importing, preserving, screening, testing, separating, labelling, packing, supplying, distributing or exporting, must be authorised in terms

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[515] This definition differs from the meaning assigned to "distribution" in context of this thesis. For the purpose of this thesis, the term is intended to have a broader meaning and must be understood as "being used for therapy, research or educational purposes and the practice of stem cell banking." See chapter 2 paragraph 4 in this regard.
[516] This is spelt "extracorporal" in the Regulations.
[517] See chapter 2 paragraph 2.2.3 *supra* for a scientific explanation of this terminology.
[518] This definition differs from the meaning assigned to "procurement" in context of the title of this thesis. For the purpose of this thesis, the term must be understood as "the process by which stem cells are made available and this includes the removal or withdrawal of stem cells and also the creation thereof."

in section 54 of the NHA and the stem cells must be subjected to certain laboratory tests.[519] Furthermore, where stem cells are intended for therapeutic, research or educational purposes the project must be registered with the Department[520] and consent must have been given by the donor who donated the material voluntarily.[521]

The provisions regarding authorisation and the application, suspension and withdrawal thereof may be found in regulations 3 and 4. These regulations give the Minister a substantial amount of power which could be problematic. What is interesting to note is that according to these regulations only three groups of persons may apply for authorisation as an authorised institution, namely health organizations, health institutions and medical scientists or human biological scientists. These institutions may, however, not operate on a profit making basis.[522] This would lead one to believe that private stem cells banks may be prohibited in terms of the 2007 Stem Cell Regulations.[523] Authorisation may be suspended or withdrawn on the strength of the report and recommendations of the inspector of anatomy.[524]

A stem cell establishment is required to keep registers of stem cell donors and donations. The records and statistics which must be kept in this regard must contain information ranging from donors,[525] donations,[526] supply of stem cells,[527] systems in place to share information regarding serious adverse events[528] and recall procedures.[529] Also, the Director-General is required to establish a publicly accessible database with information regarding the activities of the establishment.[530] Informed consent forms must be included in the records kept on stem cell donors and questions may thus be raised as to the extent to which private donor information and confidentiality will be protected. This issue is then provided for to some extent in regulations 10 and 11.[531]

Stem cell establishments are tasked with ensuring the quality and safety of stem cells. A quality system must be put in place based on the principle of good practice. This system must

[519] These include *inter alia* tests for HIV, genetic disease traits, syphilis and hepatitis.
[520] In terms of regulation 3(3)(a) of the 2007 Stem Cell Regulations.
[521] Regulation 2 of the 2007 Stem Cell Regulations.
[522] Regulation 3 of the 2007 Stem Cell Regulations.
[523] See paragraphs 5.8 *infra* for the Regulations relating to Tissue and Stem Cell Banks.
[524] Regulation 4 of the 2007 Stem Cell Regulations. See regulations 8 and 9 for the additional powers and duties of the inspector of anatomy and for the inspection and control measures.
[525] Regulation 5(a) of the 2007 Stem Cell Regulations.
[526] Regulation 5(b) of the 2007 Stem Cell Regulations.
[527] Regulation 5(c) of the 2007 Stem Cell Regulations.
[528] Regulation 5(d) of the 2007 Stem Cell Regulations.
[529] Regulation 5(e) of the 2007 Stem Cell Regulations.
[530] Regulation 6 of the 2007 Stem Cell Regulations.
[531] Regulation 10 states that a stem cell establishment must ensure that (1) all its activities can be traced from donor to recipient and vice versa and that (2) it has a unique donor identification system which assigns a code to each donation and to each of the products associated with such donation. Regulation 11 requires that an establishment must ensure that data remains confidential at all times.

furthermore include various documents.[532] Further duties which fall on the establishment are also provided for by the 2007 Stem Cell Regulations. Stem cells must be quarantined at reception until a time when donor information and the test results relating to the stem cells are available.[533] Certain processing guidelines must be adhered to as set forth in the standard operating procedures (SOPs).[534] The SOPs must also provide for storage and documentation of stem cells.[535] The labelling, documentation and packaging of stem cells must conform to the operating procedures of the establishment.[536] Lastly, the stem cell establishment must ensure that the quality and safety of the stem cells are not compromised during distribution.[537]

The 2007 Stem Cell Regulations also provide for the regulation of relationships between stem cell institutions and third parties,[538] offences and penalties[539] and the commencement of the Regulations.[540]

The 2011 Institution and Organisation Regulations supplement sections 54 and 58 of the NHA and are a modified version of the 2007 Stem Cell Regulations and they must therefore be read together. The 2011 Institution and Organisation Regulations contain the same definitions overall, with the exception of a new definition, "identity number," and an altered definition for "stem cell." These definitions are as follows:[541]

1. Identity number: "a personal identity number included in the official identification book issued by the Department of Home Affairs, a passport or driver's license;" and
2. Stem cell: "cells that have both the capacity to self-regenerate as well as to differentiate into mature, specialised cells."[542]

These Regulations are greatly similar to the 2007 Stem Cell Regulations and thus only the new or altered provisions will be discussed here. It is however necessary to take note of the general content of these Regulations. To this end the 2011 Regulations make provision for the use of stem cells;[543] the application for authorisation;[544] suspension or withdrawal of such

[532] This includes at least: standard operating procedures, guidelines, training manuals, reporting forms, donor records and information on the final destination of the stem cells. See regulation 12 of the 2007 Stem Cell Regulations.
[533] Regulation 15 of the 2007 Stem Cell Regulations.
[534] Regulation 16 of the 2007 Stem Cell Regulations.
[535] Regulation 17 of the 2007 Stem Cell Regulations.
[536] Regulation 18 of the 2007 Stem Cell Regulations.
[537] Regulation 19 of the 2007 Stem Cell Regulations.
[538] Regulation 20 of the 2007 Stem Cell Regulations.
[539] Regulation 21 of the 2007 Stem Cell Regulations.
[540] Regulation 22 of the 2007 Stem Cell Regulations.
[541] Regulation 1 of the 2011 Institution and Organisation Regulations.
[542] The definition provided in the 2007 Stem Cell Regulations is as follows: "any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, hematopoietic cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell."
[543] Regulation 2 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 2 of the 2007 Stem Cell Regulations.

authorisation;[545] record keeping and reporting obligations;[546] the additional powers and duties of the inspector of anatomy;[547] inspection and control measures;[548] traceability;[549] data protection and confidentiality;[550] the quality and safety of stem cells;[551] the responsible person;[552] personnel;[553] stem cell reception;[554] stem cell processing;[555] storage conditions;[556] labelling, packing and documentation;[557] distribution;[558] third party and institution relationships[559] and penalties and offences.[560] As mentioned, only provisions of most importance to this thesis will now be discussed in more detail.

An additional sub-regulation has been added to the provisions regarding the use of stem cells which states that where stem cells are for autologous use,[561] certain tests are not required.[562] Concerning the application process, the 2011 Institution and Organisation Regulations now provide that an application for authorisation as an authorised institution or organization must be made to the Director-General and no longer to the Minister.[563] It is suggested that this is an improvement as the Minister has excessive power in relation to stem cell related activities. Lastly, the provisions regarding distribution have been altered by the addition of a sub-

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[544] Regulation 3 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 3 of the 2007 Stem Cell Regulations.
[545] Regulation 4 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 4 of the 2007 Stem Cell Regulations.
[546] Regulation 5 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 5 of the 2007 Stem Cell Regulations.
[547] Regulation 7 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 8 of the 2007 Stem Cell Regulations.
[548] Regulation 8 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 9 of the 2007 Stem Cell Regulations.
[549] Regulation 9 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 10 of the 2007 Stem Cell Regulations.
[550] Regulation 10 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 11 of the 2007 Stem Cell Regulations.
[551] Regulation 11 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 12 of the 2007 Stem Cell Regulations.
[552]Regulation 12 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 13 of the 2007 Stem Cell Regulations.
[553] Regulation 13 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 14 of the 2007 Stem Cell Regulations.
[554] Regulation 14 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 15 of the 2007 Stem Cell Regulations.
[555] Regulation 15 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 16 of the 2007 Stem Cell Regulations.
[556] Regulation 16 2011 of the Institution and Organisation Regulations. Previously provided for by regulation 17 of the 2007 Stem Cell Regulations.
[557] Regulation 17 2011 of the Institution and Organisation Regulations. Previously provided for by regulation 18 of the 2007 Stem Cell Regulations.
[558] Regulation 18 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 19 of the 2007 Stem Cell Regulations.
[559] Regulation 19 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 20 of the 2007 Stem Cell Regulations.
[560] Regulation 20 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 21 of the 2007 Stem Cell Regulations.
[561] Autologous means that the donor of the stem cells is also the recipient thereof.
[562] These would include *inter alia* HIV, syphilis or hepatitis tests.
[563] Regulation 3 of the 2011 Institution and Organisation Regulations. Previously provided for by regulation 3 of the Stem Cell Regulations.

regulation stating that the allocation of stem cells must be guided by clinical criteria and ethical norms as the only considerations.[564]

As a side note, it should be mentioned that the 2011 Institution and Organisation Regulations are in terrible shape. The grammatical and other language aspects of the Regulations are shocking and leave a sour taste in the mouth of any person. The spelling of certain words as well as the formatting and editing are a disgrace. This does not make for a good impression, never mind one of knowledgeability. If this is the future of legal drafting in South Africa, the future looks very bleak. It is a shame that Regulations of such immense importance have almost been negated in stature in such a manner.

5.7 REGULATIONS RELATING TO IMPORT AND EXPORT

The 2011 Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Embryos, Zygotes and Gametes[565] and the 2012 Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes[566] require some attention at this juncture.

The 2011 Import and Export Regulations, which are supplementary to section 60 of the NHA were completely new and thus attended to matters which had not previously been properly regulated. Although these Regulations are of importance, they are not strictly relevant to this thesis and therefore the Regulations are only discussed in highlights as pertaining to this study. As with other Regulations discussed above, some definitions are of importance and must be mentioned here. They are as follows:[567]

1. Blood donor: "any living person who voluntarily and not for remuneration has blood withdrawn from him or her for the subsequent administering thereof to themselves or another person or for processing into blood products;"
2. Blood: "human blood intended for transfusion purposes, including the components thereof, but excluding blood specimens intended for pathology testing;"

[564] Regulation 18(2) of the 2011 Institution and Organisation Regulations.
[565] Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Embryos, Zygotes and Gametes of 1 April 2011. Hereafter referred to as the 2011 Import and Export Regulations.
[566] Regulations relating to the Import and Export of Human Tissue, Blood, Blood Products, Cultured Cells, Stem Cells, Embryos, Foetal Tissue, Zygotes and Gametes of 2 March 2012. Hereafter referred to as the 2012 Import and Export Regulations.
[567] Regulation 1 of the 2011 Import and Export Regulations.

3. cDNA: "a single stranded segment of DNA that is complimentary to the mRNA (messenger RNA) of a coding DNA segment a whole exon or a whole gene or part of a gene;"[568]
4. Embryo: "a human offspring in the first eight weeks of conception;"[569]
5. Embryonic tissue: "tissue from an embryo;"
6. Fetal tissue: "tissue form a fetus;"
7. Import: "to import into the Republic in any manner;"[570] and
8. Plasma: "(a) the fluid portion of blood obtained as a by-product of whole blood donation; or (b) plasma collected directly from a person by a process of plasmapheresis;"[571]

The 2011 Import and Export Regulations mainly provide for import and export permits[572] as well as registers to be kept of all authorised institutions involved in importing and exporting biological substances.[573] A distinction is made between the permits required firstly for whole blood, red cell concentrate, fresh frozen plasma and platelet concentrate;[574] and secondly for blood, plasma and serum, cultured cells, embryos, zygotes or gametes for reagent, research or diagnostic purposes.[575] The 2011 Import and Export Regulations further provide for disposal of tissue, blood, blood products, cultured cells, stem cells, embryos or gametes imported without a permit or contrary to the conditions of a permit.[576]

The Regulations make no mention of any consent requirement and the question may therefore be raised whether or not a person should be able to consent to export of their biological material. If not, it may be argued that importation or exportation violate a person's autonomy rights. A second concern here relates to the financial aspects of import and export. Who is making money here? Who is paying for this? Even where there are no direct profits or costs, there are direct financial gains and losses to be made. This aspect is in definite need of clarification and certain regulation.

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[568] cDNA is complimentary DNA. For more on Nucleic Acids, Deoxyribose and Ribose, see Dahm R (2008) "Discovering DNA: Friedrich Miescher and the early years of nucleic acid research" *Human Genetics* 122(6): 565-581; International Human Genome Sequencing Consortium (2001) "Initial sequencing and analysis of the human genome" *Nature* 409(6822): 860-921. See also Gilbert WG (1980) "DNA sequencing and gene structure" available online at http://nobelprize.org/nobel_prizes/chemistry/laureates/1980/gilbert-lecture.html accessed 28/5/2012; Sanger F (1980) "Determination of nucleotide sequences in DNA" available online at http://nobelprize.org/nobel_prizes/chemistry/laureates/1980/sanger-lecture.html accessed 28/5/2012.
[569] It is suggested that the definition of "embryo" should perhaps be amended to read that it is "human offspring in the first fourteen days from conception." By doing so, the South African definition would be aligned with internationally used definitions of embryos.
[570] No definition of "export" is provided and it is suggested that it must therefore be seen as meaning "to export out of the Republic in any manner."
[571] See in general, Muscle Dystrophy Association (2005) "Facts about Plasmapheresis" available online at http://www.mda.org/publications/PDFs/FA-Plasmapheresis.pdf accessed 28/5/2012.
[572] Regulation 2 of the 2011 Import and Export Regulations.
[573] Regulation 7 of the 2011 Import and Export Regulations.
[574] Regulation 4 of the 2011 Import and Export Regulations.
[575] Regulation 5 of the 2011 Import and Export Regulations.
[576] Regulation 6 of the 2011 Import and Export Regulations.

The 2012 Import and Export Regulations, which was published a year after the 2011 Regulations added the words "stem cells" and "foetal tissue" to the title of the Regulations and thereby broadened the scope thereof.[577] It provides for one new and relevant definition and states that cultured cells are "any human cells grown *in vitro* supported by suitable growth media."[578]

The remainder of the 2012 Import and Export Regulations makes provision for import and export permits;[579] whole blood, red cell concentration, plasma and platelet concentration;[580] blood, plasma and serum, cultured cells, stem cells, embryos, zygotes and gametes for reagent,[581] research or diagnostic purposes;[582] the disposal of materials imported without a permit or contrary to any conditions thereof;[583] registers;[584] the delegation of powers[585] and offences and penalties[586] The Annexures to the 2012 Import and Export Regulations provide for application forms to be completed in applying for import or export permits.

5.8 REGULATIONS RELATING TO TISSUE AND STEM CELL BANKS

Currently, there are three relevant Regulations under the NHA dealing with the banking of human material.[587] They are the 2011 Regulations relating to Tissue Banks,[588] the 2012 Regulations relating to Tissue Banks[589] and the 2012 Regulations relating to Stem Cell Banks.[590]

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[577] The definition of stem cell as provided for by regulation 1 of the 2012 Import and Export Regulations reads as follows: "any embryonic stem cell or circulating, bone marrow, umbilical cord or haemopoietic progenitor cell, or any cell that is capable of replicating or proliferating and giving rise to a different cell." This definition is consistent with the 2011 Import and Export Regulations but is differs greatly from the definition provided in some of the other Regulations discussed in the course of this thesis chapter.
[578] Regulation 1 of the 2012 Import and Export Regulations. The suitability of the growth medium will depend on the type of cells. See chapter 2 paragraph 3.5 *supra* on the culturing of cells.
[579] Regulation 2 and 3 of the 2012 Import and Export Regulations. Previously provided for by regulations 2 and 3 of the 2011 Import and Export Regulations. Gametes have been added to this provision.
[580] Regulation 4 of the 2012 Import and Export Regulations. Previously provided for by regulation 4 of the 2011 Import and Export Regulations.
[581] Meaning that it will be used in chemical analysis or other reactions.
[582] Regulation 5 of the 2012 Import and Export Regulations. Previously provided for by regulation 5 of the 2011 Import and Export Regulations. The provisions regarding the consent of a donor in instances where material is not intended for transfusion purposes but may be used for the advancement of medicine has been omitted. See regulation 5(7) of the 2011 Import and Export Regulations.
[583] Regulation 6 of the 2012 Import and Export Regulations. Previously provided for by regulation 6 of the 2011 Import and Export Regulations.
[584] Regulation 7 of the 2012 Import and Export Regulations. Previously provided for by regulation 7 of the 2011 Import and Export Regulations. Consent is still not mentioned in the new Regulations.
[585] Regulation 8 of the 2012 Import and Export Regulations. Previously provided for by regulation 8 of the 2011 Import and Export Regulations.
[586] Regulation 9 of the 2012 Import and Export Regulations. Previously provided for by regulation 9 of the 2011 Import and Export Regulations.
[587] It is interesting to note that another Regulation exists related to banking of human material namely the Regulations relating to Human Milk Banks of 3 July 2015.
[588] Regulations relating to Tissue Banks of 1 April 2011. Hereafter referred to as the 2011 Tissue Bank Regulations.
[589]Regulations relating to Tissue Banks of 2 March 2012. Hereafter referred to as the 2012 Tissue Bank Regulations.

As some attention was given to the process of banking previously,[591] it is necessary to discuss these Regulations at this juncture.

The 2011 Tissue Bank Regulations were, just as the Import and Export Regulations, first of their kind in South Africa and address a much specialised aspect of stem cell related matters. In context of this thesis, it is necessary to take note of these Regulations even though they are not of pertinent importance to this study. A definition which is required to understand the Regulations is that of a Tissue Bank. It may, according to regulation 1, be defined as "an organization, institution or person registered in terms of regulation 3 of these regulations as a tissue bank."

The Regulations, consisting of four chapters, then continue by making provision for the registration of an organisation, institution or person as a Tissue Bank. An organization, institution or person must register where it or they acquire or import human tissue; preserve, screen, test, process, store, label, separate, pack or supply or dispose of human tissue; or produce, pack, seal and label any tissue product.[592] Registration is not required where the tissue product is used for educational or scientific purposes only or where tissue is transported in the normal course of business.[593] The Regulations provide for the application procedure for registration[594] as well as suspension and revocation of such registration.[595]

Chapter 2 of the Regulation provides for the duties of the Tissue Bank.[596] These include *inter alia* keeping a register of tissue donors; keeping a record of statistics of tissue donations and keeping a record of untoward reactions. Chapter 3 handles matters concerning the quality and safety of tissues. A Tissue Bank must, according to the Regulations, have a policy of quality management as well as a person in charge thereof.[597] Furthermore, the Tissue Bank must establish certain criteria for the recruitment of tissue donors. This entails creating standards of practice for the acceptance or deferral of donors.[598] Tissue Banks will have to be mindful of not discriminating against persons on the grounds of genetic information in the creation of such criteria.[599] Tissue Banks are also required to perform mandatory tests on tissue and tissue

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[590]Regulations relating to Stem Cell Banks of 2 March 2012. Hereafter referred to as the 2012 Stem Cell Bank Regulations.
[591] See chapter 2 paragraph 4 *supra*.
[592] Regulation 2 of the 2011 Tissue Bank Regulations.
[593] Regulation 2(2) of the 2011 Tissue Bank Regulations.
[594] Regulation 3 of the 2011 Tissue Bank Regulations.
[595] Regulation 4 of the 2011 Tissue Bank Regulations.
[596] Regulation 6(1) of the 2011 Tissue Bank Regulations.
[597] Regulation 7 of the 2011 Tissue Bank Regulations.
[598] Regulation 8 of the 2011 Tissue Bank Regulations.
[599] For more on genetic discrimination see Lapham, Kozma *et al.* (1996) 621 and Low L, King S & Wilkie T (1998) "Genetic discrimination in life insurance: Empirical evidence from a cross sectional survey of genetic support groups in the United Kingdom" *British Medical Journal* 317(7173): 1632.

products.[600] Lastly, chapter 4 provides for appeals, delegation of powers and general provisions.[601]

The 2012 Tissue Bank Regulations amended and added to the 2011 Regulations. In context of this thesis, it is necessary to discuss these Regulations more for the sake of completion than for their relevance to the specific research issue. It should, however, be mentioned here that although not the focal point of this thesis, Tissue Banks are becoming more important aspects of biotechnology and further study into the regulation of these entities is recommended.[602]

The 2012 Regulations contain numerous provisions and establish a more detailed regulatory framework of Tissue Banks. The Regulations start off by providing definitions which had not appeared in the previous Regulations. All in all, almost 30 new definitions were created, some definitions were broadened[603] and others which had appeared in the 2011 Regulations were not included in the 2012 version.[604] The most important amended definition is that of a Tissue Bank and a new definition for tissue which was not provided by the 2011 Regulations. These definitions as found in the 2012 Regulations reads as follows:[605]

1. Tissue bank: "an organisation, institution or person that provides or engages in one or more services involving cells and/or tissue from living or deceased individuals for transplantation purposes;"[606] and
2. Tissue: "a functional group of cells."[607]

The 2012 Regulations then continue by providing for the use of human tissue which states the uses of tissue[608] are subject to certain requirements such as authorisation by the Department of Health, are in accordance with the Regulations and as of this new Regulation, also that

[600] Regulation 9 of the 2011 Tissue Bank Regulations.
[601] Regulations 10-12 of the 2011 Tissue Bank Regulations.
[602] See in general, Prinsen L (2015) "Meeting the standard: An overview of European biobank regulation and a comparison to the current South African position" *The African Journal of International and Comparative Law* 23(1): 54-73.
[603] For example, in the 2011 Regulations a donor is defined merely as "a person who has donated tissue in terms of the Act" while in the 2012 Regulations the definition reads that a donor is "a person from who tissue, blood, blood products or stem cells is donated in terms of this regulation."
[604] For example, the 2012 Regulations do not contain definitions for "inspector," "standard practice" or "vascular organ."
[605] Regulation 1 of the 2012 Tissue Bank Regulations.
[606] Such an organisation, institution or person must be registered in terms of the 2012 Regulations.
[607] Some ambiguity thus still remains in this definition. This term is used collectively in the Regulations to indicate both cells and tissue.
[608] The uses are: removing, acquiring, importing, preserving, screening, testing, processing, storing, separating, producing, labelling, packing, supplying, distributing, exporting or releasing for transplantation.

laboratory tests for infections agents which may cause transplantation transmitted diseases[609] have to be completed and the results of these tests must be made available.[610]

The 2011 Tissue Bank Regulations required that any organisation, institution or person wanting to partake in the activities regulated under the Regulation had to register with the Department before any banking and banking related activities were to be undertaken. In the 2012 Regulations, the application for authorisation is now provided for in that the information which such an application must contain is specified.[611] Once authorisation is granted it may, however, be suspended or withdrawn and the 2012 Regulations expand on the 2011 Regulations in that a new ground for such suspension or withdrawal is provided for, namely violation of the rights of the donor or recipient of tissue.[612] More detail on the process of suspension and withdrawal of authorisation is, however, provided for in the 2011 Regulations.

A completely new aspect which is regulated by the 2012 Tissue Bank Regulations is that of the organisational structures of a Tissue Bank. A provision which is rather progressive as it explicitly mandates adherence to an instrument of international law is regulation 5(2). This regulation states that "all activities of an authorisation [*sic*] tissue bank relating to cell and/or tissue procurement, processing and distribution shall comply with the Guiding Principles of the WHO as contained in the Declaration of Istanbul on Organ Trafficking and Transplant Tourism of 2009."[613] The main objective of the Declaration seems to be the regulation and control of the movement of tissue which would then influence any import and export of tissue. A further new

[609] This means "a disease that can be transmitted by the transplantation of tissue or a tissue product donated by a person, into the body of another person, including a genetic disease'" according to regulation 1 of the 2012 Tissue Bank Regulations.
[610] Regulation 1(1)(d)(ii) of the 2012 Tissue Bank Regulations.
[611] This is the name and nature of the applicant, location of the premises where business is to be conducted, an indication of how records and data will be kept, the quality management system to be used, details of the responsible person and any other information the Director-General may consider necessary for the consideration of the application. See regulation 3(2)(a)-(f) of the 2012 Tissue Bank Regulations.
[612] Regulation 4(1)(c) of the 2012 Tissue Bank Regulations.
[613] The Declaration emphasises the need to prohibit organ trafficking and transplant tourism as it is in violation of the principles of equity, justice and respect for human dignity. The Declaration asserts that since the commercialisation of transplantation often targets vulnerable donors, it leads to inequality and injustice and should also be prohibited. The Declaration distinguishes between "transplant tourism" and "travel for transplantation." "Travel for transplantation" is movement across jurisdictional borders of organs, donors, recipients or professionals for transplantation purposes. Travel for transplantation becomes "transplant tourism" if (1) it involves organ trafficking and/or transplant commercialisation or (2) if the resources devoted to providing transplants to patients from outside a country undermine the country's ability to provide transplant services to its own population. Not all travel with the aim of transplantation is unethical when the following requirements are met. In the case of a live donor transplantation: (1) if the recipient possesses dual citizenship and wishes to undergo transplantation from a live donor who is a family member in a country of citizenship that is not their residence and (2) if the donor and recipient are genetically related and wish to undergo transplantation in a country of which they are not residents. In the case of deceased donor transplantation, an officially regulated bilateral or multilateral reciprocal organ sharing programs must exist between the jurisdictions. For more on the Declaration of Istanbul on Organ trafficking and Transplant Tourism of 2008, see Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2014) "About the Declaration" available online at http://www.declarationofistanbul.org/index.php?option=com_content&view=article&id=77&Itemid=57 accessed 15/9/2013.

and interesting provision is that Tissue Banks must have a designated person who is responsible for policy-making. This may indicate a more ethical and transparent, responsible method of tissue banking practice.[614] In a similar vein to this, the 2012 Regulations then also provide for the duties and reporting obligations of a Tissue Bank. The 2012 Tissue Bank Regulations are similar to the 2011 Regulations in this regard but are more complete and deal with various issues, including donor particulars which are required to be kept in a register; documentation regarding the tissue banking processes for which the Tissue Bank is responsible; a record of statistics regarding tissue donations; a system with the purposes of sharing information regarding serious adverse events of quality and safety issues with the Director-General; a fast and accurate recall procedure and distribution records.[615] Additional duties of the health officer are also provided for.[616]

Inspection and control measures are provided for in a new manner as the 2012 Tissue Bank Regulations now require that Tissue Banks must be inspected at least every year in order to ensure compliance with all relevant requirements of such a bank.[617] Quality management[618] and quarantine[619] are some of the elements which may be inspected.

The 2012 Regulations now provide for new regulations which individually and specifically deal with processing;[620] storage conditions;[621] labelling, documentation and packaging of tissues,[622] as well as distribution and dispensing.[623] Further brand new and specialised provisions are those regarding traceability,[624] data protection and confidentiality.[625]

Research is also specifically provided for and the 2012 Regulations require that all activities taking place at a Tissue Bank which involve research and development of tissue samples must be done in accordance with the NHA, must be approved by a relevant ethics committee and must be supervised by a registered scientist. All such research must also be recorded and documented.[626] The Regulations lastly provide for appeals, delegations and offences.[627]

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[614] Regulation 5(3) of the 2012 Tissue Bank Regulations.
[615] Regulation 6(1)(a)-(f) of the 2012 Tissue Bank Regulations. Informed written consent is explicitly required by regulation 6(1)(b)(i) of the 2012 Tissue Bank Regulations.
[616] Regulation 7 of the 2012 Tissue Bank Regulations. Previously provided for by regulation 5 of the 2011 Tissue Bank Regulations. The new provisions, however, expand on the old ones.
[617] Regulation 8 of the 2012 Tissue Bank Regulations.
[618] Regulation 9 of the 2012 Tissue Bank Regulations.
[619] Regulation 10 of the 2012 Tissue Bank Regulations.
[620] Regulation 11 of the 2012 Tissue Bank Regulations.
[621] Regulation 12 of the 2012 Tissue Bank Regulations.
[622] Regulation 13 of the 2012 Tissue Bank Regulations.
[623] Regulation 16 of the 2012 Tissue Bank Regulations. See also regulation 18 of the 2012 Tissue Bank Regulations regarding third parties as this goes hand in hand with distribution of tissues.
[624] Regulation 14 of the 2012 Tissue Bank Regulations.
[625] Regulation 15 of the 2012 Tissue Bank Regulations.
[626] Regulation 17 of the 2012 Tissue Bank Regulations.
[627] Regulations 19-21 of the 2012 Tissue Bank Regulations.

The third set of Regulations relating to banking of human material as mentioned above is the 2012 Stem Cell Bank Regulations. The 2012 Stem Cell Bank Regulations is a first-of-its-kind legal document in South Africa and was created in terms of section 68 of the NHA. The 2012 Stem Cell Bank Regulations are greatly based on and follows the structure of the 2012 Tissue Bank Regulations which is not surprising as these two Regulations were both published in the same Government Gazette. Due to the similarity, only the provisions which differ and are of relevance to this thesis will be discussed in greater detail.

Firstly, however, the overall content of the 2012 Stem Cell Bank Regulations must be mentioned in order to illustrate the aforementioned similarity. The 2012 Stem Cell Bank Regulations therefore make provision for use of stem cells;[628] the application for authorisation;[629] suspension or withdrawal of authorisation;[630] reporting obligations and keeping of records;[631] the additional health officer duties;[632] measures for inspection and control;[633] traceability;[634] data protection and confidentiality;[635] the quality and safety of stem cells;[636] the responsible person;[637] quarantine of stem cells;[638] stem cell processing;[639] storage conditions for stem cells;[640] packaging, labelling and documentation;[641] distribution of stem cells;[642] the relationship between stem cell banks and third parties;[643] appeals;[644] delegations[645] and offences and penalties.[646]

The definitions provided for by the 2012 Stem Cell Bank Regulations are the same as the 2012 Tissue Bank Regulations except for the definition of "distribution" which explicitly speaks of stem cells rather than tissue and the definition of "responsible person" which also expressly states that it pertains to a stem cell bank.[647]

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628 Regulation 2 of the 2012 Stem Cell Bank Regulations.
629 Regulation 3 of the 2012 Stem Cell Bank Regulations.
630 Regulation 4 of the 2012 Stem Cell Bank Regulations.
631 Regulation 5 of the 2012 Stem Cell Bank Regulations.
632 Regulation 7 of the 2012 Stem Cell Bank Regulations.
633 Regulation 8 of the 2012 Stem Cell Bank Regulations.
634 Regulation 9 of the 2012 Stem Cell Bank Regulations.
635 Regulation 10 of the 2012 Stem Cell Bank Regulations.
636 Regulation 11 of the 2012 Stem Cell Bank Regulations.
637 Regulation 12 of the 2012 Stem Cell Bank Regulations.
638 Regulation 13 of the 2012 Stem Cell Bank Regulations.
639 Regulation 14 of the 2012 Stem Cell Bank Regulations.
640 Regulation 15 of the 2012 Stem Cell Bank Regulations.
641 Regulation 16 of the 2012 Stem Cell Bank Regulations.
642 Regulation 17 of the 2012 Stem Cell Bank Regulations.
643 Regulation 18 of the 2012 Stem Cell Bank Regulations.
644 Regulation 19 of the 2012 Stem Cell Bank Regulations.
645 Regulation 20 of the 2012 Stem Cell Bank Regulations.
646 Regulation 21 of the 2012 Stem Cell Bank Regulations.
647 Regulation 1 of the 2012 Stem Cell Bank Regulations. Distribution is defined as "a process that includes receipt of a request for stem cells, selection and inspection of appropriate stem cells, and inspection, and subsequent shipment and delivery of stem cells to another stem cell bank, stem cell distribution intermediary, or cell dispensing service." This definition differs from definitions of the same concept in other Regulations.

In terms of the 2012 Stem Cell Bank Regulations, stem cells may not be removed, acquired, imported, preserved, stored, packaged and distributed unless this has been authorised by section 54 of the NHA[648] and has been tested for infectious agents which may cause transplantation transmittable diseases and the results of these tests are available.[649] Stem cells for autologous use need not be tested in this manner. Stem cells may also not be used for therapy, research or education unless certain requirements are met, one of which is the informed written consent of the donor of the cells. This is not required in the 2012 Tissue Bank Regulations.

A matter which is of immense concern is that, according to regulation 17 of the 2012 Stem Cell Bank Regulations, the allocation of stem cells will be determined by the Minister of Health. The first problem with such a provision is that in the South African political system Ministers are appointed by the ruling party. If stem cells as a whole or aspects of this science and its applications do not "sit well" with the party, the Minister will therefore be able to negatively influence stem cell related matters.[650] A second issue is that stem cell science is highly specialised and does not easily fit into the health priorities of a developing country such as South Africa. When competing with real and life threatening health concerns such as HIV/Aids, tuberculosis or even high infant mortality rates, stem cell related matters are bound to draw the shortest straw. Equal attention to all these competing issues in health is not possible and even more so where the concerned issue is highly technical and specialised. The provisions regarding consent are also somewhat sparse and further clarification is recommended.

5.9 REGUALTIONS REGARDING GENERAL CONTROL

Three Regulations exist on the subject of control of certain human materials, namely, the 2011 Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes,[651] the 2012 Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes[652] and the 2016 Regulations regarding the General Control

[648] See paragraph 4.2 *supra*.
[649] The tests to be run are for syphilis, hepatitis B and C and HIV type 1 and 2. Interestingly, the 2012 Tissue Bank Regulations do not contain this requirement and it is thus rather based on the 2011 Tissue Bank Regulation which does contain a similar provision in regulation 9 of the 2011 Tissue Bank Regulations.
[650] For an example of the damage that an administration is capable of doing to stem cell science, see Murugan V (2009) "Embryonic stem cell research: A decade of debate from Bush to Obama" *Yale Journal of Biology and Medicine* 82(3): 101-103.
[651] Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes of 1 April 2011. Hereafter referred to as the 2011 Control Regulations.
[652] Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes of 2 March 2012. Hereafter referred to as the 2012 Control Regulations.

of Human Bodies, Tissue, Blood, Blood Products and Gametes: Amendment.[653] The Control Regulations are very general documents and provide for various matters but they are only relevant in as far as they provide for matters concerning gametes. The reason for this is that embryonic stem cells may be derived from excess fertilised zygotes and a zygote is the union of the male and female gamete. This should, however, clearly illustrate that the Regulations would thus have very indirect implications on stem cells when keeping in mind that embryonic stem cells are being used less and less in the practice of stem cell research and therapy. The Control Regulations were, however, made in terms of the NHA and may have a bearing, albeit minimal, on stem cell related matters and must be briefly discussed here.

The 2011 Control Regulations comprise six chapters. The first provides for definitions. No new, altered or relevant definitions need to be discussed here. The second chapter deals with the procurement and use of tissue, blood and gametes from living donors. An aspect of some interest is that when studying the provisions regarding consent, regulation 2(c) states that a gamete donor may never be younger than 18 and thus cannot give his/her consent. The purposes for the removal of tissue, blood or gametes[654] as well as the institutions and persons permitted to receive donated tissue, blood, blood products and gametes[655] are further provided for by Chapter 2 of the Control Regulations.

The procurement of and use of tissue from deceased persons and provisions regarding human bodies are found in Chapter 3 of the Regulations.[656] This then further connects to chapter 4 which deals with the handling, conveyance, export and disinterment of human bodies.[657] Matters concerning the appointment and functions of inspectors of anatomy and investigating officers are found in chapter 5[658] and lastly chapter 6 provides for all remaining supplementary and general provisions.[659]

The 2012 Control Regulations brought about some changes but none of great relevance to this thesis. The 2012 Regulations contained one new definition not found in the 2011 Regulations, namely that of "artificial insemination."[660] Other definitions were omitted while some were

[653] Regulations regarding the General Control of Human Bodies, Tissue, Blood, Blood Products and Gametes of 11 May 2016. Hereafter referred to as the 2016 Control Amendment Regulations.
[654] Regulation 3 of the 2011 Control Regulations.
[655] Regulation 4 of the 2011 Control Regulations.
[656] Regulations 5-16 of the 2011 Control Regulations.
[657] Regulations 17-19 of the 2011 Control Regulations.
[658] Regulation 20-23 of the 2011 Control Regulations.
[659] Regulations 24-27 of the 2011 Control Regulations.
[660] Regulation 1 of the 2012 Control Regulations states that this means "*in vitro* fertilisation, gamete intrafallopian tube transfer, embryo intrafallopian transfer or intracytoplasmic sperm injection." This is the same as the definition provided for in the Artificial Fertilisation Regulations. See paragraph 5.2 *supra*.

slightly altered such as the definition for "tissue bank" which states that it is "an institution authorised to store tissue."[661]

The 2012 Control Regulations then continue by providing for various matters. These provisions include consent for the removal of tissue, blood and gametes from living persons;[662] the purposes for which tissue, blood or gametes may be used or blood withdrawn;[663] the institutions or persons to whom tissue, blood, blood products or gametes may be donated;[664] donations[665] and the purpose of donations;[666] the removal of donated tissue;[667] the establishment of death[668] and other matters related to the bodies of deceased persons[669] and the import and export of bodies.[670]

The greatest difference between the 2011 and 2012 Regulations is related to health officers, previously referred to as inspectors of anatomy. The 2012 Control Regulations provide for the appointment of health officers;[671] their duties[672] and reports.[673]

Lastly, the 2012 Regulations provide for general and supplementary provisions such as the prohibition of the publication of certain facts;[674] offences and penalties[675] and exclusive rights regarding bodies, tissue, blood and gametes.[676]

The 2016 Control Amendment Regulations dealt with consent for the removal of tissue, blood and gametes from living persons. It amended regulation 2 of the 2012 Regulations. It is, however, not of great importance to this thesis. It is merely necessary to note that in terms of the amendment, blood from a living person may now only be withdrawn with the written consent thereto by a person older than 16 years. No mention is made of mentally ill persons.

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[661] See paragraph 5.8 *supra*.
[662] Regulation 2 of the 2012 Control Regulations. Provision is made for competent persons above and below 18 years.
[663] Regulation 3 of the 2012 Control Regulations.
[664] Regulation 4 of the 2012 Control Regulations. A distinction is made between tissue in sub-regulation (a), blood or blood products in sub-regulation (b) and gametes in sub-regulation (c).
[665] Regulation 6 of the 2012 Control Regulations.
[666] Regulation 7 of the 2012 Control Regulations.
[667] Regulation 8 of the 2012 Control Regulations.
[668] Regulation 9 of the 2012 Control Regulations.
[669] Regulations 10-17 and 19 of the 2012 Control Regulations.
[670] Regulation 18 of the 2012 Control Regulations.
[671] Regulations 20 and 21 of the 2012 Control Regulations
[672] Regulation 22 of the 2012 Control Regulations.
[673] Regulation 23 of the 2012 Control Regulations.
[674] Regulation 24 of the 2012 Control Regulations.
[675] Regulation 25 of the 2012 Control Regulations.
[676] Regulation 26 of the 2012 Control Regulations.

5.10 REGULATIONS RELATING TO BLOOD AND BLOOD PRODUCTS

The 2011 Blood Product Regulations was the first document to deal specifically with this topic and although not pertinent to the issue of stem cells, do supplement section 53 of the NHA[677] in regulations dealing with blood transfusion services. Previously, prior to a separate definition being provided, it was thought that stem cells might be included under blood products. This would, however, be scientifically incorrect and therefore these Regulations are not intended to read as including stem cells under this term.[678] The 2011 Regulations, however, no longer stand alone and what follows is a brief discussion of the 2011 Regulations relating to Blood and Blood Products[679] and the 2012 Regulations relating to Blood and Blood Products.[680] Only the most relevant regulations will be discussed here.[681]

The 2011 Regulations provided for new definitions not previously defined in the NHA. They are:[682]

1. Allogenéic donations: "the administering of blood or blood products to a person which has been donated by another person;" and
2. Autologous donations: "The donation of blood by a person for the later administering thereof to the same person."

Regulation 2 provides for the licensing of the national blood transfusion service. Only the blood transfusion service may:[683]

1. Be involved in the withdrawal of blood or a blood product from a living person, intended for the later administration thereof to that same person or to any other person;[684]
2. Store, preserve, process, test, separate or supply or dispose of, in any manner, blood withdrawn or imported, intended to be used as whole blood or as a blood products;
3. Produce, pack, seal and label a blood product or supply or dispose of a blood product;
4. Be involved in the withdrawal of stem cells, but not embryonic stem cells, from a living person intended to be administered to that person or another person at a later stage; or
5. Store, preserve, test, process, separate, supply or dispose of progenitor cells withdrawn or imported.

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677 The establishment of a national blood transfusion service.
678 See paragraph 4.2.10 *supra*.
679 Regulations relating to Blood and Blood Products of 1 April 2011. Hereafter the 2011 Blood Product Regulations.
680 Regulations relating to Blood and Blood Products of 2 March 2012. Hereafter the 2012 Blood Product Regulations.
681 In general, the 2011 Blood Product Regulations is divided into three chapters namely "Definitions and blood transfusion service;" "Acquisition, testing, requisition and administering of blood and blood products" and "General provisions."
682 Regulation 1 of the 2011 Blood Product Regulations.
683 Regulations 2(1) and (2) of the 2011 Blood Product Regulations.
684 See the definitions of autologous and allogenéic donations.

The blood transfusion service must conduct these activities in accordance with the Regulations and must adhere to the minimum requirements as set forth in the service's standard operating procedures.[685] The regulations pertaining to the permissible activities are not intended to hinder a medical practitioner or dentist from performing their duties and do further not apply to blood products not intended as therapeutic or prophylactic substances for human application.[686] A blood transfusion service is subject to oversight by the Director-General as provided for by regulation 3.[687]

Lastly, section 53 of the NHA is supplemented by regulation 7. A blood transfusion service must be run as a non-profit organization,[688] must be headed by a medical practitioner as medical director who takes full responsibility for the facility, must provide adequate clinical consultations facilities and must be reimbursed for services rendered.

The 2012 Blood Product Regulations brought about no major amendments except for a few slight changes in wording and omission of previously provided for definitions. It is interesting to note that among these altered definitions is the definition of "stem cell." The 2012 definition reads that a stem cell is "a cell that has both the capacity to self renew as well as to differentiate into mature, specialised cells."[689]

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[685] Regulation 2(3) of the 2011 Blood Product Regulations.
[686] Regulation 2(4) of the 2011 Blood Product Regulations.
[687] Regulation 3 reads as follows: **"Oversight of Blood Transfusion Services-**
(1) If the Director-General is of the opinion on the strength of an inspection, report or recommendation contemplated in regulation 6(1) by a health officer that there are reasonable grounds to suspect that -
(a) any premises or equipment used by a blood transfusion service or authorised institution or any of its constituent parts, as the case may be, for the purposes of any of the activities is in a way hazardous to health, or that conditions constituting a hazard to health have been or are being created in or upon such premises; or
(b) the blood transfusion service or authorised institution is not complying with these regulations or the standards of practice; the Director-General may serve a written notice, instructing the person in charge of such premises or equipment, to furnish reasons, at a place and time specified in such notice, why the matter should not be dealt with in terms of sub-regulation (3).
(2) A notice referred to in sub-regulation (1) shall set out such particulars as are reasonably adequate to inform the blood transfusion service or authorised institution why the suspension, revocation or withdrawal of the license is contemplated, and shall be served by the Director-General not less than 21 days prior to the date specified in such notice.
(3) If it still appears to the Director-General after consideration of the reasons furnished in terms of sub-regulation (1) that-
(a) the premises or equipment referred to in sub-regulation (1) is hazardous to health or that conditions constituting a hazard to health have been or are being created in or upon such premises; or
(b) the licensee does not comply with the provisions of the Act,
these regulations or the standards of practice; the Director-General may recommend to the Minister that a license be suspended or revoked."
[688] As incorporated under section 21 of the Companies Act, Act 71 of 2008.
[689] Regulation 1 of the 2012 Blood Product Regulations. Previously provided for by regulation 1 of the 2011 Blood Product Regulations, this definition read "any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, haemopoietic progenitor cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell."

The 2012 Blood Product Regulations then continue by making provision for licensing of the national blood transfusion service;[690] oversight of Blood Transfusion Services;[691] appointment of health officers;[692] duties of the health officer;[693] blood transfusion services;[694] the recruitment of blood donors;[695] mandatory testing of donated blood and blood products;[696] requisition and administering of blood and blood products;[697] autologous and designated donations;[698] record of donors, donations, containers, statistics and untoward reactions;[699] standards of practice for blood transfusion in South Africa;[700] offences and penalties[701] and the repeal of regulations.[702]

6 CONCLUSION

The purpose of this chapter was a dissection and investigation into the sections of the NHA which are relevant to this thesis. As such the body of law as found in the NHA as it stands, and the relevant Regulations made in terms of the Act pertaining to stem cells and consent were discussed. This chapter then also argued that interpretation of certain provisions of the NHA already lean towards a dynamic consent as introduced in this thesis.

In the course of this chapter, it was explained that the NHA represents a paradigm shift in the medico-legal environment of South Africa. It is the bridge by which the health system in this country will connect and interact with the systems of other, more advanced countries by bringing the South African system up to date. This will ultimately benefit all South Africans as users of the health system. Furthermore, the NHA is deemed as the legislative tool whereby stem cells and related activities will be regulated in South Africa.

The NHA, a complex legislative document, entrenches various policy principles which have been developed over many years and it fundamentally alters the manner in which South African

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690 Regulation 2 of the 2012 Blood Product Regulations. The regulations state that no other organisation, institution or person may withdraw stem cells except embryonic stem cells from a living person and administer it to another person. This raises some questions as to the role of stem cell institutions and banks which will have to be clarified by the legislator.
691 Regulation 3 of the 2012 Blood Product Regulations.
692 Regulation 4 of the 2012 Blood Product Regulations. Previously provided for by regulation 4 of the 2011 Blood Product Regulations which spoke of an inspector rather than health officer who was appointed by the Director-General rather than the Minister.
693 Regulation 5 of the 2012 Blood Product Regulations. Previously provided for by regulation 5 of the 2011 Blood Product regulations and referred to as the powers of the inspector.
694 Regulation 7 of the 2012 Blood Product Regulations.
695 Regulation 8 of the 2012 Blood Product Regulations.
696 Regulation 9 of the 2012 Blood Product Regulations.
697 Regulation 10 of the 2012 Blood Product Regulations.
698 Regulation 11 of the 2012 Blood Product Regulations.
699 Regulation 12 of the 2012 Blood Product Regulations.
700 Regulation 13 of the 2012 Blood Product Regulations.
701 Regulation 14 of the 2012 Blood Product Regulations.
702 Regulation 15 of the 2012 Blood Product Regulations. The 2012 Blood Product Regulations and 2011 Regulations both repeal the Regulations published in this regard in Government Gazette No.1935 of 26 February 1993.

health policy will be formulated in the future. At the heart of this Act lies the objective of uniting the health system of South Africa in order to improve universal access to quality health care. The Preamble of the Act recognises "the socio-economic injustices, imbalances and inequities of health services in the past; the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and the need to improve the quality of life of all citizens and to free the potential of each person." This confirms that the NHA wishes to unify the various components of the South African health system and further, to provide internationally recognised, equitable and efficient health care.

The NHA is furthermore in line with the Constitution and is based strongly thereon. This renders it "the most important piece of legislation in the health sector." This alignment with the Constitution further emphasises the revolutionary nature whereby policy will from now on be formulated. The NHA, for example, includes the right to emergency medical treatment, children's rights to basic health services and the right to an environment which is not harmful to the health or well-being of a person.

The NHA, with its spirit of transformation, replaced the last remaining vestiges of apartheid era health policy. In this chapter, certain Acts relating to health were discussed as the ancestors of the NHA with specific mention of the contribution to consent as found in these Acts. Prior to the enactment of the NHA, matters pertaining to health in South Africa were regulated firstly by the Public Health Act of 1919 and thereafter by the Health Act of 1977. The Health Act, before being repealed completely, was conservative at best and contained no provisions mindful of the user of health care services. This is blatantly obvious as no mention was made regarding consent. As it predates the Constitution, this is, however, not surprising. As was mentioned, the Constitution has rendered this Act superfluous. Some development was made by the creation of the Tissue Act of 1983. The Tissue Act was slightly more "user friendly" and leaned towards patient autonomy but still contained provisions tainted by paternalism. In spite of this, the Tissue Act broadened the legislative scope of health legislation and dealt with various new matters. Due to this, the NHA would in later years be based to some extent on the foundation as set out by this Act. It was, however, repealed by the coming into force of Chapter 8 of the NHA. Lastly, the Choice on Termination of Pregnancy Act of 1996 was discussed. This Act, which has not been repealed by the NHA, made a break from paternalism and may be described as a high point in patient autonomy. It is very liberal in nature and stands as a worthy counterpart to the NHA in regulating certain aspects of health care. The journey from the Public Health Act to the NHA has, however, been slow and tedious and many mistakes have been made in the process.

The NHA clarifies, to an extent, the legality of human cloning as well as that of stem cell research and therapy. Unprecedented protection is offered to researchers. Ethics guidelines and the adjudication of complaints by the National Health Research Ethics Council will promote thorough research protocols and protocol reviews. Overall Chapter 8 of the NHA is a good point of departure for the regulation of any biotechnology in South Africa. It is after all the first attempt at legislation of this kind in this country. As such, the NHA was drafted as framework legislation which allows for more detailed and technical matters to be addressed in subordinate legislation. As was mentioned in the course of this thesis, a process of "fine tuning" may be observed in the various Regulations, which allows for a glimmer of hope that the regulatory framework may be on the road to redemption. It, however, still has a way to go.

The development of the NHA and the subordinated legislation made in terms thereof have unfortunately fallen prey to some of the same mistakes made in the development of its predecessors as it is slow in development and often anachronistic. Also, in spite of the positive changes brought about by the NHA, it is still subpar legislation in context of stem cells as it lacks a basic understanding of the science which it wishes to attempt to regulate. This remains a troubling thought.

An attempt to remedy this led to the drafting of numerous Regulations as discussed in this chapter. The Regulations were discussed in a manner which "lumped" them together based on the commonality of their subject matter. From 2003 to 2016, a mass of legal documents have been drafted and published but this has unfortunately led to a disjointed and fragmented regulatory environment wherein stem cells are supposedly meant to be controlled and regulated. The NHA, read together with the Regulations, therefore has the opposite effect of unification and it could be said that the provisions do not harmonise or see eye to eye. This may be illustrated by the differing definitions of certain terms. This makes determining the legal position of certain aspects a more complicated task but it is not impossible. The NHA is still in need of some work but for now, the NHA as is will have to do. It is daunting to imagine how much more time will lapse should an attempt at a proper or relevant amendment be made. It is, however, strongly suggested that a system whereby this specific matter, that of stem cells, may be legislated in a fast and efficient manner be devised. It is suggested that perhaps a system of institutional self-regulation might be the most fitting manner of regulating this science. In the course of this thesis, attention will be given to the model of regulation of stem cells and related technology in the United Kingdom. This will serve as an example of such a system of independent regulation by a statutory body. Some of the first aspects which will have to be addressed by such a system should be providing for adult stem cell specific regulatory measures

and the drafting of a guideline, at least, for the process whereby consent must be obtained. It is hoped that this thesis contributes to that debate.

In context of the ultimate objective of this thesis, certain sections are of more importance and some attention must once again be given thereto at this juncture. These sections are section 6, which provides the user with the right to be informed of all relevant aspects; section 7, which requires the consent of the user; section 8, which allows the user to participate in decision making regarding treatment; section 11, which regulates health services for experimental or research purposes and section 71, which regulates experimental or research health related activities involving human subjects. It may be noted that these sections are not found in Chapter 8 of the NHA. Chapter 8 was discussed as a necessary part of the debate and background to stem cell regulation in South Africa, but for the purpose of this thesis and the arguments made that firstly, the informed consent format is insufficient and secondly, that stem cell therapy patients are better described as research participants, the provisions found in chapters 2 and 9 of the NHA become more relevant. Also, only the most pertinent Regulations are referenced in the following discussion.

Section 6 requires the user to have full knowledge and is therefore an example of a consumer-orientated provision of the NHA. This section, while taking into account the literacy of the user, requires that he or she must be informed of their health status; the available diagnostic and treatment options; the risks, consequences and costs of the discussed treatment options and their right to refuse treatment. In the event of such refusal, the implications and risks of their refusal must then also be explained to them.

It was argued in the course of this chapter that although stem cell treatment is not generally available it may well be some day in the future. Where and when it is, however, available the user must be informed of the treatment method and side effects. This thesis, however, posits that stem cell therapy is equal to research involving human subjects and therefore it is perhaps closer in nature to a health service for research purposes, for example, as envisioned in section 11 of the NHA. If this is to be accepted, the experimental nature of the treatment must be explained to the user. Returning to the application of section 6, however, the user will have to be informed of the potential consequences or risks and benefits as well as costs of treatment or refusal. This is trite common law as enunciated fully in the *Castell* case which was discussed previously.

Section 6 of the NHA is then supplemented by the Human Subjects Regulations and in particular regulation 6 of the 2007 Regulations, which provide for specific consent guidelines. Although regulation 6 provides for research scenarios, it is applicable as this thesis hypothesises that

stem cell treatment is research and therefore a patient is a research human subject which then brings the patient-participant under the jurisdiction of the Human Subject Regulations.

This regulation, as was mentioned, is of immense importance for the purpose of this thesis as it created a framework of recommendations for the proper procedure of obtaining consent. It recognises the complexity of consent in situations such as stem cell therapy-research and, it is suggested, provides a checklist of sorts of requirements for aspects which must be included in the process of obtaining consent. Regulation 6 requires that where a person participates in a research study, they must be informed of the purpose of the research; the treatments and possibility of random assignments of each treatment where the research involves treatment; the methods and procedures to be followed or used in the course of the research; any alternatives other than participating in the proposed research; potential or real harm and risks involved in participating in the study; the expected benefits to themselves and others as a result of the research; the extent to which their confidentiality and privacy will be protected; any available insurance in the event of injury or damage which may arise from participation; the contact details of a person in the event of such a research related injury; the given participation incentives as well as any differences in incentives; the participant must be informed of the availability of treatment beyond the duration of the trial in the event of clinical trials; sponsors details, if any, and any potential conflict of interests and lastly proof of ethics committee approval.

These prescriptions must be included in the dynamic consent format which is introduced in the course of this thesis. This would mean that should any of the above-mentioned aspects alter, the patient-participant must be informed thereof and allowed an opportunity to adjust their consent preferences accordingly.

According to section 7, a health service may not be rendered without the informed consent of the user, subject to section 8. Circumstances do, however, exist wherein the consent prerequisite may be excused and in these instances such as where the user is unable, proxy consent may be obtained, the health service is authorised by law, the service is in the interest of public health, or a delay in the rendering of the treatment may lead to death or irreversible damage.

It was stated in the course of the discussion of section 7, as well as previously in this thesis, that consent in context of medical interventions is understood as informed consent. Section 7(3) provides for a definition of informed consent and describes this as meaning “consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6.” It is suggested that support for the hypothesis

of this thesis, specifically the posed argument that informed consent is an insufficient consent format in context for stem cell therapy as the efficacy thereof is yet untested, may thus be found in section 7. Stem cell therapy is still so uncertain that a user cannot consent to a *specified* health service, meaning that, by definition, a user cannot give informed consent to stem cell treatment. A second conclusion which might be drawn from this is, once again, that stem cell treatment might be better suited under section 11 of the NHA which provides for health services for experimental or research purposes.

The Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics contained one of the first subsequent definitions of informed consent, which definition already indicated an improvement. According to the Regulation, informed consent may be understood as "an agreement by which a participant, donor or health care user voluntarily confirms his or her willingness to participate in research, donation or treatment, after understanding all aspects of such research, donation or treatment that are relevant to his or her decision."

This definition at least foresees the possibility of research as an additional activity to treatment. However, it is still held by this thesis that informed consent is an insufficient consent model. This is emphasised by the fact that the Regulation's definition requires that a participant or donor must understand *all* aspects. As has been explained throughout the course of this thesis, this is not possible in regard to stem cell treatment.

Section 8 gives a user the right to participate in a decision affecting their personal health and treatment. In context of this thesis, this may also be interpreted as being in support of a dynamic consent process as this entails engaging a patient-participant in decision making at every level and in a continuous manner.

Section 11 is the second of three different sections providing for health research activities. In the above discussion, it has been mentioned that stem cell treatment might sit more comfortably under section 11 of the NHA which provides for health services for experimental or research purposes. The reason for this is that prior to the provision of the health service, the user must be informed that the service is being rendered for experimental or research purposes in whole or partly. This means that from the onset, there exists a shift in perception regarding the nature of an intervention. This is in line with the argument of this thesis that stem cell treatment borders on, or is, research which then involves human subjects.

Additionally to the requirement that a user be informed that the service rendered is for experimental or research purposes, the user must grant their prior written authorisation thereto. Although "authorisation" is not expressly defined in the NHA, the term generally denotes the giving of permission or consenting to an action. In fact, in Scotland this term is used rather than making use of the term "consent" as will be shown in the course of this thesis. It is suggested that the failure to specify a particular format of consent in these instances of health services for experimental or research purposes, or then where therapy borders research, may be interpreted to support the notion that a new format of consent may be better suited than informed consent or broad consent.

From the title of section 11, it becomes clear that it provides for a specific type of health service namely experimental or research health services. Health services whose efficacy has been proven are thus excluded from the application of this section, confirming the assertion that stem cell treatment should fall under the regulatory ambit of section 11. The implications of this are that a patient-participant must be informed of the experimental nature of the therapy-research study and must understand that the health service is much more than a mere or traditional medical intervention. A patient-participant must therefore be informed that the stem cell treatment they are to receive is experimental in nature and is for research purposes.

In the same manner as the intervention becomes a fusion of medicine and science, so too does the role of the persons involved and as such a health service user is no longer a traditional patient but rather a patient-participant. The Regulations Relating to Human Subjects and Participants are therefore relevant and supplement section 11.

As they relate specifically to section 11 and the issue of consent, the 2007 Regulations state that a participant must be well informed and make informed decisions. This is in concordance with the requirement of informing the patient-participant that the health service is for research or experimental purposes. The 2013 Regulations expressly require that the bodily integrity of the patient-participant be respected and this is in line with the section 12(2)(c) of the Constitution which also provides the right to consent prior to medical or scientific experimentation. Lastly, the 2014 Regulations provide that health research which involves human subjects is dependent on the appropriate consent and that a patient-participant has freedom of choice regarding their participation in research. This means that where a potential patient-participant is informed that the proposed stem cell therapy is experimental in nature and thus for research purposes, they retain the freedom to decide to participate or to withdraw from the research.

As was mentioned in the course of this chapter, section 71 is the third of three sections pertaining to health research and it provides for the specific category of research or

experimentation with human subjects. According to section 71(1), research or experimentation which involves human subjects may only be conducted once the objects of the research have been explained to the participant and consent has been obtained. The NHA does not specify the type or format of consent to be obtained in these instances and it is argued that, in context of this thesis, this opens the door or suggests that the dynamic model of consent introduced in this thesis may be appropriate.

Subsections 71(2) and (3) provide for research involving minors and distinguish between therapeutic and non-therapeutic research. It was argued in the course of the discussion of section 71 that this division between therapeutic and non-therapeutic research, especially in context of stem cell related activities, should fall away. Working from this premise, it then becomes possible to combine the requirements of the individual subsections in order to establish one cohesive set of requirements for research involving minor subjects. It is therefore suggested that participation must be in the best interests of the minor, it may be conducted only in and under the prescribed manner and under the conditions, with consent of the parent or guardian of the minor, with the consent of the minor where the minor is capable of understanding all relevant aspects of their participation and with Ministerial consent where appropriate.

The fine grained aspects related to human subject health research, such as when Ministerial consent is required and/or appropriate, may then be provided for in Regulations. As such, the Regulations relating to Research on Human Subjects offer valuable supplementation to section 71. The 2007 Regulations require that the research participant must be well informed and must make an informed decision regarding their participation. Aspects of which the subject must be informed are the risk and benefits in participating and to this end the Regulations require that the risks and benefits of a research study must be analysed prior to the research being undertaken and that it is subject to an independent review of an ethics committee.

Section 71 makes no mention of mentally impaired persons and this aspect is addressed in the Regulations. Research involving such mentally impaired persons which necessitate their involvement, must be sufficiently justified, proper procedures for evaluating and confirming that the participant is truly incapable of giving informed consent must be in place, it must be ensured that the given consent was free from coercion and also that no or minimal risk is involved. Where minimal risk is involved, the anticipated benefits to the participant must outweigh the risk.

The Regulations expressly mandate that informed consent be obtained from the donor of stem cells prior to stem cell research or therapeutic cloning. In context of this thesis, it is argued that

informed consent is not appropriate in instances of stem cell research as the scope of the intervention is uncertain and a dynamic format should be utilised. In instances of therapeutic cloning however, informed consent may be sufficient as the efficacy and therefore the scope or ambit of the procedure or intervention has been determined and the required information may thus be provided in order to render the consent informed. Lastly, the 2007 Regulations require that all health research studies involving human participants be reviewed by a registered health research ethics committee.

The most substantial contribution of the 2013 Regulations was the recognition of the consent of a legally authorised person on behalf of a research subject. Lastly, the 2014 Regulations reiterated the requirement of appropriate consent prior to health research involving human subjects being undertaken. The failure to specifically mention a preferred consent format, once again, may be interpreted as suggesting that neither informed nor broad consent is suitable. The Regulations also stipulate that a participant has the freedom to withdraw from participating. In context of this thesis, this may be seen to support the notion that consent is a flexible concept which is not stagnant and that it must be responsive to the changing preferences of the patient-participant.

Lastly, it is necessary to discuss again the Regulations relating to Human Stem Cells of 2007. The 2007 Stem Cell Regulations are of great importance as they provide for numerous regulatory measures pertaining to stem cell related activities. The Regulations were discussed in detail in the course of this chapter and at this juncture attention is given to the consent related provisions.

Informed consent must be obtained from the donor of stem cells which are intended for therapeutic, research or educational purposes and these stem cells must have been donated voluntarily. The informed consent forms must be included in any stem cell donor records. In context of this thesis it is suggested that informed consent is not appropriate and that this must be replaced by a more dynamic consent format. The requirement of keeping records of consent will also be greatly aided by the format as introduced in the course of this thesis.

In the following part of this thesis, attention will be given to the international regulation of stem cells with focus on consent in both therapeutic and research settings. This will entail a discussion of international documents and law on these matters in the form of the various relevant instruments and guidelines of the United Nations; United Nations Educational, Scientific and Cultural Organisation; World Medical Association; World Health Organisation and the African Union.

PART C
INTERNATIONAL STANDING OF CONSENT

Part B set out the South African position as it relates to consent which included a discussion of the Constitution. The Constitution, however, mandates international legal comparison. Part C of this thesis focusses on international law which means rules and principles binding States to one another as well as a universal body of law to which States must adhere to create global unity and conformity.

Part C therefore has a dual purpose as it endeavours to examine and discuss relevant international instruments thoroughly as well as to explore the manner whereby international law informs domestic law and policy by prescribing globally accepted principles and standards. Part C winnows from a broad discussion of international instruments to specific examinations of the consent provisions found within these instruments.

In context of this thesis which aims to introduce a new model of consent in situations of medical treatment-research involving human subjects, it is necessary to assess the possibility of being guided by international instruments. A broad spectrum of instruments will be discussed as this thesis also argues that the person involved in therapy-research may be better described as a patient-participant. Instruments pertaining to both medical as well as research issues are therefore relevant. Part C includes an analysis of instruments created by the United Nations; the United Nations Educational, Scientific and Cultural Organisation; the World Medical Association; the World Health Organisation and the Council for International Organisations and Medical Sciences. Instruments created by the African Union are also dealt with. This part concludes with the insights gained into consent through these instruments.

Part C of this thesis consists of the following:

CHAPTER 6 - CONSENT IN INTERNATIONAL INSTRUMENTS

CHAPTER 6
CONSENT IN INTERNATIONAL INSTRUMENTS

1 INTRODUCTION

According to the South African Constitution, the legal community in this country has an imperative mandate to make use of comparative law in that international law must be considered in developing and interpreting human rights. International law may be understood as rules and principles which bind States to one another but it is also a universal body of law which all States must, legally or morally at least, adhere to in order to create global unity and conformity.[1] This will allow for the best cooperation between countries and optimal protection of legal subjects.

The object of this chapter is twofold as is endeavours to provide firstly, a thorough examination and discussion of relevant international instruments in order to gain knowledge and insight into these instruments, to draw inspiration therefrom and to examine the international regulatory environment regarding medicine and research involving humans. Secondly, it explores the manner in which international law determines and informs our domestic law or even policy. To achieve the general object of this thesis, a comparative study in context of consent is necessary and a comprehensive understanding of the international environment is therefore required. The specific object is the introduction of a model of consent for situations of medical therapy which are tantamount to scientific interventions involving humans. In order to assess the possibility of being influenced and informed by international instruments in the development of a valid model of consent, various international instruments will be discussed and examined in the course of this chapter. At the start of this chapter, an overview and definition of international law will be provided in order to establish some certainty as to what is meant by "international law instruments."

As was mentioned previously, the Constitution creates a mandate to make use of comparative law. To this end, sections 39 and 231 of the South African Constitution of 1996 are analysed in order to determine and illustrate the importance and motivation behind a comparative study of

[1] See in general, Andorno R (2002) "Biomedicine and international human rights law: In search of global consensus" *Bulletin of the World Health Organization* 80(12): 959-963.

international law. In context of this thesis, the human rights enshrined in the Bill of Rights are relevant. It will be shown that international law must play a role in the interpretation of these human rights since ethical guidelines alone are insufficient as they have no force of law. Ethical guidelines rely on professional sanctions and non-legal means, while human rights law, such as international human rights has monitoring and implementation systems in place which may be enforced.[2] Among these human rights, informed consent or the rights on which it is based at least, such as autonomy, integrity and dignity, may be found. Due regard must be paid to international experiences and international instruments therefore hold great informative and comparative value. This will also be illustrated in the discussion of section 233 of the Constitution in the course of this chapter. This section requires that a reasonable interpretation of legislation which is consistent with international law should prevail over one which is not. The *Makwanyane* and *Bernstein* cases[3] will also be mentioned.

This is followed by an explanation of the various different role players in the international arena wherein the United Nations (UN), United Nations Educational, Scientific and Cultural Organisation (UNESCO) including the International Bioethics Committee (IBC), the World Medical Association (WMA), the World Health Organisation (WHO) and the Council for International Organisations and Medical Sciences (COIMS) as well as the African Union (AU) will be dealt with. These entities are discussed since South Africa is a Member State thereof and is therefore bound to the instruments they create. The documents, guidelines and principles issues by these organisations will therefore have an influence on South African legislation.

The international instruments relevant in context of this thesis will then be examined and discussed. They include the Nuremburg Code, International Bill of Rights, the Declarations of the Rights of the Child and on the Rights of Disabled Persons, the Convention on the Rights of a Child, the Universal Declaration on the Human Genome and Human Rights and the International Ethical Guidelines for Biomedical Research Involving Human Subjects as well as the Universal Declaration on Bioethics and Human Rights and the Convention on the Rights of Persons with Disabilities. Also, the Declarations of Geneva and of Helsinki will be discussed. Lastly, attention is given to the African Charters on Human and Peoples' Rights and on the Rights and Welfare of the Child as well as the African Bioethics Resolution.

At the conclusion of this chapter, the insights gained into consent as gleaned from these instruments will be provided. These concluding insights will form the broad basis or philosophy whereon a dynamic model of consent in human subject medical and scientific research

[2] Nienaber A (2007) "The utility of international human rights law on informed consent in the protection of clinical research participants in Africa: 'The road less travelled'" *SA Publiekreg/SA Public Law* 22: 427.
[3] *S v Makwanyane* 1995 (3) SALR (CC) and *Bernstein v Bester* 1996 (2) SALR 751 (CC).

interventions may be developed. In order to understand the role and influence of international instruments, however, some clarity must be provided as to what constitutes international law and the instruments thereof.

1.1 DEFINING INTERNATIONAL LAW

International law may be defined as a body of rules and principles which bind or regulate States in their relationships with one another.[4] These rules may be divided into general rules, which are binding on all States, and particular rules which is international law, created by only a few States. In the early days of international law, it concerned itself with States only but today there are various other actors or role players on the international stage, such as the United Nations and its specialised agencies, and since 1949 it has been accepted that these international organisations enjoy international legal personality.[5]

This chapter deals with international instruments which should not be confused with the sources of international law. There are four sources of international law, namely international conventions or treaties; customary international law; the general principles of law recognised by civilised nations and judicial decisions and teachings.[6] International instruments consist of treaties and other documents relevant to international law and the protection of human rights in general. Two categories of instruments are identifiable, namely declarations and conventions. Declarations are adopted by bodies such as the United Nations General Assembly and are not legally binding but may function as soft law.[7] A declaration may become customary international law over time. Conventions are legally binding instruments of international law.[8] Furthermore, international instruments may be divided into global and regional instruments. Any State in the world may become party to a global instrument, such as the Universal

[4] Dugard J (2011) *International law: A South African perspective*: 1. See also Strydom H & Hopkins K (2008) "International Law: Chapter 30" in Woolman S & Bishop M (eds) *Constitutional Law of South Africa*: 30-1.
[5] It is important to mention, however, that States and inter-governmental organisations are the primary actors in the international community and the only true entities with real international personality and so the principal creators of international law rules.
[6] Article 38 of the Statute of the International Court of Justice 1946 identifies the sources of international law by stating the following: "1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting States; (b) international custom, as evidence of a general practice accepted as law; (c) the general principles of law recognized by civilized nations; (d) subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law."
2. This provision shall not prejudice the power of the Court to decide a case *ex aequo et bono*, if the parties agree thereto." See also Strydom & Hopkins (2008) in Woolman & Bishop (eds) 30-3.
[7] An example of such a declaration is the Declaration on the Rights of a Child which is discussed in paragraph 3.2.3 *infra.*
[8] An example of such a convention is the Convention on the Rights of a Child which is discussed in paragraph 3.2.5 *infra.*

Declaration of Human Rights,[9] while regional instruments are restricted to States in a particular region of the globe such as the African Charter on Human and Peoples' Rights.[10]

In the decades since the Second World War, numerous treaties have been drafted which extend various international law protections to individuals.[11] These human rights instruments impose obligations on the signatory States to afford their citizens these protections and in so doing, millions of people have become the beneficiaries of international law.[12] In South Africa, the Constitution itself echoes the language found in numerous international human rights instruments as will be evidenced in the course of this chapter. Moreover, international law is a mandatory canon of constitutional interpretation according to section 39 of the Constitution of the Republic of South Africa as will be discussed in the course of this chapter.[13] Prior to discussing the section 39 mandate, however, some attention must be given to the relationship between national and international law.

The relationship between domestic and international law is a complex one and may be approached from two different angles. The first is the monist approach and holds that international law and domestic law are not different and must automatically be regarded as a single legal concept.[14] Monists thus argue that domestic courts are obligated to directly apply international law as it does not require an act of adoption. The second approach is the dualist one which sees international law and domestic law as completely different systems of law and therefore international law may only be applied in domestic courts where it has been adopted or transformed into domestic law by legislation.[15] South Africa follows a combined approach which is closer to the "harmonization theory"[16] which states that, in cases of conflict between international and domestic law, a domestic court must follow the law of the country.

South Africa has a long history of comparative law and the most well-known example of this is the Constitution of the Republic of South Africa, which was influenced and inspired by *inter alia* Canadian, German and United Kingdom law.[17] It is of little wonder then that the Constitution itself makes express provision for the application or consideration of international law. In total there are four relevant provisions which may be divided into two groups. The first relates to the

[9] See paragraph 3.2.1.1 *infra.*
[10] See paragraph 3.4.1 *infra.*
[11] Strydom & Hopkins (2008) in Woolman & Bishop (eds) 30-3.
[12] Dugard (2011) 1
[13] See paragraph 1.1.1 *infra*.
[14] Moseneke D (2010) "The role of comparative and public international law in domestic legal systems: A South African perspective" *Advocate* 23: 63.
[15] Dugard (2011) 42.
[16] *Idem* 43.
[17] See in general, Davis DM (2003) "Constitutional borrowing: The influence of legal culture and local history in the reconstruction of comparative influence: The South African experience" *International Journal of Constitutional Law* 1(2): 181-195.

manner whereby international law may be adopted or incorporated into South African domestic law to become part of our substantive law, namely sections 231 and 232 of the Constitution. The second relates to the influence that international law may have on interpreting domestic law as provided by sections 39 and 233 of the Constitution. These sections are discussed in the course of this chapter.

As mentioned previously, South Africa follows a mixed approach to the adoption of international law. Section 231 follows a dualist approach to incorporating international law and requires certain acts of adoption before international agreements will be binding in the Republic.[18] The rationale behind the dualist approach flows from the concept of *trais politica*, or the doctrine of the separation of powers.[19] The dualist approach was confirmed in the case of *Azapo v President of the Republic of South Africa*[20] wherein Mohamed DP stated that "international conventions and treaties do not become part of the municipal law of our country…until and unless they are incorporated into the municipal law by legislative enactment."[21] Section 232 on the other hand follows a monist approach by stating that customary international law is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.[22] International law is therefore subordinate to the Constitution[23] and so it is important to examine here the relationship between the Constitution and international law.

1.1.1 Sections 39 and 233 of the Constitution: A Comparative Imperative

At this juncture, the question may be raised as to why an examination of international law and instruments is necessary and how this relates to consent.[24] In recognising the important influence that international human rights law and instruments have on domestic law, section

[18] Section 231: "**International agreements -**
(1) The negotiating and signing of all international agreements is the responsibility of the national executive.
(2) An international agreement binds the Republic only after it has been approved by resolution in both the National Assembly and the National Council of Provinces, unless it is an agreement referred to in subsection (3).
(3) An international agreement of a technical, administrative or executive nature, or an agreement which does not require either ratification or accession, entered into by the national executive, binds the Republic without approval by the National Assembly and the National Council of Provinces, but must be tabled in the Assembly and the Council within a reasonable time.
(4) Any international agreement becomes law in the Republic when it is enacted into law by national legislation; but a self-executing provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.
(5) The Republic is bound by international agreements which were binding on the Republic when this Constitution took effect."
[19] Strydom & Hopkins (2008) in Woolman & Bishop (eds) 30-9.
[20] *Azapo v President of the Republic of South Africa* 1996 (4) SA 671 (CC).
[21] *Azapo v President of the Republic of South Africa supra* paragraph [28].
[22] It is noteworthy that sections 231 and 232 of the Constitution distinguish customary international law.
[23] Strydom & Hopkins (2008) in Woolman & Bishop (eds) 30-7.
[24] See in general, Nienaber (2007) 422-443.

39(1)(b) of the Constitution mandates the consideration of international law in the interpretation of the Bill of Rights.[25] Section 39 reads:

> "(1) When interpreting the Bill of Rights, a court, tribunal or forum—
> (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom;
> (b) must consider international law; and
> (c) may consider foreign law.
> (2) When interpreting any legislation, and when developing the common law or customary law, every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.
> (3) The Bill of Rights does not deny the existence of any other rights or freedoms that are recognised or conferred by common law, customary law or legislation, to the extent that they are consistent with the Bill."

International law must therefore play its part in the interpretation of human rights within South Africa. In context of this thesis the particular human right as enshrined in the Bill of Rights is the right not to be subjected to medical or scientific experiments without informed consent.[26] The concept of informed consent therefore requires study and interpretation which considers international law. International instruments may therefore be of great informative and comparative value in attempting to formulate or develop a valid model of consent. Due regard must therefore be paid to the principles which may be extracted from international experiences.[27] Read together with section 233 of the Constitution, it becomes even clearer that a comparative analysis of international instruments is essential in any attempt at developing the South African legal *corpus* as it reads that "when interpreting any legislation, every court must prefer any reasonable interpretation of the legislation that is consistent with international law over any alternative interpretation that is inconsistent with international law."

Chaskalson P, in the course of the *Makwanyane* decision[28] stated that comparative jurisprudential analysis is of importance in the early stages of developing indigenous jurisprudence in a branch of law.[29] This was echoed in the case of *Bernstein v Bester*,[30] where Kriegler J remarked that "comparative study is always useful"[31] and particularly so where foreign jurisdictions have also grappled with whatever issues at hand. From this it therefore becomes apparent that comparative legal studies are valuable and may, where appropriate, provide guidance in establishing legal norms. It is therefore clear that international law and instruments must be considered and for this reason attention must at this juncture be given to the creators of international law and instruments and the instruments themselves.

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[25] See in general, Dugard J (1997) "International law and the South African Constitution" *European Journal of International Law*: 77-92.
[26] Section 12(2)(c) of the Constitution. See chapter 3 paragraph 6.1.1 *supra*.
[27] See *Coetzee v Government of the Republic of South Africa* 1995 (4) SA 631 (CC).
[28] *S v Makwanyane supra*.
[29] *S v Makwanyane supra* paragraphs [37]-[39].
[30] *Bernstein v Bester supra*.
[31] *Bernstein v Bester supra* paragraph [133].

2 CREATORS OF INTERNATIONAL INSTRUMENTS

Before commencing with the discussion of the instruments themselves, the international role players responsible for creating these instruments require attention. South Africa is a member of each of these organisations and as such is bound to the principles of and guidelines or documents issued by them. Instruments created by these organisations will therefore influence any domestic thinking and drafting of documents and protocols related to health, medical research, biotechnology and consent.

2.1 THE UNITED NATIONS

The United Nations (UN) is an intergovernmental organisation and promotes international cooperation. It was established as the replacement for the League of Nations and became operational after the Second World War when the UN Charter took effect on 24 October 1945. The Charter was signed on 26 June 1945 in San Francisco at the conclusion of the UN Conference on International Organisation and as the founding document of the UN it guides the objectives and principles of the organisation.[32] These objectives include maintaining international peace and security, promoting sustainable development, protecting human rights, upholding international law and delivering humanitarian aid. The powers vested in the UN Charter as well as the unique international character of the organisation allows it to take action on the issues facing humanity in modern times such as the development of human rights and humanitarian and health emergencies.[33]

There are six principal organs which constitute the UN.[34] They are the General Assembly,[35] the Security Council,[36] the Economic and Social Council,[37] the Secretariat,[38] the International Court

[32] United Nations (2015) "Introductory Note" available online at http://www.un.org/en/sections/un-charter/introductory-note/index.html accessed 16/9/2015.
[33] United Nations (2015) "Overview" available online at http://www.un.org/en/sections/about-un/overview/index.html accessed 16/9/2015.
[34] For more on the UN organs, see Chapter III of the UN Charter.
[35] The General Assembly is the main deliberative, policymaking and representative organ of the UN and enjoys universal representation. For more see United Nations (2015) "Main Organs" available online at http://www.un.org/en/sections/about-un/main-organs/index.html accessed 16/9/2015. See also Chapter IV of the UN Charter.
[36] The Security Council bears the primary responsibility for maintaining international peace and security. See Chapter V of the UN Charter.
[37] The ECOSOC is the principal body for the coordination, policy review, dialoguing and recommending of economic, social and environmental issues as well as the implementation of goals which have been internationally agreed on. See Chapter X of the UN Charter.
[38] The Secretariat includes the Secretary-General and the staff members of the UN who are responsible for the day-to-day functioning of the organisation. See Chapter XV of the UN Charter.

of Justice[39] and the UN Trusteeship Council.[40] Additionally, the UN has System Agencies, of which the most relevant to this discussion include the World Health Organisation and the UN Educational, Scientific and Cultural Organisation.[41]

In 2015, the UN celebrated its 70th anniversary and had 193 Member States, one of which is South Africa.[42] It enjoys extraterritoriality and is situated in Manhattan, New York City.

2.2 UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORGANISATION

The United Nations Educational, Scientific and Cultural Organisation (UNESCO) was created in 1945 and replaced the League of Nations' International Committee on Intellectual Cooperation. It is a specialised UN agency and has the function of contributing to peace and security by promoting international collaboration through education, science and culture in order to further a universal respect for the rule of law, justice, human rights and the fundamental freedoms proclaimed by the UN Charter. The founding thought behind the creation of this organisation was that political and economic agreements between nations, then ravaged by two world wars in less than a generation, are not sufficient in building a lasting peace. Peace must be built on the basis of humanity's moral and intellectual solidarity.[43]

The organisation attempts to build peace, eradicate poverty, promote sustainable development and intercultural dialogue through its five major programs centred on education, both human and natural science, culture, communication and information.

UNESCO may therefore be described as the "intellectual agency" of the UN and exists in order to bring creative intelligence to life in a time when the world must rely on the power of intellect in order, not only to sustain but also to expand hope and humanism.[44] It must be mentioned that UNESCO has been criticised over two aspects which are relevant in context of the discussion to follow in the course of this chapter. The first is that UNESCO is exceeding its mandate by drafting bioethical instruments as this is a charge which should be the responsibility of the

[39] The International Court of Justice is the primary judicial organ of the UN and as it is seated in the Peace Palace in The Hague in the Netherlands it is the only major UN organ not seated in New York City. See Chapter XIV of the UN Charter as well as the Statute of the International Court of Justice.
[40] The Trusteeship Council which has been inactive from 1994 was in charge of supervising certain Trust Territories. See Chapter XIII of the UN Charter.
[41] See paragraphs 2.2 and 2.4 *infra*.
[42] The UN was originally founded by a mere 51 members.
[43] See in general, United Nations Educational, Social and Cultural Organisation (2014) "Introducing UNESCO" available online at http://en.unesco.org/about-us/introducing-unesco accessed 16/9/2015.
[44] United Nations Educational, Science and Cultural Organisation (2015) "Introducing UNESCO" available online at http://en.unesco.org/about-us/introducing-unesco accessed 16/9/2015.

World Health Organisation[45] and the second is that UNESCO's reliance on international human rights norms and standards is inappropriate.[46] Today UNESCO has 159 members and 9 associate members.

2.2.1 International Bioethics Committee

The International Bioethics Committee (IBC) was created in 1993 in order to fulfil UNESCO's responsibilities in the field of bioethics.[47] The IBC comprises up to 45 persons from different countries, cultures, disciplines and backgrounds. The IBC is tasked with:[48]

1. Promoting reflection on the ethical and legal issues raised by research;
2. Encouraging the exchange of ideas and information;
3. Encouraging activities which heighten awareness among the decision makers in bioethics, be they the general public, specialized groups or public and private entities;
4. Cooperating with international governmental and non-governmental organisations concerned with bioethical issues as well as regional bioethics committees; and
5. Contributing to the dissemination of the principles found in the UNESCO instruments and to examine application issues which arise during the evolution of biotechnology.

The Committee was responsible for the Universal Declaration on the Human Genome and Human Rights,[49] the International Declaration on Human Genetic Data and the Universal Declaration of Bioethics and Human Rights.[50]

[45] It is suggested that this criticism is unfounded as CIOMS is a joint body created by the WHO and UNESCO. CIOMS is responsible for the International Ethical Guidelines for Biomedical Research Involving Human Subjects which is discussed in the course of this chapter. See paragraph 3.2.7 *infra*. A second counter argument to this critique is that the International Bioethics Committee was created in order to manage UNESCO's responsibilities pertaining to bioethics.
[46] Andorno R (2007) "Global bioethics at UNESCO: In defense of the Universal Declaration on Bioethics and Human Rights" *Journal of Medical Ethics* 33: 150 & 151-154.
[47] Kirby M (2009) "Human rights in bioethics: The Universal Declaration of Human Rights and UNESCO Universal Declaration of Bioethics and Human Rights" *Journal of Contemporary Health Law & Policy* 25(2): 318.
[48] United Nations Educational, Social and Cultural Organisation (2015) "International Bioethics Committee" available online at http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/international-bioethics-committee/ accessed 11/10/2015.
[49] See paragraph 3.2.6 *infra* for a discussion of this Declaration.
[50] See paragraph 3.2.8 *infra* for more on this Declaration.

2.3 THE WORLD MEDICAL ASSOCIATION

The World Medical Association (WMA) is an independent and international confederation of free professional Medical Associations and thus represents physicians globally. It was formally established on 17 September 1947 by the First General Assembly of the WMA in Paris, France.[51]

The purpose of the WMA is to serve mankind by endeavouring to achieve the highest of international standards in medical education, training, science, ethics, art and health care. The association provides guidance to physicians and medical associations across the globe by way of declarations, resolutions and statements covering patient rights, research on human subjects and treatment of the ill and wounded during times of armed conflict. These guiding documents include *inter alia* the International Code of Medical Ethics which is discussed in more detail in the course of this chapter.[52] Furthermore, the association offers its members a forum of free communication, active cooperation and a mechanism of reaching consensus on high professional competency and ethical standards.

Currently the WMA constitutes 111 National Member Associations which includes more than 10 million physicians. It should also be noted that the WMA is in official relations with the World Health Organisation.

2.4 THE WORLD HEALTH ORGANISATION

The World Health Organisation (WHO) is the first fully subscribed to specialised agency under the auspices of the UN and is concerned with international public health. The primary goal of the WHO is to direct and coordinate international health within the system of the UN.[53] It was created as a member of the UN Development Group on 7 April 1948 and is seated in Geneva, Switzerland.[54] During the creation of the organisation it was decided to use the word "world" rather than "international" to demonstrate the truly global nature of the objectives of the organisation.[55] These objectives are the development and implementation, in cooperation with the relevant national and international partners, of multispectral public

[51] World Medical Association (2015) "About the WMA" available online at http://www.wma.net/en/60about/index.html accessed 16/9/2015.
[52] See paragraph 3.3.1.2 *infra*.
[53] According to the WHO website, the goal of the organisation is "to improve equity in health, reduce health risks, promote healthy lifestyles and settings, and respond to the underlying determinants of health." See World Health Organisation (2015) "About Us" available online at http://www.who.int/healthpromotion/about/goals/en/ accessed 17/9/2015.
[54] This is the date that the Constitution of the WHO came into force and was signed by all the 51 founding Member States of the UN. See World Health Organisation (2015) "About WHO" available online at http://who.int/about/en/ accessed 16/9/2015.
[55] World Health Organisation (1948) "World Health Organisation" *British Medical Journal* 2(4570): 302.

policies for health, integrated gender- as well as age-sensitive approaches facilitating community empowerment along with action for health promotion, self-care and health protection during the course of life.[56]

2.4.1 Council for International Organisations and Medical Sciences

As mentioned above, the Organisation and the WMA have official relations. Likewise, WHO acts in partnership with UNESCO at times such as when acting as the Council for International Organisations and Medical Sciences (CIOMS) which is an international nongovernmental organisation jointly created by WHO and UNESCO in 1949.

CIOMS is representative of a substantial proportion of the biomedical scientific community and in 2013 the organisation's membership included 49 international, national and associated member organisations.[57] The council serves the interests of the international biomedical community and is active in the promulgation of guidelines on ethical research conduct. These guidelines are general instructions and principles of biomedical research and in 1993 CIOMS promulgated the International Ethical Guidelines for Biomedical Research Involving Human Subjects which will be discussed in the course of this chapter. [58]

The main objectives of CIOMS are to:

1. Facilitate and promote international activities in the field of biomedical sciences;
2. Maintain collaborative relations with the UN and its specialized agencies, with particular reference to WHO and UNESCO; and
3. Serve the scientific interests of the international biomedical community.

In order to achieve these objectives, the council initiated and coordinates long-term programmes which relate to bioethics and health policy, ethics and human values.[59]

[56] WHO (2015) "About Us" online.
[57] Council for International Organisations and Medical Sciences (2015) "About Us" available online at http://cioms.ch/index.php/2012-06-07-19-16-08/about-us accessed 28/8/2015.
[58] See paragraph 3.2.7 *infra.*
[59] CIOMS (2015) online.

2.5 THE AFRICAN UNION

The African Union (AU) is a continental union comprised of 51 African countries. It was established on 26 May 2001 in Addis Ababa, Ethiopia, and formally launched on 9 July 2002 in Durban, South Africa.[60] The AU replaced the Organisation of African Unity (OAU). The secretariat and AU commission is seated in Addis Ababa and the most important decisions of the Union are made by the Assembly.[61] The Union is a combination of political and administrative bodies other than the Assembly which include *inter alia* an Executive Council; the Permanent Representatives Committee; the Economic, Social and Cultural Council (ECOSOCC), as well as the Pan African Parliament which is the representative body of the union.[62]

The advent of the AU may be described as "an event of great magnitude in the institutional evolution of the continent."[63] The Union's vision is that of an integrated, prosperous and peaceful Africa which is driven by its own citizens and which is representative of a dynamic force in the global arena. As such the objectives of the Union are numerous and include most relevantly the promotion and protection of human and peoples' rights in accordance with the African Charter on Human and Peoples' Rights,[64] to collaborate with international partners in eradicating preventable diseases and promoting good health on the African continent.

3 RELEVANT INTERNATIONAL INSTRUMENTS

As the creators of international instruments have now been discussed, attention must shift to the instruments themselves. South Africa, as a member of the creating entities behind these instruments, will be bound, be it legally, morally or ethically to take into consideration these instruments in dealing with the regulation of medical treatment and research. The instruments which are discussed in the course of this chapter have been selected by virtue of their relevance to the issue of consent in medical and scientific settings. In researching these instruments, special attention was therefore given to their express provision for consent, medical treatment, research and experimentation involving human subjects.[65]

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[60] See in general, African Union (2002) "Launch of the African Union, 9 July 2002: Address by the chairperson of the AU, President Thabo Mbeki" available online at http://www.au2002.gov.za/docs/speeches/mbek097a.htm accessed 17/9/2015.
[61] The Assembly is comprised of the heads of States of the relevant member countries of the Union.
[62] African Union (2015) "AU in a Nutshell" available online at http://www.au.int/en/about/nutshell accessed 16/9/2015.
[63] *Ibid*.
[64] See paragraph 3.4.1 *infra*.
[65] This thesis focuses on international and United Kingdom laws and therefore the American instruments have been omitted.

Although the layout of the discussion that follows orders the instruments primarily into categories according to their author or creator, they are then further placed in historical order, mostly from immediately after the Second World War up to the present day or the most current instrument. Before examining each individual relevant instrument, however, it is interesting to note the overall timeline of these instruments. It indicates the international trends and universal thinking which has propelled the development of instruments addressing the development of medical encounters and technology.[66]

400 BC	:	Hippocratic Oath	
1947	:	Nuremberg Code	
1948	:	International Bill of Rights	UN
1948	:	Declaration of Geneva	WMA
1948	:	Universal Declaration of Human Rights	UN
1949	:	International Code of Medical Ethics	WMA
1959	:	Declaration of The Rights of the Child	UN
1964	:	Declaration of Helsinki	WMA
1966	:	International Covenant on Civil and Political Rights	UN
1975	:	Declaration on the Rights of Disabled Persons	UN
1986	:	African Charter on Human and Peoples' Rights	AU
1989	:	Convention on the Rights of a Child	UN
1996	:	African Bioethics Resolution	AU
1997	:	Universal Declaration on the Human Genome and Human Rights	UNESCO
1999	:	African Charter on The Rights and Welfare of the Child	AU
2002	:	International Ethical Guidelines for Biomedical Research Involving Human Subjects	UNESCO and WHO
2005	:	Universal Declaration on Bioethics and Human Rights	UNESCO
2007	:	Convention on the Rights of Persons with Disabilities	UN

Figure I: Timeline of international instruments

Each of the instruments listed above will be discussed in the course of this chapter. Firstly, however, the Nuremburg Code as the "mother" of this species of legal international instruments, will be discussed.

[66] For example, a trend which may be identified is the progression of the subject matter of instruments from general rights aspects, then to aspects pertaining to children and now to biotechnology.

3.1 NUREMBURG CODE

The Nuremberg Code is a set of research ethics principles for experimentation on human subjects which resulted from the Nuremberg Trials at the end of the Second World War. More specifically, the Nuremberg Code was the result of the "Doctors' Trial" which centred on human experiments which had been conducted in the concentration camps and wherein 23 accused were tried for various acts.[67] The "Doctors' Trial" lasted from the 9th of December 1946 to the 19th of July 1947 with the Hippocratic Oath becoming a recurring theme as well as various questions being raised regarding the ethics of human experimentation.[68] The verdict was delivered on the next day and adopted six principles aimed at defining legitimate medical research which had been submitted to the Council for War Crimes by Dr Leo Alexander in May of that same year. The verdict also expanded these six principles by the addition of four more. Together these now ten principles constituted the Nuremberg Code which includes principles regarding informed consent, the absence of coercion, proper formulation of experimentation and beneficence.

The judges of the trial recognised Hippocratic ethics and the maxim of *primum non nocere*[69] but also realised that it was necessary to specially protect subjects of medical research.[70] In order to do so, the judges articulated the ten principles in such a manner that principles of research did not fall on the physician or scientist but on the research subject.[71] The Nuremberg Code is, to an extent, a conflation of treatment and research ethics and human rights.

Although the Nuremberg Code is hailed as a landmark document in medical ethics guidelines, it is not free of criticism. One such aspect of critique relates to the claims that it is the first document of its nature. The Code resulted from the behaviour of German physicians during the Second World War, however, a German Code, namely the Guidelines for Human Experimentation of 1931 had already been in existence and had in fact replaced an even earlier document known as the Berlin Code of 1900.[72] A second aspect of dissatisfaction is that of the authorship of the Code. Harold Sebring, Leo Alexander and Andrew Ivy have all been cited as

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[67] See in general, Annas GJ & Grodin MA (1992) *The Nazi doctors and the Nuremberg Code*.
[68] Shuster E (1997) "Fifty years later: The significance of the Nuremberg Code" *New England Journal of Medicine* 337: 1437.
[69] This means "first, do no harm."
[70] Traditionally, in the Hippocratic doctor-patient relationship, the patient is silently dutiful and obedient to the beneficent and trusted doctor. Once the patient agrees to be treated by the doctor they trust that he will act in their best interest and not harm them. In research, which falls outside of the beneficence context of this relationship, such trust may be misplaced as the researcher-physician's primary objective is not treatment but to test a scientific hypothesis.
[71] Shuster (1997) 1439.
[72] Ghooi RB (2011) "The Nuremberg Code-A critique" *Perspectives in Clinical Research* 2(2): 73. See in general, Vollmann J & Winau R (1996) "Informed consent in human experimentation before the Nuremberg Code" *British Medical Journal* 313(7070): 1445-1449.

having authored the Nuremberg Code.[73] Some further points of critique are that the Code does not have the force of law, it contains some errors regarding word and language usages and it may be interpreted to contain loopholes.[74]

The Nuremberg Code is the most important document in the history of medical research ethics and serves as the blueprint to modern principles which ensure the rights of subjects in research.[75] The ten principles enshrined in the Code reads as follows:[76]

> "1. The voluntary consent of the human subject is absolutely essential.
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.
> The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
> 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
> 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge [*sic*] of the natural history of the disease or other problem under study, that the anticipated results will justify the performance of the experiment.[77]
> 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
> 5. No experiment should be conducted, where there is an *apriori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
> 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
> 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
> 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
> 9. During the course of the experiment, the human subject should be at liberty to bring the experiment to an end, if he has reached the physical or mental state, where continuation of the experiment seemed to him to be impossible.
> 10. During the course of the experiment, the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject."

The Code expressly requires that the physician-researcher protect the best interests of the subject-patient[78] but provides therefore that the patient-subjects may protect themselves[79] and

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[73] Ghooi (2011) 74. For more information on these persons' backgrounds see, Shuster (1997) 1437-1439.
[74] *Idem* 74-75.
[75] Shuster (1997) 1436.
[76] The Nuremberg Code 1947.
[77] For more on animal testing in research with human applications see Greek R, Pippus A & Hansen LA (2012) "The Nuremberg Code subverts human health and safety by requiring animal modelling" *British Medical Journal* 13:16. The authors argue that this is an outdated requirement and that it (1) serves no useful function, (2) increases the cost of developing drugs and (3) prevents otherwise safe and effective drugs and therapies from being applied.
[78] Principles 2-8 and 10 of the Code.

in so doing places both parties on an equal footing. The principles which are of most importance to this study as seen from the Code are the absolute requirement for informed consent[80] and the explicit right of the subject to withdraw their participation from research.[81]

From the 1st principle it is clear that informed consent is set as the core of the Nuremberg Code and is an absolute and essential requirement. Consent must be given by a person with the legal capacity to do so and their decision may not be forced, fraudulently coaxed, coerced or made under duress and only after the proposed subject has obtained sufficient knowledge and comprehension to make an informed decision. In order to make an informed decision, the subject must be informed of the nature, duration and method of experimentation as well as the "inconveniences and hazards" or risks and "effects" or benefits of their participation prior to them granting their consent. The person responsible for the research must be the person who ascertains the quality of the consent. Principle 9 establishes the right of a subject to withdraw their participation at any stage of the research.

Although the Nuremberg Code is not a binding legal document with force of law, it profoundly influences international law as well as medical ethics. Principles articulated in the Code have been adopted and absorbed into instruments such as the UN International Covenant on Civil and Political Rights,[82] the CIOMS International Ethical Guidelines for Biomedical Research involving Human Subjects[83] and even the Declaration of Helsinki,[84] although it focuses on the duties of the physician-researcher rather than the patient-subject. These instruments will be discussed in the course of this chapter and are divided into categories based on the authors or creators of the instruments as previously mentioned.

3.2 INSTRUMENTS OF THE UNITED NATIONS

In the following discussion, the International Bill of Rights; the Declaration of the Rights of the Child as well as the Declaration on the Rights of Disabled Persons; the Convention on the Rights of a Child; the Universal Declaration on the Human Genome and Human Rights; the International Ethical Guidelines for Biomedical Research Involving Human Subjects; the

[79] Principles 1 and 9 of the Code.
[80] Principle 1 of the Code.
[81] Principle 9 of the Code. Suggested further reading, Weindling P (2001) "Human guinea pigs and the ethics of experimentation: The BMJ's correspondent at the Nuremberg medical trial" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 15-19.
[82] See paragraph 3.2.1.2 *infra*.
[83] See paragraph 3.2.7 *infra*.
[84] See paragraph 3.3.2 *infra*.

Universal Declaration on Bioethics and Human Rights and the Convention on the Rights of Persons with Disabilities will be examined.

3.2.1 International Bill of Rights

The International Bill of Rights which has been compared with the Magna Carta[85] consists of three individual documents namely the Universal Declaration of Human Rights,[86] the International Covenant on Civil and Political Rights[87] and the International Covenant on Economic, Social and Cultural Rights.[88] In context of this study, the International Covenant on Economic, Social and Cultural Rights is not relevant and is only mentioned here for the sake of completeness. The Universal Declaration of Human Rights and the International Covenant on Civil and Political Rights each have a specific bearing on the subject of this thesis and will therefore be discussed in greater detail.

3.2.1.1 The Universal Declaration of Human Rights

The Universal Declaration of Human Rights (UDHR) is a declaration, or actually a resolution, which was adopted on the 10th of December 1948 by the UN General Assembly.[89] It is the direct result of the Second World War and may be described as the first global expression of the rights to which all humans are inherently entitled.

After the atrocious acts perpetrated under Nazi Germany came to light, the global community agreed that the UN Charter did not sufficiently define the rights which it contained. A specific universal declaration was therefore necessary in order to give effect to the provisions regarding human rights. The Declaration was commissioned in 1946 and drafted over a period of two years by the UDHR Drafting Committee which was chaired by Eleanor Roosevelt.[90] On the 10th of

[85] The Magna Carta, meaning "Great Charter" or *Magna Carta Libertatum* meaning "Great Charter of Liberties," is one of the most famous documents in the world. It was originally issued by King John of England in 1215 and established the principle that everyone, including the King himself, was subject to the law. Although it was numerously reissued during the 13th century, it remains one of the cornerstones of the British Constitution and 2015 marked the 800th anniversary of the Magna Carta. For more see in general, Miller E (1962) "The background of Magna Carta" *Past and Present* 23(1): 72-83.
[86] The Universal Declaration of Human Rights 1948.
[87] The International Covenant on Civil and Political Rights 1966.
[88] The International Covenant on Economic, Social and Cultural Rights 1966. The Covenants only came into force in 1976 after they had been ratified by a sufficient number of countries.
[89] Nienaber (2007) 427.
[90] Morsink J (1999) *The Universal Declaration of Human Rights: Origins, drafting and intent*: 1-4.

December 1948, the Declaration was adopted by the General Assembly of the United Nations.[91] It is interesting to note that Eleanor Roosevelt supported the adoption of the UDHR as a declaration rather than a treaty and although it is not legally binding it has influenced the constitutions of UN Member States since 1948. As a constitutive document of the UN it defines fundamental freedoms and human rights as established by the UN Charter which binds all members of the UN and in this indirect manner, is binding on Member States of the UN.[92]

The UDHR underwent a seven-stage drafting process[93] and the structure thereof, as prepared by René Cassin who worked from the first draft prepared by John Peters Humphrey, was introduced in the second stage. The UDHR structure was influenced by the *Code Napoléon*[94] and as such consists of a Preamble and introductory general principles, which is then followed by the 30 articles of the Declaration. The relevant articles of the UDHR will be discussed in the course of this chapter. At this juncture it is, however, interesting to elaborate on the structure of the Declaration as Cassim compared it with the portico of a Greek temple.[95] The UDHR thus has a foundation, steps, four columns and a pediment. Articles 1 and 2 form the foundation with principles of dignity, liberty, equality and brotherhood. The seven Preamble paragraphs are the steps. The columns are formed by the main body of the Declaration. Articles 3 to 11 are the first column,[96] articles 12 to 17 the second,[97] articles 18 to 21 the third[98] and 22 to 27 the fourth column.[99] The pediment in Cassim's model is provided by the last three articles of the UDHR which bring the structure together as a whole.[100]

As mentioned above, the UDHR contains 30 articles. Informed consent is not explicitly mentioned but, in context of this thesis, article 3 is of importance as it provides that "everyone has the right to life, liberty and security of person."[101] These rights are in line with and corresponding to the rights found in the South African Constitution which provides for the right

[91] The UDHR was adopted by a vote of 48 in favour, none against and 8 abstentions of which South Africa was one. The abstention by South Africa was an attempt to protect the apartheid system which was in clear violation of various provisions in the Declaration. See Morsink (1999) 26-28.
[92] See in general, Von Bernstorff J (2008) "The Changing fortunes of the Universal Declaration of Human Rights: Genesis and symbolic dimensions of the turn to rights in international law" *The European Journal of International Law* 19(5): 903-924.
[93] See in general, Morsink (1999) 5-7 for a detailed discussion of each of the drafting stages.
[94] The Napoleonic Code or as it is officially known, *Code civil des Français* is the French civil code which was established under Napoléon I in 1804.
[95] Glendon MA (2002) *A world made new: Eleanor Roosevelt and the Universal Declaration of Human Rights*: 62-64.
[96] These articles contain the rights of the individual.
[97] These articles contain the rights of the individual in a political and civil arena.
[98] These articles are centered on spiritual, political and public freedoms.
[99] These articles contain social, economic and cultural rights.
[100] Articles 28-30 contain the societal duties of the individual and the prohibition of contravening any of the purposes of the UN.
[101] Read together, articles 3 and 5 of the UDHR may be regarded as indirectly providing for consent. Article 5 guarantees that a person shall be free from torture or cruel, inhuman or degrading treatment.

to life in section 11 and the right to freedom and security of the person in section 12.[102] Freedom and security of the person includes the right to not be subjected to medical or scientific experiments without the informed consent of the person involved.[103] The requirement of informed consent is therefore indirectly provided for in the Declaration. Although the Declaration has no binding force of law, it has been transformed into a normative instrument which creates legal obligations on the UN Member States and some of these States consider the Declaration as binding customary international law.[104] The UDHR must also be read with the International Covenant on Civil and Political Rights which will now be discussed, as they form two thirds of the International Bill of Human Rights.

3.2.1.2 The International Covenant on Civil and Political Rights

The International Covenant on Civil and Political Rights (ICCPR) is a multilateral treaty adopted by the General Assembly of the UN on the 16th of December 1966. It came into force on the 23rd of March 1967. The parties thereto are bound to respect the civil and political rights of individuals which also include the right to life; various freedoms such as speech, assembly and religion; electoral rights and the right to due process and a fair trial.

The ICCPR, together with the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights (ICESCR), constitute the International Bill of Human Rights.[105] During the drafting stages of the UDHR it was decided that the document should be divided into the Declaration, which provides for general principles of human rights and a convention which contains the binding commitments of the parties. Drafting on this proposed convention commenced but due to significant differences in opinion between UN members it was also divided into two instruments. The first deals with negative civil and political rights, namely the ICCPR, and the second with positive economic, social and cultural, rights namely the ICESCR.[106] There are also two Optional Protocols to the Covenant. The First Optional Protocol establishes complaints mechanisms which allow individuals to complain to the Human Rights Committee regarding contraventions of the Covenant and the Second Optional Protocol abolishes the death penalty.[107]

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[102] Constitution of the Republic of South Africa, 1996.
[103] See chapter 3 paragraph 6.1 *supra*.
[104] Nienaber (2007) "The utility of international human rights law on informed consent in the protection of clinical research participants in Africa: 'The road less travelled'" *SA Publiekreg/SA Public Law* 22(2): 427-428.
[105] The ICESCR is not discussed in this thesis. See in general, Nienaber (2007) 434-435.
[106] Sieghart P (1983) *The international law of human rights*: 25.
[107] Some countries were, however, permitted to make reservations in this regard.

The ICCPR follows a similar structure to the UDHR and contains a Preamble and 53 articles which are grouped together into six parts. Part 1 deals predominantly with the right of people to self-determination.[108] Part 2 deals with the recognition of and duty of parties to legislate in order to give effect to the rights in the Covenant but also allows the limitation of rights in certain instances.[109] Part 3 lists the rights themselves which include physical integrity,[110] liberty and security,[111] procedural fairness,[112] individual liberty[113] and non-discrimination[114] to name only a few. Part 4 governs the establishment and operation of the Human Rights Committee.[115] Part 5 clarifies interpretative issues[116] and Part 6 governs the ratification, entry into force and amendment of the ICCPR.[117]

The ICCPR not only established informed consent as a principle of international law but also conferred enforceable rights on research participants.[118] The right to physical integrity as found in article 7 is a core provision of the Covenant and is the most relevant provision in context of this discussion.[119] It states that no person may be subjected to torture, to cruel, inhuman, degrading treatment or punishment.[120] In response to the experimentation by Nazi scientists and physicians during the Second World War, it particularly and explicitly further provides that no person may be subjected to medical or scientific experimentation without his free consent. The rights under this article cannot be derogated under any circumstances. In fact, non-compliance with article 7 is a matter of international concern according to Nienaber.[121] Similar to the provisions of the UDHR, it is interesting to note that these rights are reflected in section 12 of the South African Constitution. The express provision of the consent requirement also emphasises, once again, the absolute importance and necessity of consent in any medical or scientific experimentation. Read together, article 3 of the UDHR and article 7 of the ICCPR therefore confirm the necessity of prior consent to medical or scientific activities which involve human beings and reiterates that without such consent, no such activity will be lawful.

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[108] Article 1 of the ICCPR.
[109] Articles 2-5 of the ICCPR.
[110] Article 6-8 of the ICCPR.
[111] Articles 9-11 of the ICCPR.
[112] Articles 14-16 of the ICCPR.
[113] Articles 12, 13 and 17-24 of the ICCPR.
[114] Articles 26-27 of the ICCPR.
[115] Articles 41 and 42 of the ICCPR.
[116] Articles 46 and 47 of the ICCPR.
[117] Articles 48-53 of the ICCPR.
[118] Nienaber (2007) 429.
[119] For an in-depth discussion of the interpretation and application of article 7 see Nienaber (2007) 429-434.
[120] It was with this same sentiment that the death penalty was abolished from South African law in the case of *S v Makwanyane and Another supra* paragraph [282]. See in general, the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment 1984.
[121] Nienaber (2007) 429.

3.2.3 Declaration of the Rights of the Child

The Declaration of the Rights of a Child, also referred to as the Geneva Declaration of the Rights of the Child,[122] is a document which promotes children's rights. It was originally adopted by the League of Nations in 1924 and in 1959 an extended version thereof was adopted by the UN.

The Declaration consists of a Preamble and 10 principles which cover a variety of children's rights. In brief, the Declaration states that every child is entitled to enjoy the rights provided for in the Declaration regardless of their race, sex, language *etcetera*.[123] Furthermore, children must be protected from discrimination as well as practices which may foster discrimination,[124] meaning that a child must enjoy special protection and must be given the opportunities and facilities to enable healthy and normal physical, mental, moral, spiritual or social development.[125] All children are entitled to education[126] and disabled children must be given special treatment, education and the care necessary for their particular physical, mental or social "handicap."[127] In times of disaster, children must be the first to receive protection and relief[128] and a child is also entitled to protection against neglect, cruelty and exploitation.[129] All children are entitled to a name and nationality[130] and require love and understanding and for this reason should be allowed to be raised by their parents. Where necessary, however, a child may be separated from his parents.[131]

In context of this thesis however, principle 4 is of most relevance and reads that "the child shall enjoy the benefits of social security. He shall be entitled to grow and develop in health; to this end, special care and protection shall be provided both to him and to his mother, including adequate pre-natal and post-natal care. The child shall have the right to adequate nutrition, housing, recreation and medical services."

From this principle, the conclusion may thus be drawn that children are entitled to health and health care services. Where medical treatment or research may therefore be of benefit to a child, such child may not be excluded by virtue of their age but rather, special attention and care must be given to allow that the child is able to fully participate in and benefit from the treatment or research. This principle may therefore indicate that rather than excluding children or minors

[122] The Geneva Declaration on the Rights of the Child 1924 should not be confused with the Geneva Declaration as drafted by the WMA which relates to the duties of physicians. The Declaration of Geneva is discussed in paragraph 3.3.1 *infra*.
[123] Principle 1 of the Declaration of the Rights of the Child.
[124] Principle 10 of the Declaration of the Rights of the Child.
[125] Principle 2 of the Declaration of the Rights of the Child.
[126] Principle 7 of the Declaration of the Rights of the Child.
[127] Principle 5 of the Declaration of the Rights of the Child.
[128] Principle 8 of the Declaration of the Rights of the Child.
[129] Principle 9 of the Declaration of the Rights of the Child.
[130] Principle 3 of the Declaration of the Rights of the Child.
[131] Principle 6 of the Declaration of the Rights of the Child.

from certain processes, they must be given access thereto as long as the proper protective measures, such as requiring consent, are taken.[132]

The Declaration was followed in the Convention on the Rights of the Child of 1989. The Convention is discussed in the course of this chapter.

3.2.4 Declaration on the Rights of Disabled Persons

The Declaration on the Rights of Disabled Persons was adopted by the UN General Assembly on the 9th of December 1975. It consists of an extensive Preamble and 13 proclamations. The rights of all persons living with disabilities[133] are provided for within these proclamations and include *inter alia* the right to have their human dignity respected[134] and to be protected against exploitation, discrimination and abuse.[135] Also, they are entitled to the same civil and political rights[136] as other people as well as the right to economic and social security which include employment.[137] They are also entitled to be considered in all stages of economic and social planning.[138] Persons with disabilities have a right to measures which enable self-reliance[139] but also to live with their families and to participate in all social, creative and recreational activities.[140]

Importantly, the Declaration provides a definition for the term "disabled person." According to Proclamation 1, a disabled person is "any person unable to ensure by himself or herself, wholly or partly, the necessities of a normal individual and/or social life, as a result of deficiency, either congenital or not, in his or her physical or mental capabilities." Also of importance is Proclamation 6 which provides that all disabled persons have the right to medical, psychological and functional treatment. From these proclamations it may be inferred that regardless of the fact that a person has deficient capacity of whatever nature, they are entitled to medical treatment. Naturally such persons must be protected and, as was the case with a minor, this protection extends to obtaining consent from the person.

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[132] South Africa follows a similar approach to this issue.
[133] The Declaration applies to all persons who are disabled. Proclamation 2 reads as follows: "Disabled persons shall enjoy all the rights set forth in this Declaration. These rights shall be granted to all disabled persons without any exception whatsoever and without distinction or discrimination on the basis of race, colour, sex, language, religion, political or other opinions, national or social origin, state of wealth, birth or any other situation applying either to the disabled person himself or herself or to his or her family."
[134] Proclamation 3 of the Declaration on the Rights of Disabled Persons.
[135] Proclamation 10 of the Declaration on the Rights of Disabled Persons.
[136] Proclamation 4 of the Declaration on the Rights of Disabled Persons.
[137] Proclamation 7 of the Declaration on the Rights of Disabled Persons.
[138] Proclamation 8 of the Declaration on the Rights of Disabled Persons.
[139] Proclamation 5 of the Declaration on the Rights of Disabled Persons.
[140] Proclamation 9 of the Declaration on the Rights of Disabled Persons.

The Declaration on the Rights of Disabled Persons was the 3447th resolution made by the General Assembly and as such is not binding on the Member States of the UN. It does, however, provide a framework which has been greatly relied on in other international instruments as well as domestic laws. The Convention on the Rights of Persons with Disabilities is one such instrument and is discussed in the course of this chapter.[141]

3.2.5 Convention on the Rights of a Child

The Convention on the Rights of the Child (CRC) is a human rights treaty which provides for civil, political, social, economic and cultural as well as health rights of children. The CRC requires that States act in the best interests of the child as it is the primary consideration in matters related to children.[142] The Convention acknowledges that all children have basic rights which include the right to life, the right to a name and nationality, to be raised by their parents within their family and/ or culture and to have a continued relationship with their parents even in the event of separation. The CRC further recognises that children have the right to express their opinions, to be protected from abuse or exploitation and to have their privacy respected.[143] The UN General Assembly opened for signature and adopted the Convention on the 20th of November 1989.[144] On the 2nd of September 1990 the Convention had been ratified by sufficient members and came into force.[145] Two Optional Protocols were also adopted on the 25th of May 2000. The First Optional Protocol restricts military involvement of children and the Second prohibits child prostitution or pornography and the sale of children.[146] A Third Optional Protocol regarding the communication of complaints was also adopted during 2001.[147]

The Convention consists of a Preamble and 54 articles which are divided into three parts. Part I provides for the rights to which all children are entitled and the duties imposed on Member States in order to realise these rights. Part II explains the mechanisms of implementation of the

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[141] See paragraph 3.2.9 *infra*.
[142] Article 3 of the CRC. This sentiment is echoed in section 28(2) of the South African Constitution which states that "a child's best interests are of paramount importance in every matter concerning the child."
[143] Part I of the CRC.
[144] This was the 30th anniversary of the Declaration of the Rights of the Child.
[145] UN General Assembly Session 44, Resolution 25: Convention on the Rights of the Child A/RES/44/25. See also Office of the High Commissioner for Human Rights (2002) *Convention on the Rights of the Child* available online at http://www.ohchr.org/en.professionalinterest/pages/crc.aspx accessed 28/8/2015.
[146] United Nations (2000) *Optional Protocol to the Convention on the Rights of the Child on the involvement of children in armed conflict* available online at https://treaties.un.org/pages/viewdetails.aspx?src=ind&mtdsg_no=iv-11-b&chapter=4&lang=en and *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography* available online at https://treaties.un.org/pages/viewdetails.aspx?src=ind&mtdsg_no=iv-11-c&chapter=4&lang=en accessed 28/8/2015.
[147] United Nations (2001) *Optional Protocol to the Convention on the Rights of the Child on a communications procedure* available online at https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-11-d&chapter=4&lang=en accessed 28/8/2015.

Convention's principles and Part III relates to the procedure whereby the CRC becomes law. For the purpose of this study, the provisions found in Part I are of most importance and will be discussed here. Article 1 of the convention defines a child as "every human being below the age of 18 years, unless under the law applicable to the child majority is attained earlier." Article 3(1) provides that the best interests of the child are the primary consideration in child-related matters and article 3(3) further requires that States must ensure that this standard is upheld.

A child who is capable of forming his/her own opinion has the right to express said opinion freely in all matters which affect him/her and this opinion should be given due weight in accordance with the age and maturity of the child. A child must therefore be provided with an opportunity to be heard, directly or by way of representation, in matters affecting the child.[148] Children are further entitled to information and ideas of all kinds.[149] In context of consent, this may be interpreted to mean that a child must be given all information relevant to, as well as the opportunity to make decisions regarding their health and therefore medical treatment or participation in research, provided that they have the capacity to do so. Their informed decision must then be communicated and considered. Should a child therefore decide to undergo certain treatment procedures or partake in research, they should be permitted to consent thereto. As is evident in this thesis, this is usually aided by a parent, guardian or responsible representative person.

Lastly, the CRC specifically provides for a child's right to "the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health."[150] States must ensure that no child is deprived of this right. The argument may be made that this is a broad enough provision to include stem cell therapy or medical research.

In summary, the CRC provides that the best interests of a child below the age of 18 are of vital importance in matters regarding the child. Children are entitled to information and when a child possesses sufficient capacity to understand such information, their opinions must be considered in activities which involve them.

[148] Article 12 of the CRC.
[149] Article 13(1) of the CRC reads "the child shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of the child's choice."
[150] Article 24 of the CRC.

3.2.6 Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights is a document which was issued by UNESCO in 1997.[151] It was the first universal rather than regional instrument which established a set of ethical rules specifically focussed on bioethics which is a branch of ethical philosophy centred on biological aspects.[152] The Declaration is a vital part of any process attempting to set standards in bioethics. Due to the rapid development of reproductive technologies, biomedical research involving human participation as well as genetic testing and printing, national legislation is destined to "lag a step behind the often staggering advances of biology and genetics."[153] The legislative race to keep up with these developments may lead to delocalised laws and regulations and for this reason the Declaration attempts to provide a unified framework.[154] It is also for this reason that the Declaration is of great informative value to this study and relates to research in general as well as specific, genomic in this case, research.

The Genome Declaration is most well-known for its prohibition of human reproductive cloning[155] and the misuse of the human genome. It is interesting to note that due to the astonishing pace of progress in the field of medical science, especially the field related to the genome as well as the scope and potential reach of the Declaration itself, the General Conference of UNESCO endorsed *Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights*.[156] These guidelines were drafted by the International Bioethics Committee and approved by the Intergovernmental Bioethics Committee.[157]

The Declaration contains a Preamble as well as 25 articles grouped into 7 parts. These parts are entitled human dignity and the human genome;[158] rights of the persons concerned;[159] research on the human genome;[160] conditions for the exercise of scientific activity;[161] solidarity and international co-operation;[162] promotion of the principles set out in the Declaration[163] and implementation of the Declaration.[164]

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[151] See in general, Goldberg S & Gostin LO (2006) *Law and science*: 59-65.
[152] Lenoir N (1999) "Universal Declaration on the Human Genome and Human Rights: The first legal and ethical framework at the global level" *Columbia Human Rights Law Review* 30: 537-538.
[153] *Idem* 538 & 540.
[154] *Idem* 541.
[155] Article 11 of the Universal Declaration on the Human Genome and Human Rights.
[156] See in general, United Nations Educational, Social and Cultural Organisation (1999) "Implementation of the Universal Declaration on the Human Genome and Human Rights" available online at http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SHS/pdf/Guidelines-Genome_EN.pdf accessed 28/8/2015.
[157] Matsuura K (2000) "The Universal Declaration on the Human Genome and Human Rights: From theory to practice" available online at http://unesdoc.unesco.org/images/0012/001229/122990eo.pdf accessed 28/8/2015.
[158] Part A, articles 1-4 of the Universal Declaration on the Human Genome and Human Rights.
[159] Part B, articles 5-9 of the Universal Declaration on the Human Genome and Human Rights.
[160] Part C, articles 10-12 of the Universal Declaration on the Human Genome and Human Rights.
[161] Part D, articles 13-16 of the Universal Declaration on the Human Genome and Human Rights.
[162] Part E, articles 17-19 of the Universal Declaration on the Human Genome and Human Rights.

Although the Declaration explicitly provides for genomic research, in context of this thesis, the principles which it enshrines may be applied in a broader sense to research involving human subjects and material in general. Keeping this in mind, only the most important articles of the Declaration will be discussed here. Article 5 states that research, treatment or diagnosis of a human genome may only be undertaken after a prior and rigorous assessment of the risks and benefits involved.[165] In all instances the prior, free and informed consent of the person concerned must be obtained. Where the concerned person is not in a position to consent, such consent must be obtained in accordance to law and in the person's best interests.[166] Where a person does not have the capacity to consent, research may only be conducted on their material where they will receive a direct health benefit and subject to authorisation and the protective conditions prescribed by law.[167]

Consent may only be limited by especially prescribed laws and for compelling reasons within the bounds of public international and international human rights law.[168] This is done in order to protect the human rights and fundamental freedoms of the concerned person. No research or research applications in the field of biology, genetics and medicine should ever prevail over respect for the human rights, fundamental freedoms and human dignity of the concerned individual.[169]

The Declaration, however, also recognises the importance of scientific study. Freedom of research is necessary for the progression of knowledge. Research applications in biology, genetics and medicine must seek to offer relief from suffering and must improve the health of the concerned individual and humankind as a whole.[170]

3.2.7 International Ethical Guidelines for Biomedical Research Involving Human Subjects

The Council for International Organisations and Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS Guidelines) are general

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[163] Part F, articles 20-21 of the Universal Declaration on the Human Genome and Human Rights.
[164] Part G, articles 22-25 of the Universal Declaration on the Human Genome and Human Rights.
[165] Article 5(a) of the Universal Declaration on the Human Genome and Human Rights.
[166] Article 5(b) of the Universal Declaration on the Human Genome and Human Rights.
[167] Where research will not directly benefit the concerned person, their material may only be used on the conditions that it will be used with the utmost restraint, exposing the person to the minimal risk, if the research is intended to benefit persons in the same category as the concerned person and provided that the research is compatible with the individual's human rights.
[168] Article 9 of the Universal Declaration on the Human Genome and Human Rights. This is reminiscent of section 36 of the South African Constitution. See chapter 3 paragraph 6.2 *supra*.
[169] Article 10 of the Universal Declaration on the Human Genome and Human Rights.
[170] Article 12(b) of the Universal Declaration on the Human Genome and Human Rights.

instructions and principles for biomedical research[171] and implementation of the Declaration of Helsinki.[172] They are a set of ethical principles regarding human experimentation which were created by CIOMS in 1993 and updated in 2002. The Guidelines cover a wide variety of subjects, most important of which, in context of this thesis, includes consent.

CIOMS was jointly formed by the WHO and UNESCO in 1949 and attempts to facilitate and promote international activities in the field of biomedical sciences. In the 1970's CIOMS undertook bioethical research which culminated in the 1982 "Proposed Ethical Guidelines." These Guidelines underwent further discussion and revision and became the International Ethical Guidelines for Biomedical Research Involving Human Subjects which were originally published in 1993. The Guidelines were updated in 2002 and now consist of 21 guidelines. The concept of informed consent is greatly provided for in the Guidelines and must therefore be discussed here.[173] In order to better address this issue, the following guidelines relevant to this discussion have been grouped into four categories, namely those regarding individual informed consent; those related to the process of obtaining consent with regard to the essential information to be provided to subjects and the obligations of researchers; research involving vulnerable groups which includes children and mentally incapacitated persons and lastly the miscellaneous guidelines which have some bearing on this study.

3.2.7.1 Individual informed consent

Guideline 4 of the CIOMS Guidelines provides for individual consent and states that for all biomedical research involving humans, the investigators or researcher[174] must obtain the voluntary informed consent of the prospective subject. Where an individual is incapable of giving consent, a legally authorised person may do so. Consent may only be waived in exceptional circumstances and must be regarded as uncommon and in all cases be approved by an ethical review committee.

Consent to participate in research is therefore a decision which is made by a competent individual who has been given all the necessary information and who understands said information and then arrives at a decision after taking some time to give it consideration and

[171] Marymount University Loyola (2015) "Reports, declarations, codes and guidelines" available online at http://academics.lmu.edu/irb/reportsdeclarationscodesguidelines/ accessed 28/8/2015.
[172] Macrea DJ (2007) "The Council for International Organisations and Medical Sciences (CIOMS) Guidelines on Ethics of Clinical Trials" *Proceedings of the American Thoracic Society* 4: 176.
[173] *Idem* 177.
[174] The CIOMS Guidelines make use of the term "investigator" rather than researcher.

who has not been coerced, unduly influenced or intimidated.[175] Consent is a process and this process begins when initial contact is made with the potential subject and continues throughout the course of the research.[176] This idea is strongly linked to the concept of dynamic consent which is discussed in the course of this thesis.[177] Consent may be elicited, which is a manifestation of respect for the dignity and autonomy of the prospective subject, by providing them with information, repetition and explanation of the information, allowing them to ask questions and answering these questions as they arise and ensuring that the persons concerned understand the process.[178]

In order to properly inform the prospective subject, the researcher must convey the information in a language that is befitting of the level of understanding of the subject and must take cognisance of the maturity, intelligence, education and beliefs of the subject. The culture of the subject must also be considered.[179] The researcher must then ensure that the subject adequately understands the information.[180]

Consent is communicable in a number of ways which include voluntary assent actions, in writing or orally. It must thus be sufficiently documented and preferably in a written and signed format.[181] Any preconditions of the subject must also be noted as this may influence the continuity of the consent. When material changes occur in the procedures or conditions of the research, the researcher must seek to renew the originally-granted informed consent. A further issue which is to be noted on the consent document, preferably in a separate section, is the consent of the subject to research on their biological material, use of their medical records in research[182] and their decision regarding secondary use of research records and biological specimens. For consent to be valid, the consenting person must understand the scope of what they are consenting to. In stem cell research and therapy this is especially controversial as the true scope of the research is mostly unknown. Where secondary use is therefore foreseeable or feasible, additional consent is required. In order to enable the subject to validly consent to secondary uses, the researcher must discuss the following aspects with the subject:[183]

[175] Council for International Organisations of Medical Sciences and the World Health Organisation (2002) *International Ethical Guidelines for Biomedical Research Involving Human Subjects*: 32.
[176] *Idem* 33.
[177] See chapter 9 *infra*.
[178] CIOMS and WHO (2002) 33.
[179] This is an interesting and complicated issue in a country such as South Africa which has a diverse and colourful cultural makeup.
[180] This may entail that the researcher grant the subject the opportunity to ask questions and to answer any questions honestly, completely and promptly. See CIOMS and WHO (2002) 33.
[181] CIOMS and WHO (2002) 34.
[182] *Idem* 35.
[183] *Idem* 36.

1. The possible existence of secondary uses and in the event thereof, the limitations thereof with regard to the type of study and materials;
2. The conditions under which researchers will be required to make contact with the subject for any additional assent or authorisation;
3. The proposed measures of de-identifying the material; and
4. The rights of the subject to request that their specimens or records be destroyed or anonymised.

3.2.7.2 Obtaining informed consent: Essential information for subjects and the obligations of the researcher

Guidelines 5 and 6 respectively make provision for obtaining consent. Guideline 5 establishes the essential information which must be given to prospective research subjects and guideline 6 states the obligations of the researcher.

In terms of guideline 5, the potential human subject must be provided with certain information prior to giving their consent. This information must then also be communicated in a language or other form which the subject understands. The Guidelines list 26 aspects which the subject must be informed of. For the purpose of this thesis, however, only those most relevant to this examination will be mentioned here.[184] The subject must therefore be informed that they are

[184] "Guideline 5: **Obtaining informed consent: Essential information for prospective research subjects -** Before requesting an individual's consent to participate in research, the investigator must provide the following information, in language or another form of communication that the individual can understand:

1. That the individual is invited to participate in research, the reasons for considering the individual suitable for the research, and that participation is voluntary;
2. That the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled;
3. The purpose of the research, the procedures to be carried out by the investigator and the subject, and an explanation of how the research differs from routine medical care;
4. For controlled trials, an explanation of features of the research design (e.g., randomization, double-blinding), and that the subject will not be told of the assigned treatment until the study has been completed and the blind has been broken;
5. The expected duration of the individual's participation (including number and duration of visits to the research centre and the total time involved) and the possibility of early termination of the trial or of the individual's participation in it;
6. Whether money or other forms of material goods will be provided in return for the individual's participation and, if so, the kind and amount;
7. That, after the completion of the study, subjects will be informed of the findings of the research in general, and individual subjects will be informed of any finding that relates to their particular health status;
8. That subjects have the right of access to their data on demand, even if these data lack immediate clinical utility (unless the ethical review committee has approved temporary or permanent non-disclosure of data, in which case the subject should be informed of, and given, the reasons for such non-disclosure);
9. Any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research, including risks to the health or well-being of a subject's spouse or partner;
10. The direct benefits, if any, expected to result to subjects from participating in the research;
11. The expected benefits of the research to the community or to society at large, or contributions to scientific knowledge;

invited to participate in research, why they are considered suitable for the research and that any participation is voluntary and that they are free to refuse to participate and also to withdraw from the research at any time. Subjects must also be informed of the purpose of the research; the procedures to be carried out and how the research differs from routine medical care; of the expected duration of the their participation and that after the completion of the research study they may be informed of the general findings of the study or any findings related to their health in particular. This related thereto that the subject must be informed that they have the right of access to their data unless the ethical review committee has approved a temporary or permanent non-disclosure statement.[185]

Potential research subjects must be informed of any foreseeable risks, pain, discomfort or inconvenience which is associated with participating in the research. They must also be informed of the direct benefits, if any, expected as well as the expected benefits from the research to society at large, the community and contributions to scientific knowledge. Importantly, especially where the study is a combination of medical therapy and research, the subject must be notified of any currently available alternative interventions or treatments.

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12. Whether, when and how any products or interventions proven by the research to be safe and effective will be made available to subjects after they have completed their participation in the research, and whether they will be expected to pay for them;
13. Any currently available alternative interventions or courses of treatment;
14. The provisions that will be made to ensure respect for the privacy of subjects and for the confidentiality of records in which subjects are identified;
15. The limits, legal or other, to the investigators' ability to safeguard confidentiality, and the possible consequences of breaches of confidentiality;
16. Policy with regard to the use of results of genetic tests and familial genetic information, and the precautions in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives or to others (e.g., insurance companies or employers) without the consent of the subject;
17. The sponsors of the research, the institutional affiliation of the investigators, and the nature and sources of funding for the research;
18. The possible research uses, direct or secondary, of the subject's medical records and of biological specimens taken in the course of clinical care;
19. Whether it is planned that biological specimens collected in the research will be destroyed at its conclusion, and, if not, details about their storage (where, how, for how long, and final disposition) and possible future use, and that subjects have the right to decide about such future use, to refuse storage, and to have the material destroyed;
20. Whether commercial products may be developed from biological specimens, and whether the participant will receive monetary or other benefits from the development of such products;
21. Whether the investigator is serving only as an investigator or as both investigator and the subject's physician;
22. The extent of the investigator's responsibility to provide medical services to the participant;
23. That treatment will be provided free of charge for specified types of research-related injury or for complications associated with the research, the nature and duration of such care, the name of the organization or individual that will provide the treatment, and whether there is any uncertainty regarding funding of such treatment;
24. In what way, and by what organization, the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury (or, when indicated, that there are no plans to provide such compensation);
25. Whether or not, in the country in which the prospective subject is invited to participate in research, the right to compensation is legally guaranteed; and
26. That an ethical review committee has approved or cleared the research protocol."

[185] In this case the subject must be informed thereof and given the reasons for such non-disclosure.

The provisions to ensure respect for the privacy of subjects and for their confidentiality of identifying records; the legal or other limitations to the ability of the researcher to safeguard their confidentiality; as well as any policies regarding the use of results and genetic test information must be disclosed to the subject. This includes an explanation of the precautions in place to prevent any unlawful disclosures of results to other persons without the subject's consent.

Information regarding the possible direct or secondary uses of the subject's records and biological specimens as well as whether or not the samples collected in the course of the study will be destroyed at the conclusion thereof must be explained to the concerned person. This includes information related to the storage and possible future uses of the specimens. Lastly, the subject must be informed whether the researcher is involved in a research capacity only or also as the subject's physician and whether or not an ethical review committee has approved or cleared the research protocol.

Additionally to providing the subject with the above mentioned information, a researcher has certain obligations as stated in guideline 6. It is interesting to note that these duties are in line with the dynamic consent model discussed in the course of this thesis. These duties are to:

1. Abstain from unjustified deception, undue influence or intimidation;
2. Seek consent only after determining that the potential subject has an adequate understanding of the relevant facts and consequences of participation and has been given sufficient opportunity to consider the information and whether or not to participate;
3. Obtain a signed form as evidence of informed consent;
4. Renew a person's informed consent in the event of significant changes in the conditions or procedures of the research or where new information becomes available which might affect the willingness of persons to continue their participation; and
5. Renew the informed consent of each person in long-term studies at certain pre-determined intervals.[186]

It is noteworthy that in terms of guideline 6, the researcher is responsible for ensuring the adequacy of informed consent and should therefore have knowledge regarding the research and be capable of answering any questions the potential subject might have.[187]

In certain instances, however, the researcher may withhold information in order to ensure the validity of the research.[188] In biomedical research the purpose of specific procedures may

[186] This duty applies even where no changes have been made in the design or objectives of the research. The dynamic consent model which is discussed in the course of this thesis would be able to facilitate points 3 and 4.
[187] CIOMS and WHO (2002) 40.

sometimes be withheld. The researcher must, in these cases, obtain the consent of the subject to remain uninformed until the research concludes. Withholding information may therefore not be confused with active deception of the subject. Active deception is where researchers pretend to be patients in order to observe them in a natural setting. The subject may never be deceived where such deceit would expose the subject to more than minimal risk.[189] Researchers must be completely objective in discussing the details of the experimental study which includes the pain and discomfort as well as the known risks and hazards which it may entail. The researcher must inform the subject of aspects which the reasonable person would consider material to making a decision to participate or not.[190] In complex studies, however, it may be neither feasible nor desirable to inform the potential subject of every possible risk.[191]

Researchers must be wary as intimidation in any form invalidates consent. The physician-researcher must ensure that the potential subject is aware that their refusal to participate in no way affects their therapeutic treatment or any other benefits to which they are entitled. The prospective subject may therefore never be exposed to undue influence.

3.2.7.3 Research involving vulnerable groups: Children and mentally incapacitated persons

Special justification is required to undertake research involving vulnerable persons in order to protect their rights and welfare. In terms of the CIOMS Guidelines, a vulnerable person is a person who is relatively or absolutely incapable of protecting their own interests as they may have insufficient intelligence, power, education, strength, resources or other attributes to protect their interests.[192] For purposes of this thesis, vulnerable groups must be understood as mentally incapacitated persons and minor children.[193]

The participation of minors is indispensable in research into childhood diseases and conditions to which children are susceptible. It is currently widely accepted that any new preventative, diagnostic or therapeutic product which is likely to be used on children must be tested on children in order to evaluate the safety and efficacy thereof before it is commercially

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[188] Where deception is deemed indispensable to the methods of the study, the researcher must demonstrate the following to an ethical review committee: (1) that no other research method would suffice, (2) that the research may result in significant advances and (3) that if certain information is divulged it may cause the subject to refuse participation. See also chapter 4 paragraph 2.3 *supra* regarding the duty to disclose.
[189] CIOMS and WHO (2002) 41.
[190] This is reminiscent of the case of *Castell v De Greef* 1994 (4) SA 408 (C). See chapter 3 paragraph 5.10 *supra*.
[191] CIOMS and WHO (2002) 43. Once again, see chapter 4 paragraph 2.3 *supra* regarding the duty to disclose.
[192] *Idem* 64.
[193] Vulnerable groups may extend further than mentally incapacitated persons and children and may include women, as provided for in guideline 16; physically disabled persons; persons of a certain race as well as persons from a certain lower or no income group or geographic area.

distributed.[194] Before undertaking research involving children, the researcher must ensure that the research could not be carried out equally well on adults; the research purpose is to obtain knowledge relevant to children; an authorised person has given consent; the child has assented to the extent of their capabilities and in the event of their refusal, such refusal is respected.[195]

After the child has been informed of the relevant information to the extent of their maturity and intelligence, their willing participation should be sought. The child's mere "knowing" or assent is, however, insufficient to permit participation in research unless a parent, legal guardian or other authorised individual also gives their permission or consent.[196] Where a minor is too immature to be able to grant such assent they may still be able to object to participation in which case such objection should be respected.[197] If, during the course of the research, a child subject becomes able to give their independent informed consent, it should be sought in order for their participation to continue.[198]

As mentioned above, special justification and protections are also required where research is to be conducted on individuals who, due to mental or behavioural disorders, are not capable of giving adequate informed consent.[199] According to guideline 15, before a researcher undertakes research on incapacitated persons they must ensure that such research might not be equally well carried out on persons who have the capacity to give adequate informed consent; that the purpose of the research is to obtain knowledge which is relevant to the particular health needs of incapacitated persons; the willing consent of each subject has been obtained to the extent of their capabilities and any refusal or objections on their part is respected; and where the potential subject is wholly incapable of consenting, an authorised person has given their consent in accordance to domestic legislation.

When there is an ethical and scientific justification for research on incapable persons who are not able to give informed consent and who will not directly benefit from the study, the risks should not be likely and no greater than the risk attached to routine medical or psychological examinations. Where there is an overriding scientific or medical rationale for slight or minor increases in the risk, research may still be permitted on the condition that an ethical review committee approves these increased risk margins.[200]

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[194] CIOMS and WHO (2002) 67.
[195] Guideline 14 of the CIOMS Guidelines.
[196] The consent of the parent or guardian must be sought in accordance to the domestic legislation of a country. Where a minor has been emancipated, no parental consent is required. See CIOMS and WHO (2002) 68.
[197] The only exception is where there is no other form of treatment.
[198] CIOMS and WHO (2002) 67-68.
[199] Throughout the course of this thesis, these persons have been referred to as incapacitated persons.
[200] Guideline 9 of the CIOMS Guidelines.

3.2.7.4 Miscellaneous guidelines

As mentioned above, the guidelines relevant to this study have been grouped together in four categories. Three of these categories shared a common characteristic. There are, however, two guidelines which need to be discussed but do not neatly fall into a group, namely guidelines 7 and 8. Here, some attention is given to these guidelines.

Firstly, guideline 7 provides that research subjects may be reimbursed for loss of earnings, travel costs and other expenses incurred due to their participation in the research study. Subjects may also be entitled to free medical services. Where a subject receives no direct benefit from the research, they may be compensated for their time and the inconvenience. Caution must, however, be taken as the amount of the payment must not be so large or the scope of the medical services so extensive as to unduly induce participation against the better judgement of the subject. Ethical review committees must therefore approve all payment, reimbursements and medical services.

Secondly, guideline 8 states that for all biomedical research which involves human subjects, the researcher must ensure that potential benefits and risks are reasonably balanced and the risks are minimized. On the one hand, any interventions or procedures which may be of direct preventative, diagnostic or therapeutic benefit to the subject must be justified by the expectation that it will be at least as advantageous, taking into consideration the foreseeable risks and benefits, as any available alternative. The risks must therefore be justified in relation to the expected benefits. On the other hand, the risks involved in interventions not directly beneficial to the subject must be justified considering the expected benefits to society. In other words, the risks presented must be reasonable in relation to the importance of the knowledge which might be gained.

3.2.8 Universal Declaration on Bioethics and Human Rights

The Universal Declaration on Bioethics and Human Rights (UDBHR) is an international instrument drafted by UNESCO's IBC and adopted on the 19th of October 2005.[201] Its provisions are similar to those of the Universal Declaration on the Human Genome and Human Rights, but it has a much broader scope.[202] It is therefore an improvement on the Universal Declaration on

[201] Andorno (2007) 150.
[202] In addition to providing for informed consent, respect for privacy and confidentiality, non-discrimination and non-stigmatisation, it also provides for social responsibility and stresses that progress in science and technology must promote the welfare of humanity. See United Nations Educational, Social and Cultural Organisation (2005) "UNESCO adopts Universal Declaration on Bioethics and Human Rights" available online at

the Human Genome and Human Rights as well as other bioethical regulations.[203] The UDBHR is the first international instrument to comprehensively deal with the connection between human rights and bioethics despite the number of already existing international guidelines, statements and declarations.[204]

The rationale behind the UDBHR was the clear lack of guidelines in bioethics in developing countries and the Declaration attempts to fill this void.[205] It is therefore a proposed, comprehensive framework of principles to guide biomedical activities in order to provide for international human rights conformity. Technically, the Declaration has no legal authority, but it may be incorporated into domestic legislation and so become binding.[206]

The UDBHR contains articles which include provisions regarding respect for human dignity, human rights and fundamental freedoms as well as prioritising the interests and welfare of the individual over the interests of science and society.[207] The Declaration consists of a Preamble and 28 articles which are divided into five parts namely the general provisions,[208] principles,[209] application of the principles,[210] promotion of the Declaration,[211] and the final provisions.[212] It is interesting to note that the arrangement of the principles contained in the UDBHR involves a gradual broadening of the subject being addressed. Initially, the principles relate to individual humans, this opens up to other humans and again the subject matter is broadened into principles related to respect for cultural diversity and pluralism follow by provisions regarding living beings, the environment, the biosphere and biodiversity.[213] The articles relevant to this thesis are a good sampling of this widening of the subject matter and will be discussed in numerological order.

Article 5 provides for autonomy and individual responsibility. It states that the autonomy of persons to make decisions while also being able to take responsibility for such decisions and while respecting the autonomy of others, must be respected. Special measures must be taken in order to protect the rights and interests of persons who are not capable of exercising their autonomy. It must be noted that, although these instances must be highly restricted and

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http://www.un.org/apps/news/story.asp?NewsID=16296&Cr=UNESCO&Cr1=Bioethics#.Vg208Pmqqko accessed 2/10/2015.
[203] Wolinsky H (2006) "Bioethics for the world" *Science & Society* 7(4): 355.
[204] Andorno (2007) 150.
[205] Wolinsky (2006) 355.
[206] *Idem* 357. For more on the history and drafting of this instrument see Kirby (2009) 320-321.
[207] *Idem* 355.
[208] Articles 1 and 2 of the UDBHR.
[209] Articles 3-17 of the UDBHR.
[210] Articles 18-21 of the UDBHR.
[211] Articles 22-25 of the UDBHR.
[212] Articles 26-28 of the UDBHR.
[213] Kirby (2009) 322.

regulated by law, autonomy may be subject to certain limitations.[214] These limitations must, however, only take place where it is done to protect the autonomy of others.[215] The freedom to make decisions and thus exercise autonomy is dependent on the ability to make decisions. This has a dual implication. Firstly, the person who is required to make a decision must be competent to do so and secondly, the person must have adequate information in order to make a truly authentic decision.[216] Should either competency or information be lacking, a decision or exercise of autonomy may never be valid.

Autonomy is enshrined in the concept of consent and so the UDBHR next makes provision for consent. According to article 6, any medical preventive, diagnostic or therapeutic intervention may only to be carried out with the prior, free and informed consent of the concerned person, based on adequate information. Consent should be expressly given where appropriate and may be withdrawn at any time, for any reason without prejudice or disadvantage.[217] Likewise, scientific research may only be undertaken with the prior, free, express and informed consent of the concerned person. A person who may potentially participate in research must be informed of the research, which information must be adequate and comprehensibly provided. Once again, consent may be withdrawn at any time, for any reason and without any disadvantage or prejudice.[218]

As medical treatment and research pose potential risks to persons, protective measures are necessary to guard against unwarranted and unwanted interventions. Once again it is emphasised that prior, voluntary consent based on adequate information with the option to withdraw is an indispensable prerequisite for any medical intervention or scientific research involving humans.[219] Consent therefore limits the ability of the State, medicine, science or the community to govern the individual. However, consent is not only an ethical and legal requirement protecting patients and research subjects, but also physicians and researchers against accusations and litigation.[220]

The consent requirement as a protective measure must also be applied, perhaps even more strictly, to persons who do not have the capacity to consent. In terms of the UDBHR, persons who do not have the capacity to consent must be afforded special protection in accordance with

[214] See chapter 3 paragraph 4 *supra* for a detailed discussion on the limitations regarding autonomy.
[215] Evans D (2009) "Article 5: Autonomy and individual responsibility" in ten Have HAMJ & Jean MS (eds) *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, principles and application*: 116.
[216] Evans (2009) in ten Have & Jean (eds) 117-118.
[217] Article 6(1) of the UDBHR.
[218] Article 6(2) of the UDBHR.
[219] Kollek R (2009) "Article 6: Consent" in ten Have HAMJ & Jean MS (eds) *The UNESCO Universal Declaration on Bioethics and Human Rights: Background, principles and application*: 122-124.
[220] *Idem* 126.

domestic legislation.[221] Where a person is not able to consent, authorisation for research and medical practice must be obtained according to the best interest of the concerned person. The concerned person must be involved in the decision-making process to the greatest extent possible.[222]

Research involving such persons should only be conducted for their direct health benefit, and subject to the preconditions that authorisation and the protective conditions are prescribed by law and in the absence of an alternative research study of comparable effectiveness with participants who are able to consent. Where research will not directly benefit the concerned person, it may only be undertaken by way of exception and using the utmost restraint. Such persons may only be exposed to minimal risk and burden. In the event of refusal to participate, such refusal must be respected.[223]

3.2.9 Convention on the Rights of Persons with Disabilities

The Convention on the Rights of Persons with Disabilities (CRPD) is a UN international human rights treaty which intends to protect the rights and dignity of disabled persons. It requires the parties thereto to promote, protect and ensure the full enjoyment of human rights and equality of persons with disabilities. In 1987 during the "UN Decade of Disabled Persons" which ran from 1981 to 1992, it was decided that the UN needed to draft an international convention eliminating discrimination against disabled persons. The CRPD became the human rights instrument with the fastest growing support in history and was adopted by the General Assembly on the 13th of December 2006 making it the first human rights treaty of the third millennium.[224] The Convention is monitored by the Committee on the Rights of Persons with Disabilities.

The structure of the Convention is novel in that it is not divided into parts but it does consist of a Preamble which is then followed by 50 articles. The Preamble states that human rights are universal, indivisible, interdependent and interrelated, and that persons with disabilities should not be discriminated against in the enjoyment of their rights and freedoms. This is echoed in article 1 which reads that the purpose of the Convention is to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all disabled persons and to promote respect for their inherent dignity. Article 1 furthermore provides for a social

[221] Article 7 of the UDBHR.
[222] Article 7(a) of the UDBHR.
[223] Article 7(b) of the UDBHR.
[224] Harpur P (2010) "Ensuring equality in education: How Australian laws are leaving students with print disabilities behind" *Media and Arts Law Review* 15(1): 70.

definition of disability and defines disabled persons as "those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others."[225] The definition is rather broad and indicates that a person who is impaired in some way, is disabled. Impairment is nothing more than a lack of ability or then, of capacity and so it may be argued that this impairment or lack of ability may be understood to mean that a person who, for some reason or another, suffers from a form of incapacity may be described as a disabled person in context of the CRPD. The rights contained in the Convention are provided for in articles 4 to 32 while articles 33 to 39 govern the reporting and monitoring on the CRPD by certain institutions. Ratification, entry into force and the amendment of the Convention are dealt with in articles 40 to 50.

There are eight core guiding principles in the CRPD according to article 3.[226] The first entails that the inherent dignity, individual autonomy and freedom of decision of persons should be respected. The mention of autonomy and freedom to make decisions as core principles of the Convention is indicative of the importance of consent given by a disabled person, as consent is the personification of autonomy and freedom to make decisions. Autonomy is then also inextricably bound to integrity, mental or physical, and equal respect for integrity of the disabled is guaranteed by article 17 of the CPR.

Consent is a legal requirement and therefore the legal equality and capacity of the disabled person must be considered. Article 12 of the Convention, however, makes provision for this and provides that persons with disabilities are equal before the law with legal capacity and requires that members of the Convention recognise this equality and capacity.

The right to the enjoyment of the highest attainable standard of health is provided for in article 25. Furthermore, a person may not in pursuit of this standard of health be discriminated against on the basis of their disability. Similar to the argument made above regarding children,[227] this highest attainable standard of health may include stem cell therapy or participation in medical

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[225] Further definitions may be found in article 2.

[226] Article 3: "**General principles-**
The principles of the present Convention shall be:
a. Respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons;
b. Non-discrimination;
c. Full and effective participation and inclusion in society;
d. Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity;
e. Equality of opportunity;
f. Accessibility;
g. Equality between men and women;
h. Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities."

[227] See the discussion of the Convention on the Rights of a Child, paragraph 3.2.5 *supra*.

research. A disabled person may therefore not be excluded from treatment or research merely because they are disabled. They should then be enabled to participate and this may be facilitated to some degree by having proper consent procedures, such as the procedures suggested throughout this thesis, in place. This then concludes the discussion of UN instruments which may have an impact on establishing the correct manner and format of obtaining consent in scenarios where therapy borders on research involving human subjects, such as stem cell therapy, and the instruments of the WMA will be examined in the following section of this chapter.

3.3 INSTRUMENTS OF THE WORLD MEDICAL ASSOCIATION

Although the UN and the organisations created under the auspices thereof is responsible for the greater number of instruments relevant to this study, it is not the lone role player and attention must now be given to the instruments created by multinational, intergovernmental organisations. These instruments are of importance as they prescribe rules and principles as they pertain to the persons who are in charge of medical and scientific interventions. The instruments discussed in the following section of this chapter therefore focus on physicians, and by extension researchers or scientists who have certain roles to play and obligations.

This section examines the Declaration of Geneva, which includes discussions of the Hippocratic Oath and the International Code of Medical Ethics as well as the Declaration of Helsinki, which has been described as the cornerstone document in research involving humans.

3.3.1 Declaration of Geneva

The Declaration of Geneva, or the Physicians Oath, was adopted by the General Assembly of the WMA in Geneva in 1948. It was amended in 1968, 1983 and 1994 as well as editorially revised in 2005 and 2006. The Declaration declares the dedication of a physician to humane medicine and may be described as an intended revision of the Hippocratic Oath as it is a formulation of the moral truths of the Oath in a modern context.[228] The Declaration is also the inspirational document on which the International Code of Medical Ethics is based.[229]

[228] World Medical Association (1997) "Press release: World Medical Association Council Meeting in Paris, 8-10 May 1997" available online at http://www.wma.net/en/40news/20archives/1997/1997_14/index.html accessed 28/8/2015. It is interesting to note that this same press release asks doctors and researchers to abstain from voluntary participation in the study of human cloning until the ethical and moral issues surrounding such studies has been fully considered. See in general, Jones DA (2006) "The Hippocratic Oath II: The Declaration of Geneva and other

Today, it is a common idea that doctors should act in a humane manner but this was not always the case. The Declaration is therefore the result of the shock and moral disgust which arose from *inter alia* the experiments conducted by German Nazi doctors as well as Japanese doctors under the Japanese Imperial Army at Unit 731 in China.[230] These actions clearly illustrated that guidelines were necessary regarding human and patient rights. After some years of deliberation a draft modernised version of the Hippocratic Oath was eventually sent for consideration at the WMA Second General Assembly in Geneva in 1948. It was adopted and agreed on that the vow be named the Declaration of Geneva.[231]

The Declaration as it is published by the WMA today reads as follows:[232]

> "At the time of being admitted as a member of the medical profession:
> I SOLEMNLY PLEDGE to consecrate my life to the service of humanity;
> I WILL GIVE to my teachers the respect and gratitude that is their due;
> I WILL PRACTISE my profession with conscience and dignity;
> THE HEALTH OF MY PATIENT will be my first consideration;
> I WILL RESPECT the secrets that are confided in me, even after the patient has died;
> I WILL MAINTAIN by all the means in my power, the honour and the noble traditions of the medical profession;
> MY COLLEAGUES will be my sisters and brothers;
> I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;
> I WILL MAINTAIN the utmost respect for human life;
> I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat;
> I MAKE THESE PROMISES solemnly, freely and upon my honour."

The Declaration thus evidences an expectation of respect and consideration of the patient on the part of the physician. In context of stem cell research and therapy, the physician is also a scientist and for this reason these vows should extend to them in the context of research and to the research practice itself.

As the Declaration is a modernised version of the Hippocratic Oath, it is necessary to briefly discuss the Oath itself at this juncture. The discussion of the Oath is then followed by a brief discussion of the International Code of Medical Ethics which is based on the Declaration of Geneva and may therefore be viewed as an extension of the Hippocratic Oath.

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modern adaptations of the classical doctors' oath" *Catholic Medical Quarterly* available online at http://www.cmq.org.uk/CMQ/2006/hippocratic_oath_ii.htm accessed 3/10/2015.

[229] See paragraph 3.3.1.2 *infra* for a discussion on the International Code of Medical Ethics.

[230] See in general, Ivy AC (1948) "The history and ethics of the use of human subjects in medical experiments" *Science* 108(2): 1-5. See also Jonsen AR (2003) *The birth of bioethics*.

[231] World Medical Association (1992) "Declaration of Geneva" *Journal of Nutritional Medicine* 3(2): 153. Interestingly, the WMA Declaration of Geneva was adopted a mere three months before the UN Universal Declaration of Human Rights which provides for security of the person.

[232] For a discussion of the various changes to the Declaration see Jones (2006) online.

3.3.1.1 The Hippocratic Oath

The Hippocratic Oath is an oath which is historically taken by physicians and is one of the most famous Greek ethical texts. It is attributed to Hippocrates[233] and is still used in graduation ceremonies of medical doctors to be to this day[234] as it is regarded as a rite of passage for those entering the medical profession.

It was originally written in Ionic Greek in the late fifth century BC, *circa* 400 BC, and is normally included in the Hippocratic Corpus. In its original form,[235] it requires a new physician to vow to uphold certain ethical standards and obliges physicians and students of medicine to pledge to prescribe only beneficial treatments while refraining from causing harm, according to the abilities and judgement of the physician.[236]

Due to the belief that the Oath itself was inadequate in addressing the realities of modern medicine, the Oath was and has been revised numerous times, one of the most significant revisions being the Declaration of Geneva. No penalty exists for transgressing the Hippocratic Oath as such, but as it has been absorbed into other documents it may be thought of as being indirectly legally binding and therefore activities such as malpractice and medical negligence are punishable. One such document which has absorbed the philosophy underlying the Oath is the Declaration of Geneva and it has in turn given rise to the International Code of Medical Ethics. This Code must therefore also be briefly discussed as it is an extension of the Declaration and of the Oath.

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[233] Some scholars have argued that the Hippocratic Oath was written by students of Hippocrates while others argue that it was in fact the Pythagoreans who authored the text. See in general, Temkin O (2001) "On second thought" in Temkin O (ed) *On second thought and other essays in the history of medicine and science*. See also Ogunbanjo GA & Knapp van Bogaert D (2009) "The Hippocratic Oath: Revisited" *South African Family Practice* 51(1): 30-31.

[234] Encyclopaedia Britannica (2015) "Hippocratic Oath" available online at http://www.britannica.com/topic/Hippocratic-oath accessed 28/8/2015.

[235] As translated in 1849 by Francis Adams the Oath reads: "I swear by Apollo the physician, and Aesculapius, and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath and this stipulation—to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this Art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others. I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art. I will not cut persons labouring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further from the seduction of females or males, of freemen and slaves. Whatever, in connection with my professional practice or not, in connection with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times! But should I trespass and violate this Oath, may the reverse be my lot!" See in general, Edelstein L (1945) "The Hippocratic Oath: Texts, translations and interpretation" *The American Journal of Philology* 66(1): 105-108.

[236] Encyclopaedia Britannica (2015) online. See also Miola J (2006) "The need for informed consent: Lessons from the ancient Greeks" *Cambridge Quarterly of Healthcare Ethics* 15(2): 152-160.

3.3.1.2 The International Code of Medical Ethics

The International Code of Medical Ethics is an ethical code which attempts to establish ethical principles to be followed by physicians globally. It is based on the Declaration of Geneva and focuses on the duties of the physician to his patients and colleagues. It was originally adopted by the WMA General Assembly in 1949 and was amended in 1968, 1983 and 2006.

The Code is divided into three categories. The first relates to the duties of the physician in general. These duties include having respect for the refusal of a competent patient to treatment,[237] respect for the rights and preferences of patients and other health care professionals and respect for domestic and international codes of ethics. The second part of the Code stipulates the duties of the physician towards his patients which includes *inter alia* the obligation to respect human life and to act in the best interests of the patient in providing medical care. Importantly, a physician owes his patient complete loyalty and all of the scientific resources available to him. This may be interpreted to mean that a physician has an ethical duty to suggest, or at least inform their patients of, stem cell therapy or experimental treatments. Part three provides the duties of the physicians towards one another as colleagues.[238]

3.3.2 Declaration of Helsinki

The Declaration of Helsinki (DOH) is a set of ethical principles which were developed for the medical community by the WMA regarding human experimentation.[239] It is widely regarded as the cornerstone document on human research ethics[240] and the most recognised source of ethical guidance for biomedical research.[241] The DOH was first adopted on the 18th of June 1964 in Helsinki and has since been revised numerous times[242] and has undergone two clarifications.[243] Due to these revisions and clarifications the Declaration may be thought of as a living document which is precisely what is recommended for any instrument regarding consent.[244] The document is a very important document in the history of research ethics and was the first significant effort on behalf of the medical community to regulate research. The

[237] This is reminiscent of the case of *Phillips v De Klerk* 1983 (T) (unreported). See chapter 3 paragraph 5.9 *supra*.
[238] World Medical Association (2006) "International Code of Medical Ethics" available online at http://www.wma.net/en/30publications/10policies/c8/ accessed 28/8/2015.
[239] World Medical Association (2013) "Declaration of Helsinki: Ethical principles for medical research involving human subjects" *The Journal of the American Medical Association* 310(20): 2191.
[240] *Idem* 2193. See also Snežana B (2001) "The Declaration of Helsinki: The cornerstone of research ethics" *Archive of Oncology* 9(3): 179-184.
[241] Carlson RV, Boyd KM & Webb DJ (2004) "The revision of the Declaration of Helsinki: Past, present and future" *British Journal of Clinical Pharmacology* 57(6): 695.
[242] The most recent was in October 2013. Due to all the revisions the DOH has grown from 11 to 37 paragraphs.
[243] The DOH was clarified in 2000 and 2004. See Williams JR (2008) "The Declaration of Helsinki and public health" *Bulletin of the World Health Organisation* 86(8): 650.
[244] Carlson, Boyd *et al*. (2004) 696.

DOH is, however, not a legally binding instrument under international law and is only authoritative in the extent to which it is absorbed into national and regional legislation.

The DOH developed from the principles found in the Nuremberg Code and linked them to the Declaration of Geneva. The Declaration specifically addresses clinical research and makes explicit provisions regarding consent.[245]

The Declaration is comprised of an introduction and 11 sections. The sections are: General Principles; Risks, Burdens and Benefits; Vulnerable Groups and Individuals; Scientific Requirements and Research Protocols; Research Ethics Committees; Privacy and Confidentiality; Informed Consent; Use of Placebo; Post-Trial Provisions; Research Registration and Publication and Dissemination of Results and lastly Unproven Interventions in Clinical Practice. As the consent requirement features rather prominently in the DOH, it is of importance to discuss the evolution of consent in the Declaration through the revisions thereof:[246]

1. The First Revision (1975): The First Revision almost doubled the length of the original Declaration. The idea of oversight by an independent committee was introduced. Also, informed consent was developed and made more prescriptive and moved into the "General Principles" section of the Declaration. The consent requirement for non-therapeutic research was simplified and made to state simply that the subjects should be volunteers. The burden of proof for not requiring consent was placed on the researcher;
2. The Second Revision (1983): The Second Revision included seeking to obtain consent from minors where possible;
3. The Third Revision (1989): The Third Revision expanded the function and structure of the independent committee;[247]
4. The Fourth Revision (1996):[248] The Fourth Revision was minimal and consisted mostly of small textual changes. These changes, however, planted the seeds from which a much larger debate grew regarding the use of placebos in clinical trials. Following this revision, pressure started to build almost immediately for a more fundamental approach to revising the DOH;[249]

[245] The DOH however relaxes the consent requirement as found in the Nuremberg Code. Under the Code consent was "absolutely essential" while in terms of the DOH, physicians are required to obtain consent "if at all possible" and proxy consent is allowed under certain conditions.
[246] Only the revisions most relevant to this thesis will be discussed here. Williams (2008) 650-651. See also Carlson, Boyd *et al*. (2004) 696-704.
[247] From 1982 the DOH was not the only universal ethical guide as the CIOMS Guidelines and the WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects had been published.
[248] The Second and Third Revisions were relatively minor leaving the 1975 version as the primary document governing research for some years.
[249] Levine RJ (1999) "The need to revise the Declaration of Helsinki" *The New England Journal of Medicine* 341(7): 532.

5. The Fifth Revision (2000): The Fifth Revision was an extensive one, largely due to the expanded scope of biomedical research. This involved a restructuring of the declaration, which included a reordering and renumbering of all the articles. The Introduction established the right of all research subjects and describes the tension between the need for research in order to improve the common good and the rights of the individual. The General Principles provided a guide whereby it could be judged to what extent expected ethical standards were being met. The distinction between therapeutic and non-therapeutic research was removed in order to broaden the application of the DOH. The scope of ethical review was also broadened in order to include human tissue data;[250]
6. The Sixth Revision (2008): The Sixth Revision was greatly limited compared to the 2000 revision; and
7. The Seventh Revision (2013): The Seventh Revision emphasises the need to disseminate research results and includes the requirement to compensate research subjects for injuries incurred related to the research.

The principles contained in the Declaration are morally binding on physicians and are considered to supersede national legislation and regulations where the DOH provides a higher standard of protection. Researchers therefore still need to abide by national laws but are held to a higher standard.

The fundamental principles of the Declaration are respect for the individual,[251] the right to self-determination,[252] and the right to make informed decisions regarding participation prior to as well as during the course of research. It must be kept in mind that although there will always exist a need for research[253] the subject's welfare must continuously take precedence over the interests of science and society.[254] Also, the researcher's duty is solely to the patient or participant.[255]

The DOH is of great importance in context of this thesis study and for this reason the text thereof must be examined in some detail. The WMA developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects which includes research on identifiable human material and data.[256] The DOH is therefore primarily directed at physicians but encourages other persons involved in medical research involving human

[250] Grady C, Foster HP & Emanuel E (2001) "The 2000 revision of the Declaration of Helsinki: A step forward or more confusion?" *The Lancet* 358(9291): 1451. See also Riis P (2000) "Perspectives on the fifth revision of the Declaration of Helsinki" *The Journal of the American Medical Association* 284(23): 3045-3046.
[251] Article 8 of the DOH.
[252] Article 9 of the DOH.
[253] Article 6 of the DOH.
[254] Article 5 of the DOH.
[255] Articles 2, 3 and 10 of the DOH.
[256] Article 1 of the DOH.

subjects to adopt these principles.[257] Physicians are bound by the Declaration of Geneva and the International Code of Medical Ethics but in terms of the DOH it is the duty of the physician to promote and safeguard the health, well-being and rights of patients including those involved in medical research. The knowledge and conscience of the physician therefore need to be dedicated to the fulfilment of this duty.[258]

Medical progress is based on research and ultimately this will lead to studies involving human subjects.[259] The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and to improve preventive, diagnostic and therapeutic methods, procedures and treatments. Even those that have proven best must continually be evaluated through research to evaluate their safety, effectiveness, efficiency, accessibility and quality.[260] Medical research must be subject to ethical standards which promote and ensure respect for all human subjects and protect their rights and health.[261] Although the primary purpose of medical research is to generate new knowledge, this object may never take precedence over the rights and interests of the individual research subjects.[262]

Physicians who are involved in medical research have the duty to protect the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of their research subjects. This responsibility must always rest with the physician or other health care professionals and never with the research subjects, even where they have given consent.[263] Physicians must also consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as any applicable international norms and standards. No national or international ethical, legal or regulatory requirement may reduce or eliminate any of the protections for subjects in terms of the Declaration.[264] Where physicians combine medical research with medical care they must involve their patients in research only to the extent justifiable by its potential preventive, diagnostic or therapeutic value and where the physician has good reason to believe that participation will not adversely affect the health of the patients who serve as research subjects.[265]

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[257] Article 2 of the DOH.
[258] Articles 3 and 4 of the DOH.
[259] Article 5 of the DOH.
[260] Article 6 of the DOH.
[261] Article 7 of the DOH.
[262] Article 8 of the DOH.
[263] Article 9 of the DOH.
[264] Article 10 of the DOH. Article 12 further requires that medical research should also only be conducted by persons who have the appropriate ethical and scientific education, training and qualifications. Research on patients or healthy volunteers requires supervision of a competent and appropriately qualified physician or other such qualified health care professional.
[265] Article 14 of the DOH.

Both medical practice and medical research involve risks and burdens. In medical research involving human subjects, however, research may only be conducted where the importance of the research objective outweighs these risks and burdens.[266] All medical research involving human subjects must therefore be preceded by a careful assessment of the predictable risks and burdens compared with the foreseeable benefits.[267] For this reason physicians may not participate in research unless they are confident that the risks have been adequately assessed and can be managed in a satisfactory manner.[268]

Medical research involving human subjects must conform to generally accepted scientific principles as well as be based on a thorough knowledge of scientific literature or other relevant sources of information and adequate laboratory, and where appropriate, animal experimentation.[269] The research design and performance must be clearly described and justified in a research protocol. The protocol must contain a statement of the ethical considerations involved and should also indicate how the principles in the DOH have been addressed. It should include information regarding the funding, sponsors, any institutional affiliations, potential conflicts of interest, incentives for the subjects and relevant information regarding treating and/or compensating any subjects who are harmed as a result of participation in the study.[270]

Participation by individuals who are capable of giving informed consent must be voluntary. Although family members or community leaders may be consulted, no person may be enrolled in a research study unless they freely agree.[271] Each potential subject who is capable of consenting must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, relevant institutional affiliations of the researcher, the anticipated benefits and potential risks of the research and any discomfort the research may entail. The subject must be informed of their right to refuse to participate or to withdraw their consent at any time during the study. After ensuring that the subject has understood the information, the physician must seek the potential subject's voluntary informed consent. Preferably consent should be obtained in writing.[272] Subjects must be given the option of being informed of the general outcomes and results of the study.[273]

[266] Article 16 of the DOH.
[267] Article 17 of the DOH.
[268] Article 18 of the DOH.
[269] Article 21 of the DOH.
[270] Article 22 of the DOH.
[271] Article 25 of the DOH.
[272] If it is not possible to express consent in writing, the non-written consent must be formally documented and witnessed.
[273] Article 26 of the DOH.

When seeking to obtain informed consent for participation in research the physician must be particularly cautious where the subject is in a dependent relationship with the physician or may give consent under duress. In situations such as these, the informed consent must be sought by another appropriately qualified independent person.[274]

Where a potential subject is incapable of giving informed consent, the physician must seek informed consent from a legally authorised representative of the subject. Incapable individuals must not be included in a study which has no likelihood of benefitting them unless the research is intended to promote the health of a group which is represented by the potential subject.[275] When a potential research subject is deemed incapable of giving informed consent but is, however, able to give assent to decisions regarding their participation, the physician must seek such assent in addition to the consent of the authorised representative. Likewise the potential subject's dissent must be respected.[276] Research involving subjects who are physically or mentally incapable of giving consent may be done only where the physical or mental condition is a necessary characteristic of the research group. In these circumstances the physician must also seek informed consent from a legally authorised representative. Where no such representative is available and research should not be delayed the study may proceed without informed consent, on the condition that the specific reasons for involving such subjects have been stated in the research protocol and the research study has been approved by a research ethics committee. As soon as the person is capable of giving consent they must give consent to remain in the study.[277]

For medical research using identifiable human material or data,[278] physicians must seek informed consent for the collection, storage and/or reuse thereof. Exceptional situations may exist where consent would be impossible or impracticable to obtain and in these situations the research may be done only after the consideration and approval of a research ethics committee.[279]

3.4 INSTRUMENTS OF THE AFRICAN UNION

This chapter has now discussed the international instruments of the UN as well as those of multinational organisations such as the WMA and WHO. South Africa is a party to all the

[274] Article 27 of the DOH.
[275] Article 28 of the DOH.
[276] Article 29 of the DOH.
[277] Article 30 of the DOH.
[278] Such as research on material or data contained in biobanks or other repositories for example.
[279] Article 32 of the DOH.

instruments which have been discussed in the course of this chapter and is therefore bound to the provisions and principles thereof. South Africa, as one of the more developed and modernised countries in Africa, may be seen as a mentor in certain areas on the African continent and as such fulfils a leadership role. However, it is not enough only to examine the international instruments as South Africa is in the unique position of being a county of duality meaning that although there are modern and first world aspects of this country, it also suffers from third world issues along with the rest of the continent. As an African country, South Africa shares in certain African norms which are not found in more Westernised systems. An example of this is the philosophy of *ubuntu* which is explained in the course of the discussion below. These norms are embodied in the instruments of the AU and as a member of the African community, South Africa is also bound to these instruments, and it is therefore necessary, for the sake of completeness, to examine these instruments as this chapter draws to an end. It is after all inconceivable to think that a plausible solution for the issues facing us, in general as well as regarding consent, may be found without taking into account all of the surrounding information and conditions. What follows is therefore a brief discussion of the African Charter on Human and Peoples' Rights and the African Charter on the Rights and Welfare of the Child in order to garner insights into the African frame of mind.

3.4.1 African Charter on Human and Peoples' Rights

The African Charter on Human and Peoples' Rights, also referred to as the Banjul Charter, is an international human rights instrument with the purpose of promoting and protecting human rights and basic freedoms in Africa.[280] It originally emerged under the Organisation of African Unity which has since been replaced by the African Union. The Charter was adopted by the Assembly of Heads of State and Government in 1979 after a resolution called for a continent-wide human rights instrument to be drafted similar to those already in existence in Europe.[281]

The Charter has been ratified by most of the members of the AU. Oversight of the Charter is the responsibility of the African Commission on Human and Peoples' Rights,[282] established in 1987, with its headquarters in Banjul. A protocol to the Charter was also adopted in 1998 whereby an African Court on Human and Peoples' Rights was created.[283] This protocol came into effect in 2004.

[280] See Heyns C & Killander M (eds)(2013) *Compendium of key human rights documents of the African Union*: 29-41.
[281] Umozurike UO (1983) "The African Charter on Human and Peoples' Rights" *The American Journal of International Law* 77(4): 902.
[282] See Heyns & Killander (eds)(2013) 182-447.
[283] See *idem* 47-62.

The Banjul Charter mimicked the European and Inter-American systems by creating a regional human rights model[284] for the African continent and therefore shares numerous features with other regional instruments.[285] A characteristic which the African Charter shares with the European and UN instruments, for example, is the referencing to other instruments. For example, the Preamble of the Banjul Charter refers to the UN Charter as well as the UDHR.[286] The Charter does, however, contain novel and unique characteristics regarding recognised norms and mechanisms of supervision. An example of these novel and unique norms may be seen in article 29 of the Charter. Here the Charter not only provides persons with rights but also places certain duties on them which include: to preserve the harmonious development of the family; to serve their national community by placing their physical and intellectual abilities at its service; to work to the best of their abilities and competence and to pay taxes imposed by the law in the interest of society; to preserve and strengthen positive African cultural values in their relations with other members of society in the spirit of tolerance, dialogue and consultation and to contribute to the promotion of the moral well-being of society; and to contribute to the best of their abilities, at all times and at all levels, to the promotion and achievement of African unity. These duties show a definitive spirit of *ubuntu*.[287] *Ubuntu* is the philosophy that all persons are connected and are only human, by the humanness of others. It is thus a community-driven ideology.[288]

Amongst the numerous rights enshrined in the Charter are universally accepted civil and political rights such as the right to life and personal integrity,[289] as well as economic, social and cultural rights such as the right to health.[290] Considerable emphasis is placed on these rights. The Charter does not specifically mention informed consent but it may be inferred from reading articles 4 and 6 together.[291] Article 4 states that human beings are inviolable and are entitled to have their right to life and integrity of his person respected. Integrity is connected to autonomy and therefore their autonomy must be respected. Article 6 then provides that every person has the right to liberty and security of the person. Furthermore, every person has the right to enjoy the best attainable state of physical and mental health according to article 16 of the Charter. A person may therefore not be deprived of the opportunity to receive medical treatment which may benefit them as such a deprivation would violate their integrity and autonomy.

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[284] Heyns C (2004) "The African regional human rights system: The African Charter" *Penn State Law Review* 108: 679.
[285] See in general, Okere BO (1984) "The protection of human rights in Africa and the African Charter on Human and Peoples' Rights: A comparative analysis with the European and American systems" *Human Rights Quarterly* 6(2): 141-159.
[286] Umozurike (1983) 902.
[287] *Ubuntu* is discussed in the judgement of Mokgoro J in *S v Makwanyane and Another supra*.
[288] Suggested further reading, Metz T (2013) "African values, human rights and group rights: A philosophical foundation for the Banjul Charter" *African Legal Theory and Contemporary Problems* 29: 131-151.
[289] Article 4 of the Banjul Charter.
[290] Article 16 of the Banjul Charter.
[291] Nienaber (2007) 437.

3.4.2 African Bioethics Resolution

The African Bioethics Resolution is one of the least-known instruments of the African regional system and was adopted by the OAU Assembly of Heads of State and Government in 1996.[292] The Preamble to the Bioethics Resolution recognises the intrinsic dignity of all members of the human family and acknowledges other international instruments namely the Universal Declaration of Human Rights, the African Charter on Human and Peoples' Rights and the International Covenant on Economic, Social and Cultural Rights. The International Covenant on Civil and Political Rights is also expressly endorsed by paragraph 2 of the Bioethics Resolution which prohibits the subjection of any person to medical or scientific experimentation without their freely given consent. Although the Bioethics Resolution is not binding, it is clear that international instruments have a symbiotic relationship and that legal documents tend to influence one another. As such, an argument might be made as to the indirect binding force thereof through the application of other international instruments.

The Preamble further states that individuals have the right to benefit from scientific progress as well as the application thereof[293] while also recognising the rapid progress achieved in bioscience and the dangers which could befall the dignity and integrity of the individual. The Bioethics Resolution, "aware of the seriousness of the stakes involved, the complexity of scientific and human problems, the limitations of every human being and the need to contribute to the triumph of life,"[294] therefore gives the issues pertaining to bioethics as this has become an absolute necessity.[295]

What is of some interest is the use of the phrase "enlightened consent." The Bioethics Resolution provides for an obligation to obtain the free and enlightened consent of any person submitting to biomedical research.[296] It is suggested that "enlightened" should be understood as informed or knowledgeable. According to Nienaber, the drafters of the Bioethics Resolution unlikely intended to establish a higher standard of consent than other international documents and that the word "enlightened" might originate from a literal translation of the French version of the document which reads: "*consentement libre et éclairé*."[297] However, it transpired that the requirement of enlightened consent sums up the spirit of the proper format of consent to participate in biomedical research in that it clearly indicates that the consent obtained must be associated with the gaining of information and knowledge.

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[292] Nienaber (2007) 422-438.
[293] This is reiterated in paragraph 3(g) of the Bioethics Resolution.
[294] Preamble to the Bioethics Resolution.
[295] Paragraph 1 of the Bioethics Resolution.
[296] Paragraph 3(e) of the Bioethics Resolution.
[297] "*Éclairé*" means enlightened.

3.4.3 African Charter on the Rights and Welfare of the Child

The African Charter on the Rights and Welfare of the Child (ACRWC), or the Children's Charter, was adopted by the Organisation of African Unity on the 11th of July 1990.[298] It is similar to the UNCRC as it is also an instrument which comprehensively sets out the rights of children and defines universal principles and norms affecting children. The Children's Charter and the CRC are also the only international and regional human rights treaties which cover the entire spectrum of civil, political, economic, social and cultural rights.[299] The best interests of the child are also stated as a fundamental principle of the African Children's Charter.[300] The ACRWC, however, differs from the CRC as the members of the then OAU believed that the CRC failed to provide for important socio-cultural and economic realities particular to Africa. Africa-specific provisions are therefore found in the text of the ACRWC such as the prohibition of child marriages and betrothal of female children.[301]

The Charter recognises the child's unique and privileged place in the African community and that African children require protection and special care. The Charter thus specifically protects the child from interferences or compromises of their health or development, be it spiritual, mental, social or moral.[302]

Article 2 of the ACRWC defines a child as "every person below the age of 18 years." Children who are mentally or physically disabled are entitled to the protection of their dignity and the promotion of their self-reliance and active participation in the community.[303] Children also have the right to enjoy the best attainable state of physical, mental and spiritual health. This includes the provision of safe drinking water, nutritional food and adequate health care.[304]

Once again the right of a child to health care is emphasised and specifically provided for. This is therefore a right of the utmost importance. Children are not only entitled to physical and mental well-being according to the ACRWC, but also to spiritual well-being. Child health care, which may include medical treatment, should therefore not be denied and should be undertaken in the best interests of the child.

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[298] See in general, Viljoen F (1998) "Supra-national human rights instruments for the protection of children in Africa: The Convention on the Rights of the Child and the African Charter on the Rights and Welfare of the Child" *The Comparative and International Law Journal of Southern Africa* 31(2): 199-212.
[299] Lloyd A (2002) "A theoretical analysis of the reality of children's rights in Africa: An introduction to the African Charter on the Rights and Welfare of the Child" *African Human Rights Law Journal* 2: 11-12.
[300] Article 20 of the ACRWC. See also Grover SC (2014) "Reliance on the best interests of the child principle" in Grover SC *Children defending their human rights under the CRC Communications Procedure*: 110.
[301] Article 21 of the ACRWC.
[302] Lloyd (2002) 11 & 12.
[303] Article 13 of the ACRWC. Child participation is a fundamental principle of the African Children's Charter along with the best interests of the child; non-discrimination; life, survival and development of the child as well as provision for the responsibilities of the child towards their society, the State and international community.
[304] Article 16 of the ACRWC.

4 CONCLUSION

The object of this chapter was twofold. Firstly, it was a comprehensive examination and discussion of numerous relevant international instruments in order to gain an understanding of the content thereof, to draw inspiration and insight therefrom and to examine the international regulatory environment of medicine and research involving human subjects. Secondly this chapter explored the manner wherein international instruments might inform and influence South African law and policy.

The Constitution is the supreme law of South Africa and as such cannot be ignored. It establishes a constitutional imperative to consider international law as section 39(1)(b) requires that international law must be considered in interpreting human rights and section 233 states that an interpretation which is consistent with international law must be preferred above any other. From this as well as the decisions of the *Makwanyane* and *Bernstein* cases,[305] it was concluded that comparative study of international law is important and useful in the early or developmental stages of a new branch of law. International instruments may therefore be great informative and even educational tools in developing a model of consent which will be valid and effective in protecting the rights enshrined in section 12(2)(c) of the Constitution, namely the right to consent, especially in a controversial arena such as where medical treatment hinges on research involving human subjects.

In order to form a complete picture of the international environment, numerous instruments were discussed. Each of these instruments provided for certain principles which must be incorporated into proposed consent models. What follows is a summary of the conclusions drawn from each of the instruments which have been discussed throughout this chapter.

The Nuremberg Code is, to an extent, a conflation of treatment and research ethics and human rights and provides certain tenants to ensure that medical research is conducted in an ethical and lawful manner. Most importantly, it states that:

1. The Physician-researcher and patient-subject are equals;
2. Consent is an absolute requirement;
3. A patient-subject must have the legal capacity to consent;
4. The patient-subject must exercise free choice without force, fraud, deceit, duress or coercion. Consent must therefore be voluntary;
5. There must be sufficient knowledge and comprehension on the part of the patient-subject in order to make an informed decision;

[305] *S v Makwanyane* and *Bernstein v Bester supra*.

6. The patient-subject should therefore be informed of the following prior to consenting:
    - Nature of the study;
    - Duration and purpose of the experiment;
    - Method and means of conduction;
    - Inconveniences and hazards reasonably expected; and
    - Effects on the subject.
7. It is the responsibility of the person undertaking the research to ascertain the quality, and thus the validity of the consent; and
8. A subject may withdraw their participation and therefore consent at any stage of the research.

According to the International Bill of Human Rights which consists of the Universal Declaration of Human Rights read together with the International Covenant on Civil and Political Rights, everyone has the right to life, liberty and security of person in terms of article 3 of the UDHR. This corresponds with section 12 of our Constitution and therefore includes the right not to be subjected to medical or scientific experiments without consent. It therefore indirectly provides for and reiterates the necessity of informed consent. No person may be subjected to medical or scientific experimentation without his free consent according to article 7 of the ICCPR. This article corresponds with the South African Constitution as well and once again emphasises the importance of prior consent in medical and scientific activities involving humans. Therefore, read together, these articles confirm the necessity of prior consent and reiterate that without such consent no medical or scientific activity will be lawful.

Vulnerable groups are dealt with in the Declaration of the Rights of the Child and the Declaration on the Rights of Disabled Persons. The Declaration of the Rights of the Child states that children should not be excluded from medical treatment or research merely because they are minors. However, protective measures need to be in place for their participation. Consent is one such protective measure and is therefore also a requirement in treating or conducting research on minors. The Declaration, however, omits further details regarding special protection of children in medical research. Importantly, the Declaration on the Rights of Disabled Persons provides a definition of "disabled person" as "any person unable to ensure by himself or herself, wholly or partly, the necessities of a normal individual and/or social life, as a result of deficiency, either congenital or not, in his or her physical or mental capabilities." The Declaration further states that disabled persons are entitled to medical, psychological and functional treatment. In other words, persons with disabilities have the right to medical treatment regardless of the fact that a person has deficient capacity of whatever nature.

Children are again dealt with in the Convention on the Rights of the Child. It states that a child is a person below the age of 18 and the best interests of such a person are of paramount importance and must always be considered in any activity which involves a child. This includes any health-related intervention to which all children are entitled and which must be of the highest attainable standard. A capable child must be given the required information and the opportunity to express their views or opinions on matters which have a bearing on them and in matters of health, treatment or research, this may be personified by the requirement that consent be granted by the child themselves or a responsible person. Should a child wish to receive a certain treatment or partake in research, their choice should not be discounted. Likewise, where a child does not wish to do so, their choice and best interest must be considered and respected.

The Universal Declaration on the Human Genome and Human Rights, although it provides specifically for research on the human genome, may be applied in more general terms to other forms of research on human material and subjects. Research, treatment or diagnosis of human material and subjects, should always be preceded by a prior and rigorous assessment of the risks and benefits involved as well as prior, free and informed consent of the person concerned.

Where a person is incapable of consenting, research may only be conducted where they will receive a direct health benefit and subject to authorisation and the protective conditions prescribed, which must be prescribed by law. Consent laws must also prescribe the conditions under which consent may be limited and it must then also specify compelling reasons to limit consent. Research applications in biology, genetics and medicine must seek to offer relief from suffering and must improve the health of the concerned individual and humankind as a whole, and no research in the field of biology, genetics and medicine may prevail over respect for the human rights, fundamental freedoms and human dignity of the concerned individual under any circumstances.

The CIOMS Guidelines are a set of ethical principles regarding human experimentation and cover a wide variety of subjects including consent which is greatly provided for. They attempt to facilitate and promote international activities in the field of biomedical sciences. Consent is a voluntary decision made by a competent individual who has been given all the necessary information and who understands the information and who then arrives at a decision after taking some time to consider the information. Consent is also not an event but a process which commences when initial contact is made with the potential subject and which continues throughout the course of the research. This is in concordance with the philosophy which underlies dynamic consent which will be discussed in the course of this thesis.

Since consent is communicable in a number of ways, it must be sufficiently documented and preferably in a written and signed format. In the event of material changes in the procedures or conditions of the research, the researcher is obliged to seek to renew the original consent. Once again, dynamic consent becomes relevant as it is precisely this: a method of continuously changing and renewing or revoking consent. Also, note must be taken of the subject's consent to research on their biological material, the use of their medical records in research and any decision regarding secondary use of research records and biological specimens. Where secondary use is therefore foreseeable or feasible, additional consent is required.

Prior to giving consent, the potential human subject must be provided with certain information. This is the task of the researcher. Additionally, the researcher has certain other obligations towards the subject. In certain instances, however, the researcher is permitted to withhold information to ensure the validity of the research. In these instances, the researcher must obtain the consent of the subject to remain uninformed until the conclusion of the research.

Special justification is required to undertake research involving vulnerable persons. In context of this thesis, this means children and mentally incapacitated persons. Before research is conducted on minors or mentally incapacitated persons, the researcher must therefore ensure that such research might not be equally well carried out on persons who are not qualified as vulnerable; that the purpose of the research is to obtain knowledge which is relevant to the particular health needs of the vulnerable group; the willing consent of each subject has been obtained to the extent of their ability to understand and any refusal or objections on their part is respected and where the potential subject is wholly unable to consent, an authorised person has given their consent in accordance with domestic legislation.

According to the Universal Declaration on Bioethics and Human Rights, the interests and welfare of the individual must always enjoy priority above those of science. One such interest is the exercise of autonomy and this freedom to make decisions must be respected. For this reason, special measures are necessary where persons are not capable of exercising their autonomy. Autonomy may, however, be subject to certain limitations, usually in order to protect the autonomy of others. The freedom to make decisions and to exercise autonomy depends on the ability to actually make decisions, meaning firstly that a person must have the capacity to do so and secondly, must have adequate information on which to base their decision. In other words, once again it is made clear that prior, voluntary consent based on adequate information, with the option to withdraw, is an indispensable requirement for valid medical interventions or scientific research which involves humans. Consent protects physicians and researchers.

The requirement of consent must be applied in all instances of medical or scientific interactions involving humans, especially where those humans do not have the capacity to consent themselves. In these instances, authorisation for research and medical practice must be obtained in accordance to the best interest of the person concerned and such person must be involved in the decision making process to whatever extent possible. Research involving such persons should preferably hold a direct health benefit to the person concerned and must only be carried out where protective conditions have been prescribed by law and in the absence of an alternative research study involving persons who are capable of consenting. If the research study will not be of direct benefit to the incapable person, it may only be carried out in exceptional circumstances and with the utmost restraint.

Disabled persons are also provided for again in the Convention on the Rights of Persons with Disabilities. As the definition of disability as found in the CRPD is broad enough to include mental and physical disability, it is suggested that incapacity may be understood as a disability in context of the CRPD which in turns makes the Convention applicable to questions of consent of incapacitated persons. Furthermore, disabled persons may not be excluded from enjoying the highest attainable standard of health merely due to their disability. They may therefore be permitted to receive certain treatments and participate in research but certain protective measures should be in place. Consent is one such measure and it is therefore of great importance that consent procedures make provision for persons who are disabled or incapacitated.

The Declaration of Geneva read with the Hippocratic Oath and the International Code of Medical Ethics, as well as the Declaration of Helsinki provide for the duties and obligations of the physician and by extension, the researcher. The Declaration of Geneva declares that physicians should practise in a manner that is humane and formulates certain moral truths. It is a modernised version of the Hippocratic Oath and the inspirational document behind the International Code of Medical Ethics. It illustrates an expectation of respect and consideration of the patient on the part of the physician. This vow taken by physicians should extend to research and to the research practice itself. The Hippocratic Oath requires a new physician to vow to uphold certain ethical standards and obliges them to pledge to prescribe only beneficial treatments while also refraining from causing harm. Physicians have certain additional duties in terms of the International Code of Medical Ethics. These duties include having respect for the refusal of a competent patient to treatment, respect for the rights and preferences of patients as well as other health care professionals and respect for domestic and international codes of ethics. Physicians also have an obligation to respect human life and to act in the best interests of the patient in providing medical care.

In terms of the Declaration of Helsinki the physician has the duty of promoting and safeguarding the health, well-being and rights of patients including those involved in medical research. They have the further duty of protecting the life, health, dignity, integrity, right to self-determination, privacy and confidentiality of personal information of their research subjects.

The primary purpose of medical research is to understand the causes, development and effects of diseases and to improve preventive, diagnostic and therapeutic methods, procedures and treatments for such diseases. Medical research must therefore be subject to ethical standards which promote and ensure respect for human subjects and protect their rights and their health. Although the primary purpose of research is the generation of new knowledge, the purpose of the research may never take precedence over the rights and interests of the subjects.

National and international ethical, legal or regulatory requirements may never reduce or eliminate any of the protection given to research subjects in terms of this Declaration. In circumstances where medical research and medical care are combined, physicians may only involve their patients in the research to a justifiable extent. Participation may be justified by the potential preventive, diagnostic or therapeutic value of the research. A physician must have good reason to believe that participation will not adversely affect the health of the patients who serve as research subjects.

In medical research involving humans, research may only be conducted where the importance of the research outweighs the risks and burdens involved. All such research activities must therefore be preceded by a careful assessment of predictable risks and burdens as compared with the foreseeable benefits. Research protocols must include information regarding the funding, sponsors, any institutional affiliations, potential conflicts of interest, incentives and relevant information regarding treatment and/or compensation of subjects who were harmed in the course of the study.

Participation by individuals who are capable of giving informed consent must be voluntary although the potential subject may consult a trusted person. Each potential subject capable of consenting must then be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, relevant institutional affiliations of the researcher, the anticipated benefits and potential risks of the research and any discomfort the research may entail. Also, the subject must be informed of their right to refuse participation or to withdraw their consent at any time during the study. Preferably consent should be obtained in writing.

Where a subject is incapable of giving informed consent, it must be sought from a legally authorised representative of the subject. Research may only be done on such incapacitated

persons where their physical or mental condition is a necessary characteristic of the research group. In these circumstances, the physician must also seek informed consent from a legally authorised representative and any dissent of the subject must be respected. For medical research which uses identifiable human material or data, physicians must seek informed consent for the collection, storage and/or reuse of such material or data.

The African instruments were also discussed and from the African Charter on Human and Peoples' Rights or Banjul Charter it was established that a person is inviolable and is entitled to have their integrity, or autonomy, respected. People are entitled to health and this entitlement is a part of the exercise of autonomy. Therefore, barring a person one right also infringes on the other. When taking the concept of *ubuntu* into consideration, the argument may even be made that by interfering with the rights of one person, the rights of the entire community are infringed upon. Health and the promotion thereof is thus a universal right and the promotion thereof is a public and community interest.

The African Bioethics Resolution recognises bioethics as a priority and provides for the right of individuals to benefit from scientific progress. This instrument also refers to "enlightened consent" which, it is suggested accurately sums up the need of consent to be associated with a process of gained information and knowledge. Lastly, the African Charter on the Rights and Welfare of the Child was examined. It provides for the right of a child to physical, mental and spiritual well-being and this includes the right to adequate health care. This right is of great importance and should not be interfered with. Also, in the enabling of this right, all measures must be taken to ensure the best interests of the child are being served.

At the conclusion of this chapter it must be noted that although the instruments discussed make reference to informed consent, these instruments are not lost in terms of the argument of this thesis and still offer important insights. Although it is suggested that informed consent is not sufficient in instances where medical treatment is equal to research involving human participants, the importance of consent has now constantly been confirmed and the information and knowledge component has been made clearer. Information and knowledge serve an inalienable function in the dynamic consent format introduced in the course of this thesis and as such, international law instruments lay a solid foundation for the development of a new consent format.

This chapter and the various instruments which have been discussed emphasise the indispensable nature of consent. The format of consent is, however, other than informed, not always specified and it is suggested that the dynamic model of consent introduced in this thesis offers a solution to the consent issue. As the broader international guidelines have now been

discussed, the focus of this thesis becomes narrower and attention is given to the laws of the United Kingdom in the following Part and chapters in order to examine consent more specifically in medical and scientific settings involving human subjects.

PART D
CONSENT IN THE UNITED KINGDOM

Relevant international instruments were analysed in Part C of this thesis and Part D may therefore pay attention to a more specific foreign jurisdiction, namely the United Kingdom. The purpose of Part D is an analysis of the law existing in the United Kingdom with the ultimate goal of introducing a dynamic consent format. Once again the discussion commences by first examining general and broad aspects of the United Kingdom's law which then systematically narrows to particular legislative and regulatory documents and finally a solution to the consent concern is introduced in a highly particular and specialised fashion.

The United Kingdom has three separately identifiable legal systems and the first chapter of Part D sets out the separate legal systems to provide an overview and explanation as well as some insight into the complexities of each system. This is done in order to understand the legislative environment in place in the United Kingdom where the dynamic consent model promoted throughout this thesis is being developed and perfected. The interplay between the different jurisdictions is also explained in order to understand the relationship between the Human Tissue Act of 2004 and the Human Tissue (Scotland) Act of 2006.

Although this thesis focuses on legislative documents found in the United Kingdom, a holistic picture of the total regulatory environment is necessary. To this end key cases pertaining to consent will be given. This will be done for two reasons. First, the Human Tissue Acts of 2004 and 2006 are founded on the concept of consent and as the cornerstone of the legislation, consent manifestations as interpreted in case law ought not to be ignored and second, UK case law deserves attention for completion sake as part of the multi-layer approach of this thesis.

The South African Constitution obliges comparative study of foreign law and as such the law of the United Kingdom is of obvious interest. Should it be found that the legal environment existing in South Africa and the United Kingdom is sufficiently similar, it stands to reason that these two jurisdictions will suffer the same dilemmas regarding consent. If this is true, it may further be assumed that where the United Kingdom has found solutions to these dilemmas, the solutions may also be helpful, at least in theory, in a South African context.

Specific laws, policy documents and other legislative instruments regulating human tissues and cells will be investigated which, additionally to the abovementioned Human Tissue Acts, includes the Human Tissue (Quality and Safety for Human Application) Regulations of 2007, the *Guide to Quality and Safety Assurance of Human Tissue and Cells for Patient Treatment*, the European Union Tissue and Cells Directives as well as certain Codes of Practice. The Human Tissue Authority is also examined in Part D of this thesis.

This thesis argues that stem cell treatment is tantamount to human subject research due to the greatly uncertain nature of the scope of such research as well as the incredible potential of a proposed intervention. This has two implications. The first is that a patient is also a research participant and thus the regulatory provisions providing for patients and research participants must be taken into considered in obtaining consent for stem cell technologies. The second implication is that since the concerned person is an amalgamated person referred to as a "patient-participant" in the course of this thesis, the consent formats of informed or broad consent as such are incapable of allowing truly valid, meaningful and appropriate consent. Informed and broad consent need also to be amalgamated or combined.

The final chapter of Part D therefore contributes to South African law by the introduction and explanation of a new format for consent by suggesting that differing types of consent might be amalgamated in the same manner as the concerned person is to develop a new dynamic consent format. Attention is also given to the Ensuring Consent and Revocation project.

Part D of this thesis consists of the following:

CHAPTER 7 - THE LAW OF THE UNITED KINGDOM: AN INTRODUCTION TO THE LEGAL SYSTEMS OF THE UNITED KINGDOM

CHAPTER 8 - THE HUMAN TISSUE ACTS 2004 AND 2006, THE HUMAN TISSUE AUTHORITY AND OTHER RELEVANT REGULATORY INSTRUMENTS

CHAPTER 9 - DYNAMIC CONSENT

CHAPTER 7
THE LAW OF THE UNITED KINGDOM: AN INTRODUCTION TO THE LEGAL SYSTEMS OF THE UNITED KINGDOM

1 INTRODUCTION

The United Kingdom has three separately identifiable legal systems, namely that of England and Wales, Northern Ireland and Scotland. The aim of this chapter is to set out the different legal systems in place in the United Kingdom and to provide an overview and explanation as well as some insight into the intricacies of each individual system. Although each system on its own bears weight, as a legal system must do, it is important to keep in mind that these individual systems work in unison, sometimes to a lesser degree and sometimes more so, to form one regulatory system.

The ultimate aim of this thesis is to develop a model of obtaining informed consent and the Dynamic Consent and EnCoRe model which will be discussed in the course of this thesis will be greatly drawn from and was developed in the United Kingdom.[1] Also, the Human Tissue Act 2004, the Human Tissue (Scotland) Act of 2006 as well as the Human Tissue Authority are analysed and discussed as inspirations for the development of a workable model of consent. In order to understand specific legislation, regulating authorities and the Dynamic Consent and EnCoRe model, the background and context of the United Kingdom's legal system must first be explained in a general sense. This is especially necessary in order to understand why England and Wales on the one hand and Scotland and Ireland to some extent on the other, while together forming the United Kingdom, are governed by differing Acts.

This chapter will thus provide some history and background to the development of the law of the United Kingdom as a whole and of each separate system, explain the interplay between the different legal systems, identify the legislature, explain the court systems and point out the distinct jurisdictions and their relationships to one another.[2]

[1] See chapter 9 *infra*.
[2] An explanatory note on the different styles of citation of legislation found throughout the United Kingdom is provided in the course of this thesis. See Bibliography *infra*. Thank you to Professor Gordon Anthony of the School of

Lastly, some key cases pertaining to the concept of consent will be discussed in order to sketch a holistic picture of the regulatory environment of the United Kingdom. The cases of *Bolam v Friern Hospital Management Committee*, *Sidaway v Bethlem Royal Hospital Governors*, *Gillick v West Norfolk and Wisbeck Area Health Authority*, *Re C (Adult Refusal to Treatment)*, *Pearce and Pearce v United Bristol Healthcare Trust*, *Re B (Consent to Treatment: Capacity)*, *Simms v Simms*, *Chester v Afshar* and *Montgomery v Lanarkshire Health Board* will be discussed. The UK has a complex and richly texture legal regime and as such it is necessary to follow a layered approach in attempting to understand and it for comparative purposes.

1.1 BACKGROUND AND THE CONSTITUTION

The United Kingdom has three distinct legal systems each with its own distinct history and origins. The first is English law which applies to both England and Wales, the second is Northern Irish law and the third is Scottish law. The laws of England and Northern Ireland are based on common law principles. Scottish law, or Scots law, is a pluralistic system with elements of both common law and civil law and dates back to the High Middle Ages.

The Constitution of the United Kingdom, which is largely built on Parliamentary sovereignty and the rule of law,[3] is not comprised of one single document and is better described as an uncodified Constitution as it is the sum of various laws and principles. The Constitution is greatly embodied in written documents, statutes, case law, authoritative works and treaties. It is concerned with the relationship between the State and the individual as well as the functioning of the executive, legislature and the judiciary. However, unlike the South African Constitution, it is not supreme. Under European Law, the validity of a law of the European Union may not be impeded by national law. European Union law will only be enforceable where it is empowered by an Act of Parliament. The supremacy of European Union law within the United Kingdom was confirmed by the House of Lords in the *Factortame* case.[4] The United Kingdom's Constitution is the subject of much debate and reforms have taken place, such as the Constitutional Reform Act 2005[5] which is mentioned in the course of this chapter, while further reforms are proposed. For

Law, Queen's University Belfast for his correspondence and assistance in understanding the finer details of Northern Irish Legislation.

[3] See in general, Dicey AV (1889) *Introduction to* the s*tudy of the law of Constitution*. This book was first published in 1885 under the title of *Lectures introductory to the study of the law of the Constitution*.

[4] *Regina v Secretary of State for Transport Ex Parte Factortame Limited and Others* C-213/89, 1989 E.C.R.

[5] Constitutional Reform Act 2005 (c.4).

purposes of this chapter, the Constitution of the United Kingdom need not be discussed in further detail.[6]

While there are Acts, legal documents and substantive fields of law which apply across the territory of the United Kingdom, all three jurisdictions split off when it comes to the more detailed rules of law to be followed. Each of these jurisdictions will be discussed in somewhat more detail in the course of this chapter. The bigger picture, however, namely the law of the United Kingdom as an entity, requires some attention first.

The reason for the UK not having a single legal system lies in the fact that it is a political union of previously independent countries. The Kingdom of Great Britain was created by the Treaty of Union which was put into effect by the Acts of Union in 1707.[7] The continued existence of Scotland's separate legal system was also guaranteed in Article 19 of the Treaty of Union. The Acts of Union of 1800 combined Great Britain and Ireland into the United Kingdom of Great Britain and Ireland, today the United Kingdom of Great Britain and Northern Ireland, but did not contain an equivalent provision regarding a separate system of law.[8] The principle of separate courts in Ireland was, however, preserved.

The highest court in the UK regarding criminal and civil matters in England, Wales and Northern Ireland but only civil cases in Scots law, is the Supreme Court of the United Kingdom which is situated at the Middlesex Guildhall in London, England.[9] The court was established in October 2009 and replaced the Appellate Committee of the House of Lords.[10] In England and Wales, the courts are headed by the Senior Courts of England and Wales which consist of the Court of Appeal, the High Court of Justice[11] and the Crown Court.[12] In Northern Ireland the courts also share this model and in Scotland the chief courts are the Court of Session[13] and the Court of Justciary[14] and in Scotland Sheriff courts also exist.[15]

Some smaller, specialised courts and tribunals also exist with jurisdiction across the United Kingdom such as immigration courts or the Asylum and Immigration Tribunal and Special Immigration Appeals Commission. The Judicial Committee of the Privy Council is the highest court of appeal for various independent Commonwealth countries, the British Overseas

[6] See in general, Jowell J & Oliver D (eds)(2011) *The changing Constitution*.
[7] Acts of Union 1707 (6 Anne c.11).
[8] Acts of Union 1800 (39 & 40 Geo. 3 c.67).
[9] Department for Constitutional Affairs (2003) *Constitutional reform: A Supreme Court for the United Kingdom* available online at http://www.dca.gov.uk/consult/supremecourt/supreme.pdf accessed 23/10/2013.
[10] Department for Constitutional Affairs (2003) online. See also BBC News (2009) "UK Supreme Court judges sworn in" *BBC News*, 1 October available online at http://news.bbc.co.uk/1/hi/uk/8283939.stm accessed 23/10/2013.
[11] For civil matters.
[12] For criminal matters.
[13] For civil matters.
[14] For criminal matters.
[15] For both civil and criminal matters.

Territories and the British Crown dependencies. Lastly, there are also Employment tribunals and the Employment Appeal Tribunal which has jurisdiction across the territory of Great Britain excluding Northern Ireland. Each of the separate jurisdictions falling under the greater union umbrella of the United Kingdom will now be discussed.

2 ENGLISH LAW

English law refers to the system of law which is applied in England and Wales and it is a system of common law.[16] Although the Welsh Assembly now has some devolved powers, Wales still greatly falls under the same jurisdiction as England and together they form one of the three jurisdictions of the United Kingdom.

2.1 HISTORY AND BACKGROUND

Prior to the Norman conquest of England, different areas were governed by different systems of law which were often adapted from the systems of the invaders of that area or were based on local customs. Dane law applied in the north, Mercian law in the midlands and Wessex law applied in the south and west. No central government existed and the monarch of the day had very little control over the country.[17]

William the Conqueror, however, established a strong central government and began to standardise the law after he gained the throne in 1066. Under the King, representatives or "itinerant justices" were dispatched to the countryside and tasked with adjudicating disputes according to the law. Upon their return to Westminster, they would then discuss and sift through the various customs, rejecting the unreasonable and accepting the rational to shape a consistent, uniform body of legal rules. It is during this period that the principle of *stare decisis*, meaning that the decision stands, came to be and similar cases were judged in the same manner, making the law more predictable, ultimately leading to the formation of a "common law" in 1250.[18]

The common law meant that a single system of law now existed whereby the country could be ruled. The law would be applied consistently and courts became predictable and stable.

[16] For interpretation purposes "England" includes Wales and Berwick, the adjacent islands of the Isle of Wight and Anglesey and the adjacent territorial waters.
[17] See in general, Roberts C (1980) *A history of England*.
[18] Elliot C & Quinn F (2008) *English legal system*: 9-10. See in general, Hale M (1979) *The history of the common law of England*.

Common law principles are still in use today as is evidenced by the precedent system wherein a hierarchy of the courts is established and a subordinate court is bound to the decisions of a more superior court and these decisions may be found in case law which is regularly published and reported on.[19]

2.2 SOURCES OF ENGLISH LAW

English law stems from various primary sources of law from where the law has come into existence. Each source, however, varies in its importance. The sources of English law are:[20]

1. Legislation.[21] Legislation is the most important source of English law today due to the emergence of Parliament as the dominant force within the United Kingdom. It thus transcends both common law and equity in its importance and legislation may amend or abolish common law principles and repeal earlier statutes;

2. Case law. Case law as found through the doctrine of judicial precedent may also be referred to as common law and it is the basis of law today and therefore is still very important;[22]

3. Equity. Equity is a minor source of English law and developed primarily to address the deficiencies in the common law. Courts may apply both common law or equity principles and it is still correct to refer to principles of equity or equitable remedies;[23]

4. Custom. Custom is now a minor source of law, but much of early common law was developed through the application of existing customs in English courts. Now customary uses mostly either form part of common law or have been codified into legislation;[24]

5. European law. Since the United Kingdom joined the European Union, European law is now an increasingly important source of law. Section 2(4) of the European Communities Act 1972[25] states that English law should be interpreted and have effect subject to the

[19] Of course not every aspect of a judicial decision is binding and therefore only the *ratio decidendi* (reasons for the decision) forms part of judicial precedent as authoritative. *Obiter dicta* (statements made in passing) do, however, have persuasive power.
[20] Ward R & Akhtar A (2008) *Walker & Walker's English legal system*: 5-12. See also Elliot & Quinn (2008) 9-126.
[21] This is both primary and secondary legislation.
[22] Criminal law is still inextricably bound to common law and the common law has influenced legal procedure immensely.
[23] Equity undoubtedly influenced English law and in particular in the fields of property and trusts, the law of contract and remedies such as injunction.
[24] Customs include: monogamy, parental rights, the right to make use of the seashore for navigation or for fishing and numerous early criminal law principles.
[25] European Communities Act 1972 (c.68).

principle that European law is supreme and therefore takes precedence above domestic sources of law;[26]

6. Treaties. Treaties are a minor source of English law but the highest source of European law and must be signed into law in the United Kingdom. Some treaties do, however, find direct application in British courts and create rights and duties which have an influence on English law; and

7. Other sources which include Canon law, Roman law textbooks and legal writing.

2.3 ENGLISH STATUTORY LAW

Statutes or Acts of Parliament are created by the Parliament which consists of the House of Commons, the House of Lords and the monarch. Since the Parliament is sovereign, Acts of Parliament traditionally take precedence in deciding matters but this will no longer ring true as European law trumps domestic law and the courts are to interpret domestic law as such.[27]

Multiple types of legislation may be found in the English legal system. Firstly, there are Acts of Parliament which are seen as sovereign unless overriding European legislation exists. These Acts may be subdivided into public and private Acts. Secondly, delegated legislation may be identified in the form of Rules, Orders, Regulations and Bylaws and these documents are typically created under a delegated power which is derived from a primary Act or Act of Parliament.[28] There is also autonomic legislation which is the legislation made by an autonomous body regarding its own members and sometimes members of the public, for example laws made by the General Medical Council. Lastly there are Codes of Practice which are not enforced by courts but aid in determining the issue before the court.[29]

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[26] The United Kingdom's European Union Referendum, colloquially referred to as the Brexit Referendum, held on the 23rd of June 2016 must be mentioned at this juncture. Depending on whether the UK does in fact leave the EU some legislative ramifications will be felt. The most significant effect of the UK exiting from the EU will be the repeal of the European Communities Act 1972 which provides for the supremacy of EU law. Such repeal would bring about an end to the constitutional relationship between the law of the UK and the EU. Other legislative instruments, such as EU Regulations and Directives, the EU Directives on the Safety of Tissue and Cells which is discussed in chapter 5.3.3 *infra* for example, will have to be reconsidered by Parliament and a decision will have to be made regarding maintaining, replacing or repealing these instruments. At this point in time, however, the EU legal documents are still in force and therefore Brexit does not impact on their discussion in the course of this thesis. See in general, Norton Rose Fulbright (2016) "Brexit-UK and EU legal framework" available online at http://www.nortonrosefulbright.com/knowledge/publications/136975/brexit-uk-and-eu-legal-framework accessed 30/6/2016.
[27] Elliot & Quinn (2008) 34.
[28] Interestingly, in English law, subordinate legislation may in certain instances amend primary legislation by making use of a "Henry VIII clause." No equivalent to such clause exists in South African law.
[29] Ward & Akhtar (2008) 30-41.

2.4 COMMON LAW

English law is described as a system of common law rather than civil law, meaning that the law is greatly uncodified and judicial precedents are binding and not simply persuasive. Common law is built on the precedent system and the principle of *stare decisis*. Early in the development of common law, justices and judges were responsible for creating the Writ system which was intended to meet the everyday needs of the public and applied a combination of common law and judicial precedent in an attempt to create a consistent body of law.[30] This system provided legal certainty but was not without its faults. A major problem with this system was that judges were partial or incompetent or had acquired their position due to their status in society meaning that where mistakes were made by one court, other courts were bound to follow such mistakes. The development of Parliament, however, rendered legislation more important than judicial precedent and today common law is a secondary source of English law in comparison to statutory law.

2.5 LEGISLATURE

The Parliament of the United Kingdom of Great Britain and Northern Ireland, or Westminster, is the supreme legislative body in the United Kingdom. The Parliament sits in the Palace of Westminster in London. It is sovereign and at its head sits the Sovereign, Queen Elizabeth II. The Westminster Parliament is then also the legislature for England and Wales.[31]

The Parliament is bicameral, consisting of an upper house, the House of Lords, and a lower house, the House of Commons.[32] There is, however, a third component, namely the Queen, as Royal Assent is required in passing of legislation.[33] The House of Lords is comprised of two types of members, the first of which is the Lords Spiritual and these are the senior bishops of the Church of England and are appointed by the Sovereign on advice from the Prime Minister.[34] The second type of member is the Lords Temporal, consisting of members of the Peerage.[35] The

[30] See in general, Fifoot CHS (1949) *History and sources of the common law: Tort and contract*.
[31] Ward & Akhtar (2008) 30.
[32] Encyclopaedia Britannica (2014) "Bicameral system: Political science" available online at http://www.britannica.com/EBchecked/topic/64614/bicameral-system accessed 23/6/2014.
[33] Parliament.UK (2007) "Parliament and Crown" available online at http://www.parliament.uk/about/how/role/parliament-crown/ accessed 23/10/2013.
[34] Parliament.UK (2007) "Different types of Lords" available online at http://www.parliament.uk/about/mps-and-lords/about-lords/lords-types/ accessed 23/10/2013.
[35] Peerage is a system of hereditary titles and is connected to the British nobility. Persons from this community are referred to as Peers of the Realm.

House of Commons is the chamber of Parliament which is democratically elected every five years.[36] The two Houses meet separately in the Houses of Parliament.

The Parliament of Great Britain was created in 1707 after the Treaty of Union was ratified by the Kingdoms of England and Scotland and each passed the Acts of Union 1707. It has been argued that in practice, however, it is a continuation of the English Parliament and it had only been enlarged by the addition of Scots Members of Parliament, forming the Parliament of Great Britain and even more so by the addition of Irish members after the Act of Union 1800,[37] forming the Parliament of the United Kingdom of Great Britain and Ireland.[38]

The Parliament of the United Kingdom may make laws which apply to the whole of the United Kingdom which may or may not include Scotland. Scotland may in certain instances legislate equivalent laws. The Human Tissue Act is a fine example of this, as there is the Human Tissue Act 2004[39] which applies to England, Wales and Northern Ireland and then there is the Human Tissue (Scotland) Act 2006[40] which applies to Scotland only.[41] This is referred to as the "West Lothian Question" and leads to some debate as it means that Scottish Members of the Westminster Parliament have a direct impact on English constituencies but they may not have any impact in their own Scots constituencies.[42] Westminster may overturn, amend or ignore any Act of the Scottish Parliament but this has not yet happened. This may be due to the existence of the "Legislative Consent Motion" which enables English Members of Parliament to vote on devolved issues as part of United Kingdom legislation.[43] Since no devolved "English Parliament" exists, the converse is, however, not true.

Before a law is passed and while it is still in draft form, it is referred to as a Bill and it may be introduced to Parliament by a member of either of the Houses.[44] Each Bill must go through various stages in each House of Parliament in order to become law. The first stage, or the first

[36] All Ministers, including the Prime Minister, are members of the House of Commons or the House of Lords in some instances, and are accountable to the legislature.
[37] Acts of Union1800 (c.67).
[38] As Southern Ireland is the independent Republic of Ireland, the Parliament is now known as The Parliament of the United Kingdom of Great Britain and Northern Ireland. See section 2 of the Royal and Parliamentary Titles Act 1927 (c.4).
[39] Human Tissue Act 2004 (c.30).
[40] Human Tissue (Scotland) Act 2006 (asp 4). See, Jackson E (2010) *Medical law: text, cases and materials*: 70.
[41] Both the Human Tissue Acts are discussed in detail in the course of this thesis. See chapter 8 *infra*.
[42] McLean I (2005) *Barnett and the West Lothian Question: No nearer solutions than when the devolution programme started* presented at the ESRC Devolution Conference, London, 20-23 April. Hereafter referred to as ESCR Devolution Conference.
[43] *Ibid*. See also Leyland P (2011) "The multifaceted constitutional dynamic of UK devolution" *International Journal of Constitutional Law* 9(1): 251-273.
[44] A Bill which is introduced by a Minister is known as a "Government Bill" and a Bill which is introduced by another member is a "Private Member's Bill." Bills may also be categorised by subject. Most Bills which are related to the general public are called "Public Bills." A "Private Bill" is one that attempts to grant an individual or small group of individuals, or a body such as a local authority, special rights. When a Public Bill affects private rights in the same manner as a Private Bill would, it is referred to as a "Hybrid Bill."

reading as it is referred to, is a formality. The second stage or reading, entails a debate regarding the principles of the Bill. At this stage the Bill may be rejected by the House. If the Bill is not rejected it is sent to the relevant committee which will then consider the Bill clause by clause.[45] The Bill is then, in what is known as the reporting or consideration stage, reported back to the House as amended and it is then considered further. The Speaker of the House may select the amendments which will be debated in accordance to a practice referred to as *kangaroo*.[46]

The third stage or reading follows after the House has considered the Bill. After the Bill has been read a third time a motion to that effect is passed.[47] In the House of Commons no further amendments may be made and should a motion be passed on the Bill, it is passed on the whole of the Bill. In the House of Lords however, there may be some further amendments to the Bill and after the passage of the third reading motion, the House of Lords must vote on the motion "That the Bill do now pass." At this stage the Bill is sent from one House to the other and if both Houses have passed the Bill in identical form it is presented to the Sovereign, the Queen, for Royal Assent. Where, however, one House has passed amendments which the other House will not agree to and the Houses cannot come to an agreement, the Bill fails. In theory the Sovereign may also *veto* the Bill and withhold Assent. Every Bill therefore obtains the assent of three Parliamentary components before it becomes law.[48]

2.6 ENGLISH COURTS

Her Majesty's Courts of Justice of England and Wales were established by Acts of the Parliament of the United Kingdom and are the civil and criminal courts for the area of England and Wales.[49] The courts are responsible for the administration of justice and apply both to English law and the law of England and Wales. The Courts may be divided into a hierarchy which ranks from higher, senior courts to lower subordinate courts. They are the Supreme Court of the United

[45] In the House of Lords, the Bill may be referred to either the Committee of the Whole House or the Grand Committee. In the House of Commons, the Bill is usually referred to a Public Bill Committee but where the legislation is of great importance it will be referred to the Committee of the Whole House. Other committees, such as Select Committees, may be used but rarely are.
[46] See Standing Order 32. Standing Order 89 also allows committee debate to be restricted by a committee chairman by making use of *kangaroo*.
[47] This is a motion "That the Bill be now read a third time."
[48] This is reflected in the enacting formula of the Acts themselves as they will state: "BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:-" or "BE IT ENACTED by The Queen's most Excellent Majesty, by and with the advice and consent of the Commons in this present Parliament assembled, in accordance with the provisions of the Parliament Acts 1911 and 1949, and by the authority of the same, as follows:-" depending on whether or not one House had overriding power or not.
[49] The National Archives (2013) "Criminal courts in England and Wales from 1972" available online at http://www.nationalarchives.gov.uk/records/research-guides/criminal-courts-from-1972.htm accessed 23/10/2013.

Kingdom, the Judicial Committee of the Privy Council, the Senior Courts of England and Wales,[50] the subordinate courts[51] and any special courts and tribunals.[52] The Court of Appeal, High Court, Crown Court, Magistrates' courts and the county courts are administered by an executive agency of the Ministry of Justice known as Her Majesty's Courts and Tribunals Service.

As of the 1st of October 2009, the Supreme Court was created by Part 3 of the Constitutional Reform Act 2005[53] and is the highest court of appeal in almost all cases in England and Wales. This role was previously held by the House of Lords but it was transferred to the Supreme Court by the Constitutional Reform Act 2005.[54] It is also the highest court of appeal regarding devolution matters which were previously seen to by the Privy Council.

The Parliament of the United Kingdom is sovereign and for this reason the Supreme Court cannot judicially review the actions of Parliament in the same manner as the Constitutional or Supreme Courts in other countries are able to. It may also not overturn any primary legislation of the Parliament. It may, however, overturn secondary legislation if such legislation is found to be *ultra vires* of the powers conferred thereto by primary legislation.[55] The Court may also make a declaration of incompatibility in terms of section 4 of the Human Rights Act 1998[56] if it believes that either primary or secondary legislation is incompatible with rights enshrined in the Convention for the Protection of Human Rights and Fundamental Freedoms.[57] This does not overturn the legislation and Parliament does not have to agree with such a declaration. Where Parliament does agree, however, amendments may be made to the legislation in terms of section 19 of the Act.

The Privy Council serves as the highest court of appeal for a small number of Commonwealth countries, former colonies, the Channel Islands and the Isle of Man.[58] It was established by the Judicial Committee Act 1833[59] to hear appeals formerly heard by the King in Council. The judges seated on the Judicial Committee of the Privy Council are also the members of the Supreme Court and the Court of Appeal. Interestingly, judgements of the Judicial Committee are not generally binding within the United Kingdom and have only persuasive powers. These

[50] Such as the Court of Appeal, the High Court and the Crown Court.
[51] Such as the Magistrates' and country courts.
[52] Such as the Coroners', Ecclesiastical or other courts.
[53] Constitutional Reform Act 2005.
[54] *Ibid*.
[55] Rozenburg J (2009) "Britain's new Supreme Court" *Times Literary Supplement*, 2 September.
[56] Human Rights Act 1998 (c.42).
[57] European Convention for the Protection of Human Rights and Fundamental Freedoms 1950. Hereafter referred to as the European Convention on Human Rights.
[58] Section 2 of Practice Direction 1 of the Judicial Committee of the Privy Council. See in general, Howell PA (1979) *The Judicial Committee of the Privy Council, 1833-1876: Its origins, structure, and development*. See also Schedule 1 of the Interpretation Act 1978 (c.30).
[59] Judicial Committee Act 1833 (c.41).

judgements are, however, binding on all the courts in other Commonwealth countries from where appeals are brought and heard.

Originally created as the "Supreme Court of the Judicature" by the Judicature Act,[60] the Senior Courts of England and Wales were renamed the "Supreme Court of England and Wales" in 1981.[61] They were then renamed again as the "Senior Courts of England and Wales" by the Constitutional Reform Act 2005[62] in order to distinguish it from the new Supreme Court of the United Kingdom. The Senior Courts consists of the Court of Appeal,[63] the High Court of Justice[64] and the Crown Court. Each of these courts requires some attention.

Firstly, the Court of Appeal sees to appeals from other courts or tribunals and consists of two divisions, namely the Civil Division and the Criminal Division. The Civil Division hears appeals from the High Court and County Court and from certain superior tribunals. The Criminal Division hears appeals from the Crown Court connected with a trial on indictment only. The decisions of the Court of Appeal are binding on all courts including itself but the decisions of the court are not binding on the Supreme Court.[65] Secondly, the High Court of Justice has a dual function. The court functions firstly as a civil court of first instance and secondly as an appellant court for civil and criminal cases from lower courts. The High Court consists of three divisions which do not form separate courts but do follow slightly different procedures and practices. Cases are assigned to specific courts based on the subject matter of the case and the divisions exercise the jurisdiction of the High Court. The divisions of the High Court are the Queen's Bench, the Chancery and the Family divisions. Lastly, the Crown Court was established by the Crown Courts Act 1971[66] and replaced the Assizes[67] and Quarter Sessions.[68] The Crown Court is a criminal court,[69] hearing cases both as court of first instance and as a court of appeal. The Court also deals with a limited number of civil hearings as first instance and appeal court. The Court also hears appeals from the Magistrates' courts. Since the Crown Court is the only court in England and Wales with the jurisdiction to try cases on indictment, it then acts as a superior

[60] Supreme Court of Judicature Act 1873 (36 & 37 Vict. c.66).
[61] Section 1(1) of the Senior Court Act 1981 (c.54). This section states "the Supreme Court of England and Wales shall consist of the Court of Appeal, the High Court of Justice and the Crown Court, each having such jurisdiction as is conferred on it by or under this or any other Act."
[62] Constitutional Reform Act 2005.
[63] Formally "Her Majesty's Court of Appeal in England." See Schedule 1 of the Interpretation Act 1978.
[64] Formally "Her Majesty's High Court of Justice in England." See Schedule 1 of the Interpretation Act 1978.
[65] The National Archives (2013) online. See also Courts and Tribunals Judiciary (2013) "Structure of the courts system" available online at https://www.judiciary.gov.uk/about-the-judiciary/the-justice-system/court-structure/ accessed 23/10/2013. See also Courts and Tribunals Judiciary (2013) "The Structure of the courts" available online at https://www.judiciary.gov.uk/wp-content/uploads/JCO/Images/Layout/courts_structure.pdf accessed 23/10/2013.
[66] Crown Courts Act 1971 (c.23).
[67] According to this system, High Court judges periodically travelled around the country hearing cases.
[68] These were periodic county courts.
[69] London's most famous Criminal Court is unofficially referred to as the Old Bailey and it is now part of the Crown Court. Officially, it is referred to as the "Central Criminal Court."

court in that its judgments may not be reviewed by the Administrative Court of the Queen's Bench Division of the High Court. The Crown Court, however, is a subordinate court regarding appeals from the Magistrates' courts and other tribunals.[70]

Below the senior courts are the subordinate courts of which the most common courts are the Magistrates' courts, the Family Proceedings Courts,[71] Youth courts[72] and the County courts. The Magistrates' courts bench is presided over by a lay Magistrate[73] or a legally trained district judge,[74] sitting in each of the local justice areas. The court hears minor criminal cases and certain licensing appeals and there are no juries.[75] County courts are courts of statutory creation with civil jurisdiction only and sit in about 92 different towns and cities across England and Wales. They are presided over by either a district or circuit judge who sits alone as trier of fact and law without a jury. These courts function as a local court in that each court has an area over which it exercises certain authority.

Tribunals are part of the national system of administrative justice and are classed as non-departmental public bodies. They may, however, be considered the lowest rung of the hierarchy of courts in England and Wales and are administered by the Court Services falling under the responsibility of the Lord Chancellor. Tribunals were originally created on an *ad hoc* basis, but since 2007 certain reforms have been put in place which establish a unified system for the functioning of tribunals and which recognise their judicial authority, appeal routes and regulation and control.[76]

Besides the usual courts, various specialist courts exist which are often referred to as Tribunals. Generally, a statutory right of appeal exists from a tribunal to a particular court or specially constituted appellate tribunal. Where there is no such appeal court, the only remedy from a

[70] Courts and Tribunals Judiciary (2013) "Structure of the courts system" online. See also Courts and Tribunals Judiciary (2013) "The Structure of the courts" online.
[71] The Family Proceedings Court Rules 1991 apply to cases in the Family Proceedings Court. As a Family Proceedings Court the Magistrates' court hears family law cases which include care cases and the Court has the power to make adoption orders. Family Proceedings Court is not open to the public. See the Family Proceedings Courts (Matrimonial Proceedings etc.) Rules 1991 (L.32), the Family Proceedings Courts (Constitution)(Metropolitan Area) Rules 1991 (L.19), the Family Proceedings Courts (Constitution) Rules 1991 (L.18) and the Family Proceedings Courts (Children Act 1989) Rules 1991 (L.17).
[72] Youth courts are administered similarly to Adult Magistrates' courts but deal with offenders aged 10 to 17. Youth courts are presided over by specially trained Magistrates or a district judge and they have a wider catalogue of disposals available to them in order to deal with the young. Youth courts are not open to the public and only the parties involved in a case are admitted to court.
[73] Also known as "Justices of the Peace."
[74] Known formally as a "Stipendiary Magistrate."
[75] Courts and Tribunals Judiciary (2013) "Structure of the courts system" online. See also Courts and Tribunals Judiciary (2013) "The Structure of the courts" online.
[76] Bradley A & Ewing K (2003) *Constitutional and administrative law*: 292.

decision of a Tribunal may be judicial review to the High Court. There are also Coroners' courts, Ecclesiastical courts and other courts[77] working in England and Wales.

2.7 ENGLAND AND WALES AS DISTINCT JURISDICTIONS

As previously stated, the United Kingdom consists of three legal jurisdictions of which one is England and Wales together since Wales, formerly a separate jurisdiction, was absorbed into the Kingdom of England by King Henry VIII.[78] The distinction between these jurisdictions, however, becomes relevant regarding matters of nationality and domicile. Traditionally authors have referred to the State of England and Wales as England but in recent decades this usage has become increasingly politically and culturally unacceptable.[79]

Devolution now accords Wales some autonomy but it was only granted some legislative powers after the general election in 2007 when the Government of Wales Act 2006[80] granted powers to the Welsh Government to enact some primary legislation. The legal system whereby civil and criminal matters are adjudicated, however, remains unified. A further important distinction between England and Wales concerns the use of the Welsh language since laws related to this language apply only in Wales and not in England. Welsh may also be spoken in Welsh courts. Most lawyers have referred to the legal system of England and Wales as "the Laws of England and Wales" since 1967 following the Welsh Language Act 1967.[81] At this juncture some separate attention must be given to Welsh law.

3 WELSH LAW

Welsh law is the collective name for both primary and secondary legislation generated by the National Assembly for Wales in accordance with devolved authority which is granted in terms of the Government of Wales Act 2006.[82] Each piece of legislation is referred to as an Act of the Assembly and these powers have been in effect from May 2007. The first Assembly legislation to be officially proposed was the National Health System Redress (Wales) Measure 2008.[83] Since

[77] Such as Military Courts of the United Kingdom, Patents County Court, the Restrictive Practices Court, Election Court, Court of Chivalry and the Court of Leet.
[78] In contrast, Northern Ireland did not cease to exist as a distinct jurisdiction when its legislature was suspended.
[79] See in general, Stauch M, Wheat K & Tingle J (2012) *Text, cases and materials on medical law and ethics*: 44-56 regarding health care in England and Wales.
[80] Government of Wales Act 2006 (c.32).
[81] Welsh Language Act 1967 (c.66).
[82] Devolution is where powers are granted by a central government to a sub-national government via statute. It is a form of decentralization and devolved territories retain the power to enact legislation relevant in its area.
[83] National Health System Redress (Wales) Measure 2008 (nawm 1).

the abolishment and subsequent replacement of *Cyfraith Hywel*,[84] a Celtic form of law,[85] by English law nearly 500 years ago, Wales has its own laws.

3.1 LEGISLATIVE COMPETENCE OF THE WELSH NATIONAL ASSEMBLY

The Welsh Assembly has devolved areas of power in terms of the Government of Wales Act 1998[86] and the Government of Wales Act 2006.[87] The Act of 2006 granted the Assembly legislative powers over certain specified areas. The legislation made as a result is known as Assembly Measures. Where the Assembly does not have devolved powers, a request for legislative competence must be made to the central United Kingdom government by way of a Legislative Competency Order. This must then be approved by the Secretary of State for Wales, both houses of Parliament and the Queen in Council. After the Queen has approved the Order, the new area of devolved legislative competence is added to Schedule 5 Part 1 of the Government of Wales Act 2006.[88] As a result of a referendum held in March 2011,[89] the Assembly now also has the legislative competence to pass primary legislation on 20 devolved subjects[90] and these Acts are referred to as Acts of the Assembly. The United Kingdom Parliament must now obtain a Legislative Consent Motion from the Assembly if it wishes to legislate a matter which falls within one of the devolved areas of competence of the Welsh Assembly.[91] The reason for this is to prevent any legal uncertainty and confusion and to protect the Welsh Assembly's autonomy.

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[84] *Cyfraith Hywel* is also known as Laws of Hywel and was the legal system in medieval Wales before the final English conquest. It was a form of Celtic law with similarities to the Brehon law of Ireland and also to the customs of the Britons. It was first codified during the reign of Hywel the Good in the mid-10th century. See in general, BBC News (2013) "Welsh law" available online at http://www.bbc.co.uk/wales/history/sites/themes/periods/dark_ages06.shtml accessed 14/10/2013.

[85] This was done by the Laws in Wales Acts which were passed by King Henry VIII between 1535 and 1542. See in general, Fryde EB, Greenway DE, Porter S & Roy I (eds)(1986) *Handbook of British chronology*.

[86] Government of Wales Act 1998 (c.38).

[87] Government of Wales Act 2006.

[88] See in general, Gov.UK (2013) "Maintaining and strengthening the Welsh devolution settlement" available online at https://www.gov.uk/government/policies/maintaining-and-strengthening-the-welsh-devolution-settlement accessed 16/10/2013. See also Gov.UK (2013) "Devolution of powers to Scotland, Wales and Northern Ireland" available online at Gov.UK (2013) "Devolution settlement: Wales" available online at https://www.gov.uk/devolution-settlement-wales accessed 16/10/2013.

[89] For more on the referendum, see Welsh Government (2011) "Welsh referendum 2011" available online at http://wales.gov.uk/legislation/referendumpowers/?lang=en accessed 16/10/2013.

[90] These are agriculture, fisheries, forestry and rural development; ancient monuments and historic buildings; culture; economic development; education and training; environment; fire and rescue services and promotion of fire safety; food; heath and health services; highways and transport; housing; local government; public administration; National Assembly for Wales; social welfare; sport and recreation; tourism; town and country planning; water and flood defence and the Welsh language. See Schedule 7 Part 1 of the Government of Wales Act 2006. The Assembly may legislate areas which affect only the Assembly itself and it therefore forms a subject as listed here.

[91] Assembly Standing Order 26 of the Welsh National Assembly.

3.2 THE RELATIONSHIP BETWEEN ENGLISH AND WELSH LAW

Although Welsh law is separate in operation, Wales cannot be considered a fourth and separate jurisdiction of the United Kingdom as no separate criminal law exists, so the Parliament of the United Kingdom still greatly legislates for Wales and Wales follows the courts and judiciary of England.[92]

Some Acts of the United Kingdom are classified as "Wales only laws" and these Acts contain provisions allowing the Welsh National Assembly to make subordinate legislation.[93] Also, the role of the Welsh language cannot be down played as these laws are applied in the Welsh territory and not the English territory. The Welsh language stands equal to English in the public sector in accordance to the Welsh Language Act 1993[94] and for this reason legislation may be published in Welsh and it may be spoken in court.

Under the present system of devolution, however, English law still applies to Wales but where English law regulates the general and broad aspects, Welsh law governs the local aspects. Unlike Scottish law, where a separate civil and criminal system from the English one exists, the Welsh system is unified with the English system and is sometimes considered a new system or different branch of English law.[95] The Scots system will be discussed in the course of this chapter but first, the Northern Irish system of law, which is closer to the English and Welsh systems, must be discussed.

4 NORTHERN IRISH LAW

Northern Irish law is the system of statutory law and common law which has been in use in Northern Ireland since the partition of Ireland in 1921 which established Northern Ireland as a separate jurisdiction of the United Kingdom. The law of Northern Ireland has been strongly influenced by political factors and for this reason the history and background of not only

[92] See paragraph 2.6 *infra* for a discussion regarding the courts of England and Wales. See in this regard the One Wales Agreement 2007. See Welsh Government (2011) "One Wales agreement" available online at http://wales.gov.uk/legislation/referendumpowers/referendumjourney/onewales/?lang=en accessed 16/10/2013.
[93] Welsh Government (2011) "Can we make our own Welsh laws?" available online at http://wales.gov.uk/about/organisationexplained/laws/?lang=en accessed 16/10/2013.
[94] Welsh Language Act 1993 (c.38).
[95] See in general, One Wales (2007) "One Wales: A progressive agenda for the government of Wales: An agreement between the Labour and Plaid Cymru Groups in the National Assembly" available online at http://news.bbc.co.uk/1/shared/bsp/hi/pdfs/27_06_07_onewales.pdf accessed 21/10/2013.

Northern Ireland, but also the Republic of Ireland, deserve some attention as these two States have only been parted since 1921 but the legal system dates back centuries.[96]

4.1 HISTORY AND BACKGROUND

Prior to English rule, Ireland had its own indigenous legal system known as Brehon law which dated back to Celtic times. This native system had developed from customs which had been orally passed on from generation to generation. The first codification of the law took place in the 7th century AD and the laws were then administered by Brehons, or "*brithem*" which is the Gaelic word for "judges," who acted as arbitrators. This law was based on an individual's identity which was then defined in terms of clan and personal wealth. A person's honour was evaluated in terms of their personal wealth and in turn each person's wealth or honour reflected their legal status. The law expected more from persons who had received more from God.[97]

Brehon law came under siege for the first time in 1155, when Pope Adrian IV issued the *Bull Laudabiliter*[98] which endorsed King Henry II's plan to conquer Ireland. This was followed by the Anglo-Norman invasion in 1169. Then, in 1171 King Henry II held the *Curia Regis* or King's Council which declared that the laws of England were freely received and confirmed by all and English law was initially applied in most of the Leinster province where Henry II had granted feudal land rights.[99] Then in 1172 Henry II appointed as his representative, Hugh de Lacy, as the first Justiciar of Ireland. King John, in 1204, authorised the issuing of writs whereby Irish courts were to apply common law and in 1226 King Henry III ordered that the Irish Judiciary was to adhere to the laws and customs of England. During the time of the Normans in the 14th and 15th century the influence of English law declined. England, however, sought to re-assert the supremacy of its laws and its Parliament and to this end, enacted the Statutes of Kilkenny in 1366.[100] This was followed by the further enactment of Poynings' Law in 1494.[101] In a nutshell, this determined that all laws passed in England were to be applied in Ireland.[102]

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[96] For a comprehensive read on the History of the Irish Legal system, see Sinder J (2001) "Irish legal history: An overview and guide to the sources" *Law Library Journal* 93(2): 232-260.
[97] An tSeirbhis Chúteanna Court Service (2011) "Brehon law" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/3CBAE4FE856E917B80256DF800494ED9?opendocument accessed 22/10/2013. See also Wilson L (1989) "The Brehon laws" available online at www.irish-society.org/home/hedgemaster-archives-2/history-events/the-brehon-laws accessed 21/10/2013.
[98] For more on the Bull Laudabiliter, see Sheehy M (1961) "The Bull Laudabiliter: A problem in medieval diplomatique and history" *Journal of the Galway Archaeological and Historical Society* 29(3/4): 45-70.
[99] Wilson L (1989) "The Brehon laws" online.
[100] Statutes of Kilkenny 1366 (40 Edw. 3).
[101] Poynings' Law or Statute of Drogheda 1494 (10 Hen. 7 c.4).
[102] An tSeirbhis Chúteanna Court Service (2011) "Brehon law" online.

Around 1500, English law was confined to an area referred to as the Pale[103] and it was not until the reign of King Henry VIII in the mid-16th century that it extended further. Due to this, Ireland has a system of common law similar to the English and Welsh common law which also shares some sources thereof. Ireland is sometimes referred to as "the first adventure of the English common law" and the modern Irish system of law is derived from common law and Oliver Cromwell's military campaign from 1649 to 1652 consolidated English law by forcing many Irish landowners to resettle in Connaught. In 1691, the Protestant William of Orange was victorious over King James II at the Battle of the Boyne and this led to repression of the Catholics by way of brutal penal laws. Further legal enactments during the 18th century purported to politically and economically disenfranchise the Catholics even more by excluding them from education and restricting their property rights.[104]

Under the Irish Appeals Act 1783,[105] the English Parliament repealed Poynings' Law[106] and until 1800 the Irish Parliament, known as Grattan's Parliament, attempted to improve the Catholic plight by enacting the Roman Catholic Relief Act 1793.[107] However, due to the American and French revolutions and the failed 1798 rebellion, the Act of Union 1800[108] was passed which dissolved the Irish Parliament and established the Parliament of Westminster in London as the sole legislature for the United Kingdom of Great Britain and Ireland and so governmental power was centralised in London.[109]

The need for reform of legal institutions became more and more apparent after the Industrial Revolution and some reforms were introduced by the Supreme Court of Judicature Act 1873[110] and its Irish counterpart in 1877 which merged common law and equity into a unified court system. The Supreme Court of Judicature was established[111] while the Judicial Committee of the House of Lords remained the ultimate court of appeal for Ireland. In addition to the creation of

[103] This area was comprised of Dublin and the east coast.
[104] An tSeirbhis Chúteanna Court Service (2011) "History of the law: Background" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/8B9125171CFBA78080256DE5004011F8?opendocument accessed 22/10/2013.
[105] Irish Appeals Act 1783 (22 Geo. 3. c.53). This is also known as the Renunciation Act.
[106] See footnote 141 *infra* for more on Poynings' Law.
[107] Roman Catholic Relief Act 1793 (23 Geo. 3 c.28). Under this Act limited voting rights and admittance to the Bar was permitted.
[108] Acts of Union (Ireland) 1800 (c.38).
[109] This lasted until 1922 when the Irish Free State was established.
[110] Supreme Court of Judicature Act 1873.
[111] This court consisted of the High Court of Justice, which had original and appeals jurisdiction and the Court of Appeal which had appeal jurisdiction. The numerous courts which had developed over many centuries, such as the Court of Exchequer and the Court of Probate, were subsumed into divisions of the High Court. The High Court of Justice of Ireland sat in Dublin.

superior courts, subordinate courts were also created. The focal point of reform, however, became land law reform after the Irish Famine from 1845 to 1850.[112]

Calls for the repeal of the Act of Union, however, became emphasised with Home Rule being the motivation. This was not possible until the Government of Ireland Act 1914[113] was passed. This Act was postponed during World War I. The failed 1916 Rising and the subsequent hard response thereto by the British, however, defeated Home Rule possibilities as it hardened public attitudes and swayed the vote of the 1918 election in favour of Sinn Féin rather than the Irish Parliamentary Party.[114]

The Sinn Féin deputies did not take their seats at Westminster and held the first Dáil Éireann meeting in January 1919.[115] Here they approved the Declaration of Independence, adopted a Provisional Constitution and established a court system. The British attempted to suppress this so-called seditious association by passing the Government of Ireland Act 1920[116] which partitioned Ireland into Northern and Southern Ireland, each with a Parliament of its own. Elections for these new Parliaments were held in May 1921 and since the Act had been accepted in Northern Ireland, the Parliament opened there in June 1921.

The Articles of Agreement for a Treaty Between Great Britain and Ireland[117] was signed on the 6th of December 1921 after a truce had been agreed on and this provided for the establishment of the Irish Free State in 1922. The unification of Ireland was also provided for but Northern Ireland had the option to opt out which would mean *inter alia* that Northern Ireland would be a member of the Commonwealth and the Crown would remain the head of State. Northern Ireland opted out of a united Ireland and in January 1922 the Treaty was approved by the Dáil.[118]

The Westminster Parliament repealed the Government of Ireland Act 1920 in so far as it applied to Southern Ireland and passed the Irish Free State (Constitution) Act 1922.[119] The Irish Free State Constitution, based on the Treaty, was implemented by the enactment of the Constitution of the Irish Free State (Saorstát Éireann) Act 1922[120] by the Dáil. The Constitution provided the

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[112] This resulted in the passing of the Land Law (Ireland) Act 1881 (44 & 45 Vict. c.49) which established the Irish Land Commission and granted Irish tenant farmers the three F's namely: fair rent, freedom of sale and fixity of tenure. See An tSeirbhis Chúteanna Court Service (2011) "History of the law: Reform" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/8B9125171CFBA78080256DE5004011F8?opendocument accessed 22/10/2013.
[113] Government of Ireland Act 1914 (4 & 5 Geo. 5 c.90). This Act is also known as the Home Rule Act.
[114] See in general, Laffan M (1999) *The resurrection of Ireland: The Sinn Féin Party 1916-1923*: 21-22.
[115] Dáil Éireann is the lower house of the Irish Parliament.
[116] The Government of Ireland Act 1920 (10 & 11 Geo. 5 c.67).
[117] Hereafter referred to as the Anglo-Irish Treaty.
[118] An tSeirbhis Chúteanna Court Service (2011) "History of the law: Independence" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/8B9125171CFBA78080256DE5004011F8?opendocument accessed 22/10/2013.
[119] Irish Free State (Constitution) Act 1922 (Session 2)(13 Geo. 5. Sess. 2. c.1).
[120] Constitution of the Irish Free State (Saorstát Éireann) Act, 1922.

right of appeal to the Judicial Committee of the Privy Council and for the separation of powers. The judicial branch consisted of a Supreme Court, High Court and local courts with limited jurisdiction. Since two court systems, the ordinary courts and the "Dáil courts,"[121] had been in place since 1920, the transition between the old and new court system as provided for by the Constitution was complicated and the decisions made by the previous courts were held to be void in law.[122]

In 1923 the Judiciary Committee was appointed to advise the Cabinet, or Executive Council, on the establishment of a new court system.[123] The recommendations made by the Committee were largely accepted and adopted in the Courts of Justice Act 1924.[124] This Act created new courts, assigned new and altered jurisdictions to the courts, and importantly, provided for a further right of appeal to the Supreme Court which was then the final court of appeal as a result of the Act and it was presided over by a Chief Justice. The structures created by the Courts of Justice Act remain the same to this day.[125]

The 1922 Constitution was amended various times until 1936 when all vestiges of the Treaty had been erased.[126] In 1937, however, the Fianna Fáil Government drafted a new Constitution. It closely reflected the 1922 Constitution in its amended state but it also enshrined Republican ethos in that sovereignty was claimed over Northern Ireland and it established that the Head of State was to be the President. It furthermore integrated an altered Bill of Rights and renamed the State as Ireland. Southern Ireland's final break from Britain came with the Republic of Ireland Act 1948[127] which stated that the State was to be described as the Republic of Ireland and withdrew the Republic of Ireland from the Commonwealth.[128]

The Constitution was amended further when Ireland became a member of the European Union since it required a degree of cession of sovereignty and the subordination of national law to European law. The conclusion of the Good Friday Agreement also caused a significant

[121] The "Dáil courts" were comprised of the Parish Court which dealt with the minor civil and criminal matters, the District Court which heard more serious civil and criminal matters as well as appeals from the Parish Court, a Circuit Court which was comprised of four circuits with unlimited civil and criminal jurisdiction and lastly a Supreme Court functioning as both court of first instance and appellate court.
[122] See the case of *R (Kelly) v Maguire* [1923] 2.I.R 58.
[123] An tSeirbhis Chúteanna Court Service (2011) "History of the law: New court system" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/8B9125171CFBA78080256DE5004011F8?opendocument accessed 22/10/2013.
[124] Courts of Justice Act 1924 (No.10 of 1924).
[125] It was replicated in the 1937 Constitution and again in 1961.
[126] These amendments included *inter alia* abolishing the right of appeal to the Privy Council, abolishing the Senate as well as the office of Governor General and conferring the power to enter into international treaties to the Executive Council and also the power to appoint diplomatic representatives. Furthermore, all references to the Crown were removed as well as the oath of allegiance.
[127] Republic of Ireland Act 1948 (No.22 of 1948).
[128] An tSeirbhis Chúteanna Court Service (2011) "History of the law: New Constitution" available online at www.courts.ie/Courts.ie/library3.nsf/pagecurrent/8B9125171CFBA78080256DE5004011F8?opendocument accessed 22/10/2013.

amendment as Ireland had to relinquish their territorial claim over Northern Ireland and replace this claim with the principle of unity by consent.[129]

Events of 1979[130] severely set back Northern Irish jurisprudence and created a shortage of authoritative work such as annotated statutes, law reports and rules of court and even textbooks.[131] Some mention must therefore be made of "the Troubles" which lasted for roughly 30 years.[132] This was the period of conflict between different factions in Northern Ireland[133] which ended with the conclusion of the Good Friday Agreement[134] and the Declaration of Downing Street.[135] The Troubles left a legacy of doubts regarding the system of justice since fundamental human rights, such as the right to life, and freedoms were severely denied and violated during this time. This may be clearly illustrated in the functioning of the "conveyor-belt justice" dispensed by the "Diplock courts."[136]

4.2 LEGISLATION

Although the meaning of the phrase "Northern Ireland legislation" has been altered various times,[137] it is defined in the Interpretation Act 1978[138] and reads as follows:[139]

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[129] *Ibid*.
[130] These may include tax related upsets, ending pound's parity to join the European Monetary System, petrol shortages which cause delays, the first election of the European Parliament in the Republic of Ireland and Northern Ireland.
[131] See in general, Great Britain (1979) *Royal Commission on Legal Services command paper: Final report*: 704 paragraphs 42.66-42.67.
[132] Conway B (2003) "Active remembering, selective forgetting and collective identity: The case of Bloody Sunday" *Identity: An International Journal of Theory and Research* 3(4): 309.
[133] These factions were the Catholics and the Protestants or the Republicans and the Loyalists. It must be mentioned that the Troubles were never about religion but about the national identity and territory of Ireland. Southern Ireland became independent in 1921 and Northern Ireland remained a part of the United Kingdom. On the one hand, the Republicans wanted to end centuries of British Rule and unite Ireland. The Loyalists, on the other hand wanted to maintain the link to the rest of the United Kingdom.
[134] The Good Friday Agreement is the agreement between the major political parties in Northern Ireland which was reached on Good Friday, April 1998, following multi-party talks. The agreement was endorsed in referendums in Northern Ireland as well as the Republic of Ireland. Among the issues agreed upon was the establishment of new North-South institutions, an Assembly or Parliament for Northern Ireland, that a referendum was to be held regarding the removal of the Republic of Ireland's constitutional claim to Northern Ireland, reforms in policing, the decommissioning of paramilitary weapons and human rights and equality reforms. See Conway (2003) 323.
[135] The Downing Street Declaration was signed between John Major the then British Prime Minster and Albert Reynolds, the then Irish Taoiseach or Prime Minister, on the 15th of December 1993 as the foundation of the current Northern Ireland peace process. The Declaration endorses the principal of consent and it commits itself to removing the causes of the conflict by making use of exclusively democratic means. See Conway (2003) 323.
[136] Walsh D (2000) *Bloody Sunday and the rule of law in Northern Ireland*: 13-14 and 216-217. See paragraph 4.4 *infra*.
[137] Sections 24(5)(d)-(g) were substituted by Schedule 13 paragraph 3 of the Northern Ireland Act 1998 (c.47). Until the 2nd of December 1999 Schedule 2 paragraph 7(2) to the Northern Ireland Act 1982 provided that Orders in Council in terms of section 38(1)(b) of the Northern Ireland Constitution Act 1973 (c.36) were deemed Northern Irish legislation for the purposes of section 24 of the Interpretation Act 1978. Section 5 of the Interpretation Act 1978 provides that unless the intention to the contrary appears the expression "Northern Ireland legislation" is to be understood in accordance with Schedule 1 of that Act which states that " 'Northern Ireland legislation' has the meaning assigned by section 24(5) of this Act." See section 22(1) and also Schedule 2 paragraph 4(1)(a) of the Interpretation Act 1978.

"In this section 'Northern Ireland legislation' means—
(a) Acts of the Parliament of Ireland;
(b) Acts of the Parliament of Northern Ireland;
(c) Orders in Council under section 1(3) of the Northern Ireland (Temporary Provisions) Act 1972;
(d) Measures of the Northern Ireland Assembly established under section 1 of the Northern Ireland Assembly Act 1973;
(e) Orders in Council under Schedule 1 to the Northern Ireland Act 1974;
(f) Acts of the Northern Ireland Assembly; and
(g) Orders in Council under section 85 of the Northern Ireland Act 1998."

Statutory law in Northern Ireland consists of numerous different Acts. These include Acts of the Parliament of the United Kingdom which apply to Northern Ireland, Acts of the Northern Ireland Assembly and also statutory instruments created by different departments of the Northern Ireland Executive and the Government of the United Kingdom.[140] The statute books of Northern Ireland also still contain old order legislation such as some Acts of the Parliament of England and the Parliament of Great Britain which extended to Ireland under Poynings' Law[141] between 1494 and 1782, Acts of the Parliament of Ireland made before the Act of Union 1800 and Acts of the Parliament of Northern Ireland which were passed between 1921 and 1972.

Legislative law in Northern Ireland is divided into primary and secondary legislation.[142] Primary legislation generally provides for a framework and it is created by the legislature which in Northern Ireland includes the Parliament of the United Kingdom and the Northern Ireland Assembly. The Assembly may only legislate on "transferred matters" whereas the United Kingdom's Parliament legislates on "excepted" and "reserved matters." Secondary legislation normally contains more detailed provisions and is derived from primary legislation.

4.3 LEGISLATURE

The Northern Ireland Assembly is the devolved legislature for Northern Ireland and is responsible for creating laws on "transferred matters"[143] in Northern Ireland and for monitoring Ministers and Government Departments. The Parliament Buildings, Stormont Estate, in Belfast serve as the seat to the Assembly. Members of the Assembly meet to debate issues, question

[138] Interpretation Act 1978.
[139] Section 24(5) of the Interpretation Act 1978.
[140] Legislation.gov.uk (2013) "Acts of the Northern Ireland Assembly and explanatory notes" available online at http://www.legislation.gov.uk/nia accessed 23/10/2013.
[141] Poynings' Law 1495 (c.22). Poynings' Law is an Act which had the purpose of bringing Ireland under the authority of the English monarchy. It was initiated by Sir Edward Poynings in the Irish Parliament at Drogheda in 1494 in his position as Lord Deputy of Ireland appointed by King Henry VII of England. This marked the beginning of Tudor rule in Ireland and it remained in force until the Irish Constitution of 1782 gave the Irish parliament legislative independence. See in general, Curtis E, McDowell RB (eds)(1968) *Irish historical documents 1172-1922*. See also Ellis SG (1985) *Tudor Ireland: Crown, community and the conflict of cultures 1470-1603*. Suggested further reading, McGrath CI (2000) *The making of the eighteenth century Irish Constitution*.
[142] Also referred to as delegated or subordinate legislation.
[143] These are matters not explicitly reserved as falling under the authority of the Parliament of the United Kingdom.

Ministers and make laws to the benefit of the people of Northern Ireland.[144] The Assembly is one of two "mutually inter-dependent" institutions created under the 1998 Good Friday Agreement or Belfast Agreement.[145] The purpose of the Agreement was to bring an end to the Troubles in Ireland which had lasted for 30 years.[146] Members of the Legislative Assembly (MLAs) are elected by a single transferable vote form of proportional representation and most of the Ministers are selected by making use of the D'Hondt method.[147] The Assembly has been suspended repeatedly and the longest period of suspension which lasted from 14 October 2002 to 7 May 2007, ended in the St Andrews Agreement being accepted.[148] The Assembly is responsible for electing the Northern Ireland Executive and has legislative powers. For the purpose of this thesis attention will be focused on the legislative functions of the Assembly rather than those related to the Executive.

The Assembly legislates in a field of competence referred to as "transferred matters."[149] The Northern Ireland Act 1998[150] does not set a limit on these matters and they have been grouped into the responsibilities of the Northern Ireland Executive. Differently stated, they may be seen as any competencies which have not been explicitly retained by the Westminster Parliament. The powers reserved by the Parliament of Westminster are divided into "excepted matters"[151] and "reserved matters."[152] Excepted matters are indefinitely reserved and reserved matters may be transferred to the competence of the Northern Ireland Assembly at a future date.

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[144] Northern Ireland Assembly (2013) "The Northern Ireland Assembly" available online at http://www.niassembly.gov.uk/Assembly-Business/ accessed 15/10/2013.
[145] The Good Friday Agreement 1998. See Bell C (2003) *Peace agreements and human rights*: 141. The other is the North/South Ministerial Council with the Republic of Ireland. See in general, Morgan A (2000) *The Belfast Agreement: A practical legal analysis*.
[146] See paragraph 4.1 *supra*.
[147] This ensures that the largest political communities in Northern Ireland, the unionists and nationalists, both participate in the governing of the region. For more on this system see BBC News (1999) "The D'Hondt system explained" *BBC News*, 28 November available online at http://news.bbc.co.uk/1/hi/northern_ireland/91150.stm accessed 16/10/2013.
[148] The St Andrews Agreement 2006. Talks started in November 2006, an election to the Assembly was held on the 7th of March 2007 and full power was restored to the devolved institutions on the 8th of May 2007. See BBC News (2007) "Historic return for NI Assembly" *BBC News*, 3 July available online at http://news.bbc.co.uk/2/hi/uk_news/northern_ireland/6634373.stm accessed 15/10/2013. The Northern Ireland (St Andrews Agreement) Act 2006 (c.53) which implemented this agreement received Royal Assent on 22 November 2006.
[149] A transferred matter is defined as "any matter which is not an excepted or reserved matter," according to section 4(1) Part 1 of the Northern Ireland Act 1998.
[150] Northern Ireland Act 1998.
[151] Schedule 2 of the Northern Ireland Act 1998 provides for the following excepted matters: the Crown; parliament; international relations; defence; immigration and nationality; taxation; national insurance; elections; currency; national security; nuclear energy; outer space and activities in Antarctica.
[152] Schedule 3 of the Northern Ireland Act 1998 provides for the following reserved matters: navigation; civil aviation; the foreshore, sea bed and subsoil and their natural resources; postal services; import and export controls and external trade; national minimum wage; financial services; financial markets; intellectual property; units of measurement; telecommunications, broadcasting and internet services; the national lottery; xenotransplantation; surrogacy; human fertilisation and embryology; human genetics and consumer safety in relation to goods. The issues of human fertilisation and embryology and human genetics are dealt with in the Human Tissue Act 2004. See chapter 8 paragraph 2 *infra*.

As mentioned earlier, the Assembly has been suspended at times and during those periods the legislative powers of the Assembly were exercised by the United Kingdom Government. Laws that would have been within the competence of the Assembly were then passed by the United Kingdom Parliament in the form of Orders-in-Council rather than legislative actions.

Acts of the Assembly, unlike Westminster enacted laws, are subject to judicial review and may be struck down if they are found to exceed the competences of the Assembly, violate the law of the European Union, violate the European Convention on Human Rights or discriminate against individuals on the grounds of political opinion or religious belief. Assembly Bills however, as with Westminster Bills, must receive Royal Assent in order to become law even though the British Monarch is not formally a part of the Assembly. The Bill may be refused submission for Assent if the Secretary of State believes that it violates the constitutional limitations on the powers of the Assembly. If the Bill is submitted the Monarch will sign it into law.[153]

4.4 COURTS OF NORTHERN IRELAND

There is no single, unified judicial system in the United Kingdom. England and Wales share the same system, Scotland has its own separate system and so does Northern Ireland. In specified instances, however, certain entities have jurisdiction across the entire United Kingdom, such as the Asylum and Immigration Tribunal which deals with matters of immigration law. Also, the Military Court Service has jurisdiction over all the members of the United Kingdom's armed forces regarding offences against military law. In other instances, Northern Ireland is excluded from the jurisdiction of certain bodies but England, Wales and Scotland are subject thereto. An example of this is the Employment Tribunals for England and Wales and Scotland.

The recent violent history of Ireland has also affected the court system and in 1972 trial by jury was suspended for certain terrorist offences in order to overcome the issue of intimidation of jurors and witnesses.[154] Also, Diplock courts were introduced in order to try persons accused of paramilitary activities and these courts become common for crimes related to terrorism.[155] The Diplock courts, established in 1973 and abolished in 2007, were non-jury courts where cases were heard by a single judge and conviction on the basis of confession was possible. The judge

[153] Northern Ireland Assembly Acts begin with the enacting formula: "Be it enacted by being passed by the Northern Ireland Assembly and assented to by Her Majesty as follows:"
[154] BBC News (2007) "Diplock courts" *BBC News*, 3 July available online at http://news.bbc.co.uk/1/hi/programmes/law_in_action/6265734.stm accessed 15/10/2013.
[155] Mallet M (2012) "Two jailed for life for killing policeman Stephen Carroll" available online at http://www.itv.com/news/2012-03-30/two-jailed-for-life-for-killing-policeman-stephen-carroll/ accessed 14/10/2013.

would give a written verdict which included their reasons for reaching such decision and the defendant had an automatic right to appeal.[156]

Northern Ireland has both civil and criminal courts which are created and governed by Northern Irish law and administration of the courts falls to the Northern Ireland Courts and Tribunals Service.[157] The courts may be divided between higher and lower courts and form a hierarchy which ranks from high to low as the Supreme Court of the United Kingdom, the Court of Judicature of Northern Ireland, County Courts and subordinate courts such as Magistrates' courts.[158] Each of the courts will be discussed briefly here.

The Constitutional Reform Act 2005[159] created the Supreme Court of the United Kingdom. It replaced the appellate jurisdiction which was previously vested in the House of Lords and took up its duties on the 1st of October 2009. The Supreme Court of the United Kingdom is the highest appeal court in Northern Ireland and is also the ultimate court of appeal for all cases in the United Kingdom, bar Scots criminal cases.[160]

Below the Supreme Court is the Court of Judicature of Northern Ireland[161] as constituted by the Judicature (Northern Ireland) Act 1978.[162] This is the most important superior court in Northern Ireland and consists of three courts namely[163] the Court of Appeal in Northern Ireland or Court of Appeal,[164] the High Court of Justice in Northern Ireland or High Court[165] and the Crown Court. The Court of Appeal is the highest court specifically for Northern Ireland and appeals from this court are made to the Supreme Court of the United Kingdom. The Court of Appeal hears appeals from the Crown Court, the High Court, county courts and the subordinate courts. The High Court is divided into three divisions. They are the Queen's Bench Division, the

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156 De Londras F (2010) "Police brutality, torture and the Diplock courts in Northern Ireland: The Guardian investigates" available online at http://humanrights.ie/civil-liberties/police-brutality-torture-and-the-diplock-courts-in-northern-ireland-the-guardian-investigates/ accessed 15/10/2013. See also Transitional Justice: Reconstructing Self and Society (2009) "Institutional reform in Northern Ireland: Ending the Diplock courts" available online at http://tj.facinghistory.org/reading/institutional-reform-northern-ireland-endi accessed 15/10/2013.

157 NIdirect Government Services (2013) "Introduction to the justice system" available online at http://www.nidirect.gov.uk/introduction-to-the-justice-system accessed 23/10/2013. See also CAIN (2013) "The structure of the courts and the judicial system" available online at http://cain.ulst.ac.uk/issues/law/cjr/chap5.pdf accessed 23/10/2013.

158 See in general, the Magistrates' Court (Northern Ireland) Order 1981 No.1675 (NI 26).

159 Constitutional Reform Act 2005.

160 LawTeacher (2013) "The Constitutional Reform Act 2005" available online at http://www.lawteacher.net/free-law-essays/human-rights/constitutional-reform-act-2005.php accessed 23/10/2013.

161 Prior to 1 October 2009 the court was called the "Supreme Court of Judicature." The name of the court was changed when the relevant provisions of the Constitutional Reform Act 2005 came into effect as this established the Supreme Court of the United Kingdom. See subsection 59(2) of The Constitutional Reform Act 2005.

162 Judicature (Northern Ireland) Act 1978 (c.23).

163 Section 1 of the Judicature (Northern Ireland) Act 1978.

164 Formally "Her Majesty's Court of Appeal in Northern Ireland." See Schedule 1 of the Interpretation Act 1978.

165 Formally "Her Majesty's High Court of Justice in Northern Ireland." See Schedule 1 of the Interpretation Act 1978.

Family Division and the Chancery Division.[166] The Crown Court hears serious criminal cases such as indictable offences and offences earmarked for trial in the Crown Courts rather than the magistrates' courts.[167]

County courts fall between High courts and Magistrates' courts and are the primary civil courts in Northern Ireland. High courts may still hear matters with higher value but county courts hear cases ranging from civil actions to appeals from the Magistrates' courts. In fact, the case load of the county court is so wide that in certain instances the court acts as a differently named institution such as when the court hears proceedings brought under the Children (Northern Ireland) Order 1995[168] and appeals from the family proceedings courts, it is called a family care centre. There are seven county court divisions in Northern Ireland.

Below the High Court there are various lower subordinate courts such as Crown courts, which have been discussed, and Magistrates' courts. The Magistrates' courts undertake the preliminary hearings in more serious criminal cases and hear less serious criminal cases. Magistrates' courts include youth courts, family proceedings courts[169] and domestic proceedings courts and are divided into 21 districts. Northern Ireland also has an Enforcement of Judgments Office and coroners' courts, which investigate the circumstances surrounding sudden, violent or unnatural deaths. Lastly, the fourth jurisdiction of which the UK is comprised must be discussed and to this end attention must be given to the law of Scotland.

5 SCOTTISH LAW

The Scottish legal system was given some autonomy by the Acts of Union 1707 and due to this separate co-existence along with England, Wales and Northern Ireland, Scots law as a civil legal system is very interesting in comparison to the common law system in operation in the rest of the United Kingdom. As was mentioned previously, Scotland has its own Human Tissue Act and as this Act has some bearing on the topic of this thesis, it is discussed in greater detail in the following chapter. The context and environment in which the Scots Human Tissue Act functions must therefore be explained.

[166] The English High Court is also divided into different divisions.
[167] See in general, Dickson B (2011) *Law in Northern Ireland*.
[168] Children (Northern Ireland) Order 1995 No.755 (NI 2).
[169] When sitting as the family proceedings court, the Magistrates' court hears proceedings brought in terms of the Children (Northern Ireland) Order 1995.

5.1 HISTORY AND BACKGROUND

Scottish law may be traced to its early origins in the various different customs of early Scots cultures and the numerous historic sources of law have resulted in the Scottish system being a hybrid legal system.[170]

Prior to the 11th century, Scottish law was probably a mixture of different customs and traditions from the Celts, Welsh, Irish, Norse and Anglo-Saxons who had inhabited the area[171] and the Kingdom of Scotland and the approximate borders of Scotland as it is today, and was established after the Battle of Carham between 1016 and 1018.[172] In 1263 the Outer Hebrides were added and in 1469 the Northern Isles, and this completed the legal jurisdiction of Scotland as it is to this day.[173] As feudalism gradually spread through Scotland in the 11th century, early forms of Sheriff courts also developed.[174] Under Robert the Bruce, however, the Scottish Parliament gained importance and representation of the burghs[175] increased while that of landowners became less.[176] In 1318, a parliament seated at Scone enacted a code of law which drew upon older practices but also drew on current events and focused on military matters and war,[177] and the General Council stated in 1399 that the King should hold parliament at least once a year so that his subjects would be served by the law.[178]

The influence of Roman law is visible in Scottish legal texts from the 14th century such as the *Regiam Majestatem*[179] and the *Quoniam Attachiamenta*[180] which both contain provisions of the *Ius Commune*.[181]

During the reigns of Kings James I to James V, the legal profession began to develop and the administration of both civil and criminal justice was centralised[182] and Parliament normally sat

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170 These include custom, feudal law, Canon law, Roman law and English law.
171 Morais Y (2010) "Scottish legal history research guide" available online at http://www.law.georgetown.edu/library/research/guides/scottishlegalhistory.cfm accessed 13/10/2013.
172 Reid KGC & Zimmermann R (2000) *A history of private law in Scotland: Introduction and property*: 15.
173 *Idem* 16.
174 Black R, Henderson H, Thomson J, Miller K & Whitty N (eds)(1996) T*he law of Scotland: Stair memorial encyclopaedia*: paragraph 505. See also Reid & Zimmermann (2000) 20.
175 A burgh was an autonomous entity in Scotland and Northern England which formed an administrative division usually in the form of town or city, for example Edinburgh.
176 Reid & Zimmermann (2000) 38.
177 *Idem* 40.
178 Records of the Parliament of Scotland (1399) "Parliamentary Records" as translated and available online at http://www.rps.ac.uk/search.php?%20action=fetch_jump&filename=robertiii_trans&jump=robertiii_m1399_1_1_d6_ms&type=trans&fragment=t1399%20_1_13_d6_trans accessed 13/10/2013. See also Reid & Zimmermann (2000) 40. For more on the development and history of Scots law prior to the 15th century, see The Law Society of Scotland (2013) "A general history of Scots law (Pre-1400s)" available online at https://www.lawscot.org.uk/media/3374/AGeneralHistoryofScotsLaw_Pre1400s.pdf accessed 23/10/2013.
179 On procedure at the royal courts.
180 On procedure at the baron courts. See Black, Henderson *et al*. (eds)(1996) paragraph 512.
181 *Idem* 46.
182 *Idem* 52.

on an annual basis.[183] The modern Court of Session can be traced to the 15th and early 16th century with the establishment of a specialised group of councillors to the King. This group evolved from the King's Council and dealt solely with the administration of justice and this body later became the College of Justice.[184]

The Kingdoms of Scotland and England were merged by the Act of Union 1707[185] to form the Kingdom of Great Britain. The Estates of Scotland and the Parliament of England were combined to form the Parliament of Great Britain seated in the Palace of Westminster in London.[186] Scotland, however, retained some autonomy in that Article 19 of the Act assured the continued existence of the College of Justice, Court of Session and the Court of Justiciary, and the education system in Scotland was also kept separate.[187] Other than that, however, the Parliament of Great

[183] *Idem* 54.
[184] Black, Henderson *et al*. (eds)(1996) paragraph 515.
[185] Acts of Union1707 (6 Anne c. 11). See Union with Scotland (Amendment) Act 1707 (c.40) and Union with England Act 1707 (c.7). For more on the legal developments and history of Scotland from the 15th to 18th centuries, see The Law Society of Scotland (2013) "A general History of Scots law (15th-18th Centuries)" available online at http://www.lawscot.org.uk/media/3371/AGeneralHistoryofScotsLaw_15th18th.pdf accessed 23/10/2013.
[186] Article 3 of the Acts of Union1707.
[187] Article 19 reads as follows: "That the Court of Session or Colledge [*sic*] of Justice, do after the Union and notwithstanding thereof, remain in all time coming within Scotland as it is now constituted by the Laws of that Kingdom, and with the same Authority and Priviledges [*sic*] as before the Union; subject nevertheless to such Regulations for the better Administration of Justice as shall be made by the Parliament of Great Britain; And that hereafter none shall be named by Her Majesty or Her Royal Successors to be Ordinary Lords of Session but such who have served in the Colledge [*sic*] of Justice as Advocats [*sic*] or Principal Clerks of Session for the space of five years, or as Writers to the Signet for the space of ten years With this provision That no Writer to the Signet be capable to be admitted a Lord of the Session unless he undergo a private and publick Tryal [*sic*] on the Civil Law before the Faculty of Advocats [*sic*] and be found by them qualified for the said Office two years before he be named to be a Lord of the Session, yet so as the Qualifications made or to be made for capacitating persons to be named Ordinary Lords of Session may be altered by the Parliament of Great Britain.
And that the Court of Justiciary [*sic*] do also after the Union, and notwithstanding thereof remain in all time coming within Scotland, as it is now constituted by the Laws of that Kingdom, and with the same Authority and Priviledges [*sic*] as before the Union; subject nevertheless to such Regulations as shall be made by the Parliament of Great Britain, and without prejudice of other Rights of Justiciary[*sic*]:
And that all Admiralty Jurisdictions be under the Lord High Admirall [*sic*] or Commissioners for the Admiralty of Great Britain for the time being; And that the Court of Admiralty now Established in Scotland be continued, And that all Reviews, Reductions or Suspensions of the Sentences in Maritime Cases competent to the Jurisdiction of that Court remain the same manner after the Union as now in Scotland, until the Parliament of Great Britain shall make such Regulations and Alterations, as shall be judged expedient for the whole United Kingdom, so as there be alwayes [*sic*] continued in Scotland a Court of Admiralty such as in England, for determination of all Maritime Cases relating to private Rights in Scotland competent to the Jurisdiction of the Admiralty Court; subject nevertheless to such Regulations and Alterations as shall be thought proper to be made by the Parliament of Great Britain; And that the Heritable Rights of Admiralty and Vice-Admiralties in Scotland be reserved to the respective Proprietors as Rights of Property, subject nevertheless, as to the manner of Exercising such Heritable Rights to such Regulations and Alterations as shall be thought proper to be made by the Parliament of Great Britain;
And that all other Courts now in being within the Kingdom of Scotland do remain, but subject to Alterations by the Parliament of Great Britain; And that all Inferior Courts within the said Limits do remain subordinate, as they are now to the Supream [*sic*] Courts of Justice within the same in all time coming;
And that no Causes in Scotland be cognoscible by the Courts of Chancery, Queens-Bench, Common-Pleas, or any other Court in Westminster-hall; And that the said Courts, or any other of the like nature after the Union, shall have no power to Cognosce [*sic*], Review or Alter the Acts or Sentences of the Judicatures within Scotland, or stop the Execution of the same;
And that there be a Court of Exchequer in Scotland after the Union, for deciding Questions concerning the Revenues of Customs and Excises there, having the same power and authority in such cases, as the Court of Exchequer has in England And that the said Court of Exchequer in Scotland have power of passing Signatures, Gifts Tutories, and in other things as the Court of Exchequer in Scotland hath; And that the Court of Exchequer that now is in Scotland do remain, until a New Court of Exchequer be settled by the Parliament of Great Britain in Scotland after the Union;

Britain suffered no restrictions in altering laws which concerned public right,[188] policy and civil government.

The development of Scots law after 1707 was of great significance as it coincided with the Scottish Enlightenment which meant that intellectual activity and all aspects of human life were embraced. This in turn ensured Scots law as a university-taught discipline which led to an increase in Scots legal writers and the appointment of exceptional judges.[189] The transfer of legislative power to London coupled with the new procedure of appeals heard by the House of Lords, however, strengthened the English influence on Scots law and Acts of Parliament began to create a unified system of statutes which applied in both England and Scotland. Scottish Lords of Appeal in Ordinary were appointed in the 19th century to address the concerns regarding a foreign system of appeal[190] and at the same time it was shown that no appeal lay from the High Court of Justiciary to the House of Lords.[191] To this day, Scottish law continues to develop and change especially due to devolution and the formation of the Scottish Parliament in 1999.

Devolution, as facilitated by the Scotland Act 1998,[192] is the most important recent development of Scottish law. Section 1 of the Act states that "there shall be a Scottish Parliament" and this, the establishment of a Scottish Parliament, was a watershed moment in the history of Scots law. The Act follows the scheme as adopted in the Government of Ireland Act 1920,[193] rather than that of the Scotland Act 1978,[194] meaning that instead of listing the powers of the Scottish Parliament, it details the powers reserved to the Parliament of the United Kingdom.[195] This open-endedness indicates more independence.[196] This open-ended authority to create legislation is personified by the Human Tissue Act 2006 which is discussed in the course of this thesis.[197]

And that after the Union the Queens Majesty and Her Royal Successors, may Continue a Privy Council in Scotland, for preserving of public Peace and Order, until the Parliament of Great Britain shall think fit to alter it or establish any other effectual method for that end."

[188] Only alterations for the evident utility of the subjects in Scotland were permitted in relation to private right, however.

[189] The Law Society of Scotland (2013) "A general history of Scots law (19th Century)" available online at http://www.lawscot.org.uk/media/3372/AGeneralHistoryofScotsLaw_19thCentury.pdf accessed 23/10/2013.

[190] Today there is usually a minimum of two Scottish justices appointed to the Supreme Court of the United Kingdom to ensure some Scottish experience is present in Scottish appeals.

[191] BBC News (2009) "Profiles: UK supreme justices" *BBC News*, 30 September available online at http://news.bbc.co.uk/1/hi/uk/8283961.stm accessed 20/10/2013.

[192] Scotland Act 1998 (c.46).

[193] Government of Ireland Act 1920.

[194] Scotland Act 1978 (c.51).

[195] The Law Society of Scotland (2013) "A general history of Scots law (20th Century)" available online at http://www.lawscot.org.uk/media/3373/AGeneralHistoryofScotsLaw_20thCentury.pdf accessed 23/10/2013.

[196] It is interesting to note, however, that when given the chance to become independent, the people of Scotland opted to remain attached to the United Kingdom as per the results of the Scottish Independence Referendum of 18 September 2014.

[197] See chapter 8 *infra*.

5.2 SOURCES OF LAW

Scottish law is drawn from various sources which include legislation, common law, custom, academic writing and European law.[198] Each of these sources require some attention:

1. Legislation. Legislation forms only one of a number of sources and should not be confused with a civil code as it does not attempt to comprehensively codify the law. The United Kingdom's Parliament has the power to pass statutes on any issue for Scotland but under the Sewel Convention,[199] however, the Scottish Parliament must consent to the passing of legislation on any devolved matter.[200] Statutes will thus explicitly state that they have application to Scotland. The Scottish Parliament is a devolved unicameral legislature and may pass legislation within its area of competence on matters which affect Scotland only.[201] This legislation, like legislation of the Parliament of the United Kingdom, also requires Royal Assent which is automatically granted.[202] Acts of the United Kingdom Parliament often delegate powers to Ministers of the Crown or other bodies to create legislation known as statutory instruments and these legislative documents have legal effect in Scotland in the extent to which it is intended to have. Also, all laws passed by the Scottish Parliament must comply with the Human Rights Act 1998[203] and European law in general, and, should a conflict exist, the Court of Session or High Court of Justiciary may strike down the legislation as *ultra vires*.[204] It is also interesting to note that a limited amount of pre-1707 legislation of the Parliament of Scotland still has legal effect;
2. Common law. In Scotland, common law is still an important source of law.[205] Common law is derived from the decisions of the Scottish courts and from some rulings by the Supreme Court of the United Kingdom. Scottish common law and English common law

[198] See in general, European Judicial Network (2007) "Legal order-Scotland" available online at http://ec.europa.eu/civiljustice/legal_order/legal_order_sco_en.htm accessed 20/10/2013.
[199] See in general, Devolution Matters (2011) "The Sewel Convention" available online at http://devolutionmatters.wordpress.com/devolution-the-basics/the-sewel-convention/ accessed 20/10/2013. See also The Scottish Government (2008) "The Sewel Convention: Key features" available online at http://www.scotland.gov.uk/About/Government/Sewel/KeyFacts accessed 20/10/2013. See footnote 235 *infra*.
[200] Bradley A & Ewing K (2006) *Constitutional and administrative law*: 22. See also Gov.UK (2012) "Devolved government in the UK" available online at http://webarchive.nationalarchives.gov.uk/20121015000000/http://www.direct.gov.uk/en/Governmentcitizensandrights/UKgovernment/Devolvedgovernment/DG_073306 accessed 21/10/2013.
[201] The Scottish Parliament (2012) "Devolved and reserved matters explained" available online at http://www.scottish.parliament.uk/visitandlearn/25488.aspx accessed 20/10/2013.
[202] Parliament.UK (2011) "Royal assent" available online at http://www.parliament.uk/about/how/laws/passage-bill/lords/lrds-royal-assent/ accessed 20/10/2013.
[203] Human Rights Act 1998.
[204] Boyle A, Himsworth C, MacQueen H & Loux A (eds)(2002) *Human rights and Scots law*: 309 & 311.
[205] This is especially true in the field of criminal law where not all crimes, such are murder, are codified and a large body of legal precedent has been developed over the years.

should not be confused as they do not share historical origins.[206] In Scotland, common law originated from the customary laws of the different cultures who inhabited the region and in later feudal concepts.[207] The English influence on Scottish common law by way of Supreme Court of the United Kingdom rulings has, however, been considerable and cannot be negated. The rulings of the European Court of Human Rights and the Court of Justice of the European Union also contribute to the Scots common law, specifically when interpreting the European Convention on Human Rights or European law respectively;

3. Custom. Custom may be described as "that which, without any express enactment by the supreme power, derives force from its tacit consent, which consent is presumed from the inveterate or immemorial usage of the community," by John Erskine of Carnock.[208] Today, custom plays a historical role as its importance has been eroded by legislation and by academic writings.[209] Some traces of custom have survived such as the influence of Udal law in Orkney and Shetland;[210]
4. Academic writings. Some specified academic works[211] have been identified as formal sources of Scots law since the 19th century. Generally,[212] the academic works considered as sources of Scots law are *Jus Feudale* by Sir Thomas Craig,[213] the *Institutions of the law of Scotland* by Sir James Dalrymple,[214] *An Institute of the Laws of Scotland* by Andrew MacDouall,[215] *An Institute of the Law of Scotland* by John Erskine[216] and *Commentaries on the Law of Scotland and on the Principles of Mercantile Jurisprudence*[217] as well as *Principles of the Law of Scotland*[218] by George Joseph Bell. The degree of authority attached to these sources is not precise[219] and the recognition thereof was gradual but also encouraged by the principle of *stare decisis*;[220] and

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[206] Black, Henderson *et al*. (eds)(1996) paragraph 359.
[207] *Ibid*. See in general, Barrow GWS (2003) *The Kingdom of the Scots: Government, church and society from the eleventh to the fourteenth century*.
[208] John Erskine was an institutional writer. See paragraph 5.2 *supra* for more on Erskine's work.
[209] The last court ruling wherein customary law was cited was in 1890.See Black, Henderson *et al*. (eds)(1996) paragraph 531.
[210] Black, Henderson *et al*. (eds)(1996) paragraph 530.
[211] These are academic works authored by writers referred to as "institutional writers."
[212] Some commentators also consider the following works to be important sources of law in Scotland: *The institutions of the law of Scotland (1684)* by Sir George Mackenzie, *Principles of the law of Scotland (1754)* by John Erskine and *Principles of equity (1760)* by Henry Home. See Black, Henderson *et al*. (eds)(1996) paragraph 537.
[213] 1603. See also Black, Henderson *et al*. (eds)(1996) paragraph 535.
[214] 1681.
[215] 1751-1753.
[216] 1773.
[217] 1804.
[218] 1829.
[219] Professor Sir Thomas Smith of the University of Edinburgh once remarked that "the authority of an institutional writer is approximately equal to that of a decision by a Division of the Inner House of the Court of Session." See Reid E & Miller DLC (eds)(2005) *A mixed legal system in transition: TB Smith and the progress of Scots law*.
[220] Black, Henderson *et al*. (eds)(1996) paragraph 538.

5. European law. Scots law has in recent years also been affected by European law under the Treaties of the European Union and the requirements of the European Convention on Human Rights[221] which was entered into by members of the Council of Europe. The European Parliament and Council of the European Union have the power to create legislation which directly impacts Scotland in a range of matters in terms of the Treaty on the Functioning of the European Union.[222] Furthermore, Scottish courts are required to enforce European law.[223] Only the Court of Justice of the European Union may legally review the competency of any legislative act of the European Parliament or the Council of the European Union.[224]

5.3 LEGISLATURE

Scotland has two legal institutions.[225] The first is the executive and the second, the legislature. The executive is the Scottish Government which is led by the First Minister and is responsible for implementing laws as passed by the Scottish Parliament.[226] The Government has executive responsibility for the Scottish legal system and its functions are exercised by the Cabinet Secretary for Justice. The Cabinet Secretary for Justice has the responsibility *inter alia* for law enforcement, the Scottish courts and civil justice. The second institution is the Parliament which acts as the legislature of Scotland.[227]

The first Parliament of Scotland existed as the national legislature from early in the 13th century until the Kingdom of Scotland was merged with the Kingdom of England by the Acts of Union in 1707, forming the Kingdom of Great Britain. This original Parliament was known as the "Estates

[221] European Convention on Human Rights 1953.
[222] Treaty on the Functioning of the European Union 2007. See European Commission (2012) "What is EU law?" available online at http://ec.europa.eu/eu_law/introduction/treaty_en.htm accessed 20/10/2013.
[223] The Journal of the Law Society of Scotland (1999) "European law in the Scottish courts" available online at http://www.journalonline.co.uk/Magazine/44-10/1001089.aspx#.UmZzVPlAR9M accessed 20/10/2013.
[224] European legislation will be nullified if it is found to be in conflict with the Treaties of the European Union or with their spirit, if it is *ultra vires* or where the proper procedures of creating such legislation were not adhered to.
[225] See in general, Little GFM (2014) *Modern Scottish legal institutions and the administration of justice*.
[226] The Scottish Parliament (2011) "The Scottish Parliament and the Scottish Government: What is the difference" available online at http://www.scottish.parliament.uk/visitandlearn/24332.aspx accessed 20/10/2013.
[227] The Scottish Parliament is able to make laws and this legislative process begins with the drafting of Bills which are then presented to Parliament. This may be done in different manners. The Government may introduce new laws or amendments to existing laws in the form of a Bill, a committee of the Parliament may present a Bill, a MSP may introduce a Bill in the capacity of a private member or a private Bill may be submitted to Parliament by a person outside of Parliament. The Bill will then go through numerous stages. First, the Bill and its accompanying documents are introduced into Parliament formally and if the entire Parliament agrees in a vote to the general principles of the Bill, it proceeds to the next stage. Secondly, the Bill is considered by relevant committees who may recommend amendments to the Bill. Thirdly and finally, the Bill is considered at a meeting of the entire Parliament. This stage comprises two parts. A consideration of proposed amendments takes place in the form of a general debate which is followed by a final vote on the Bill. After the Bill has then been passed it is submitted to the Monarch for Royal Assent by the Presiding Officer and it then becomes an Act of the Scottish Parliament. See The Scottish Parliament (2012) "Stages of a bill" available online at http://www.scottish.parliament.uk/visitandlearn/Education/18641.aspx accessed 20/10/2013.

of Scotland" and as a consequence of the merger between Scotland and England, it and the English Parliament ceased to exist, and was replaced by the Parliament of Great Britain, seated at Westminster, London.[228]

The current, new Parliament was convened in terms of the Scotland Act 1998 after a referendum held in 1997 and met for the first time on 12 May 1999.[229] The Scottish Parliament is the devolved, unicameral, national legislature of Scotland and is located in the Holyrood area of Edinburgh.[230] The Parliament consists of 129 Members of Scottish Parliament (MSPs) who are elected for four-year terms under the additional member system.[231]

The Scotland Act 1998[232] sets out the devolved powers of the Parliament and also delineates the legislative competence of the Parliament by explicitly specifying powers which are "reserved" to the Parliament of the United Kingdom.[233] All issues not explicitly reserved automatically fall to the Scottish Parliament.[234] Due to certain legislative powers being reserved by the Parliament of the United Kingdom the argument could be made that it technically retains full power to legislate for Scotland but, in terms of the Sewel Convention it will, however, not legislate on devolved matters without the consent of the Scottish Parliament.[235] The Scots Parliament legislates various areas of law which have devolved from the Parliament of the United Kingdom, including health.[236] The Scotland Act 2012[237] extends the devolved competencies. The Scotland Act thus enables the Scottish Parliament to pass primary legislation on certain devolved

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[228] Sutherland E, Goodall K, Little G & Davidson F (eds)(2011) *Law making and the Scottish Parliament: The early years*: 3.
[229] Scottish Parliament Corporate Body (1999) "Official Report (12/05/99)" available online at http://www.scottishcorpus.ac.uk/corpus/search/document.php?documentid=1237 accessed 20/10/2013.
[230] The Parliament is informally referred to as Holyrood.
[231] This means that 73 MSPs represent individual geographical constituencies as elected by the plurality system or "first past the post" system. A further 56 MSPs are elected from an additional eight member regions each electing 7 members.
[232] The Act was passed by the Parliament of the United Kingdom and was given Royal Assent by Queen Elizabeth II on 19 November 1998. See the Preamble of the Scotland Act 1998.
[233] See Schedule 5 of the Scotland Act 1998. Reserved matters thus fall outside of the legislative competence of the Scots Parliament and it is unable to legislate on such issues. These issues include *inter alia* abortion; border protection; broadcasting policy; civil service; coal; common markets for UK goods and services; Constitution; defence and national security; drug policy; electricity; employment; foreign policy and relations with Europe; gas; National Lottery; nuclear energy; oil; social security; stability of the United Kingdom's fiscal, economic and monetary system and transport safety and regulation.
[234] Schedule 5 of the Scotland Act 1998.
[235] On the 21st of July 1998, during the passage of the Scotland Bill 1997-98, Lord Sewel stated in the House of Lords as follows: "Clause 27 makes it clear that the devolution of legislative competence to the Scottish Parliament does not affect the ability of Westminster to legislate for Scotland even in relation to devolved matters. Indeed, as paragraph 4.4 of the White Paper explained, we envisage that there could be instances where it would be more convenient for legislation on devolved matters to be passed by the United Kingdom Parliament. However, ... ***we would expect a convention to be established that Westminster would not normally legislate with regard to devolved matters in Scotland without the consent of the Scottish parliament*** [original emphasis]."
[236] This includes agriculture, fisheries and forestry; economic development; education; environment; food standards; health; home affairs; Scots law; courts; police and fire services; local government; sport and the arts; transport; training; tourism; research and statistics and social work and now also some tax matters.
[237] Scotland Act 2012 (c.11). The 2012 Act conferred further fiscal devolution which includes borrowing powers and other unconnected matters such as setting speed limits and controlling of air guns.

issues.[238] An important role of the Parliament is to hold the Scottish Government accountable for its actions.

Unlike the Parliament of the United Kingdom, members of the public may take part in the Scottish Parliament in two ways. The first is a public petitioning system and secondly, cross-party groups on policy topics as joined by the public attend meetings alongside MSPs.[239]

5.4 COURTS OF SCOTLAND

In Scotland the administration of justice is the responsibility of the civil, criminal and heraldic courts. The Scottish courts may be loosely ranked from the highest court to the lowest in the order of Supreme Court of the United Kingdom, Court of Session, the High Court of the Justiciary, the Court of the Lord Lyon,[240] Sheriff courts, Justice of the Peace courts and lastly some special courts and tribunals.

Before individual attention is given to each court, some explanation is required regarding the division of the courts. Since Scotland greatly retained autonomy of law and related matters, the structures of the courts are somewhat different to those of the courts of England and Wales and of the Northern Irish courts. This means that some of the appeal processes and powers are different in Scotland from the rest of the United Kingdom. Scotland furthermore has the Sheriff Court which is unique to the Scottish legal system within the United Kingdom. The courts in Scotland may therefore also be divided and ranked according to the subject matter with which the court deals. Civil courts may thus be ranked from the Supreme Court of the United Kingdom, down to the Court of Session and then the Sheriff courts. The Criminal Courts, however, rank from highest to lowest as the High Court of Justiciary,[241] the Sheriff courts and District (now Justice of the Peace) courts. Each court will now be explained in some further detail.

The Supreme Court of the United Kingdom is the highest court concerning Scottish civil appeals. It is also the court of appeals from civil and criminal courts for the rest of the United Kingdom. Prior to the creation of this court, the House of Lords held the ultimate appeal authority. This changed when on the 1st of October 2009, the Supreme Court took over such authority from the

[238] BBC News (2002) "Devolution to Scotland" *BBC News*, 14 October available online at http://news.bbc.co.uk/1/hi/programmes/bbc_parliament/2321531.stm accessed 20/10/2013.
[239] See Scott N & Boyd A (1999) "How the Scottish Parliament will work" *The Journal Online* available online at http://web.archive.org/web/20061004144012/http://www.journalonline.co.uk/article/1001141.aspx accessed 20/10/2013. Also, interestingly, Parliament is permitted to debate any issue but if this issue falls outside the scope of its competence, it cannot legislate thereon, no matter the outcome of the debate.
[240] See in general, The Court of the Lord Lyon (2009) "The Court of the Lord Lyon-The official heraldry office for Scotland" available online at http://www.lyon-court.com/lordlyon/CCC_FirstPage.jsp accessed 21/10/2013.
[241] Only in criminal matters related to devolution may an appeal be made from the High Court of Justiciary to the Supreme Court of the United Kingdom.

House of Lords as well as the devolution jurisdiction which was held by the Judicial Committee of the Privy Council.[242] The Court also resides over matters related to devolution issues in terms of the Scotland Act 1998 which include disputes regarding the validity of an Act of the Scottish Parliament or executive functions of the Scottish Government.

The Court of Session is the supreme civil court in Scotland itself and sits exclusively in Parliament House in Edinburgh. It is both a court of first instance and is then referred to as the Outer House, as well as a court of appeal and is then referred to as the Inner House.[243]

The High Court of the Justiciary is a court of first instance and the supreme criminal court of Scotland. The geographic seat of the court alters in accordance to the function of the court in that as a court of first instance, for example, it sits permanently in Lawnmarket in Edinburgh, Saltmarket in Glasgow and Mercatgate in Aberdeen, while it sits in Edinburgh only as a court of appeal.[244] Appeals from lower courts may be heard as well as from the High Court itself where it functioned as court of first instance in the concerned case. Where an appeal is brought regarding sentencing, it is heard by two judges but three judges will hear an appeal against conviction.[245] The only appeals which will be heard beyond the High Court of the Justiciary are those related to devolution matters under the Scotland Act 1998 and matters under the Human Rights Act 1998.

Sheriff courts are both civil and criminal courts and sit locally within the sheriffdoms of Scotland.[246] Sheriff courts share co-extensive jurisdiction with the Court of Session and the choice of court is left to the pursuer, or claimant, in civil cases.[247] When acting as a criminal court, procedures may be either "solemn" or "summary." When procedures are "solemn," they are heard by a Sheriff and a jury of 15 members whereas in a "summary" procedure, the Sheriff sits alone.[248]

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[242] Part 3 of the Constitutional Reform Act 2005. See also the Constitutional Reform Act 2005 (Commencement No.11) Order 2009.
[243] Scottish Courts (2013) "About the Court of Session" available online at http://www.scotcourts.gov.uk/the-courts/court-of-session/about-the-court-of-session accessed 21/10/2013.
[244] Scottish Courts (2013) "High court locations" available online at http://www.scotcourts.gov.uk/the-courts/high-court/high-court-locations accessed 21/10/2013.
[245] Scottish Courts (2013) "About the High Court of the Justiciary" available online at http://www.scotcourts.gov.uk/the-courts/high-court/about-the-high-court accessed 21/10/2013. See also Scottish Courts (2013) "More about the High Court of the Justiciary" available online at http://www.scotcourts.gov.uk/the-courts/high-court/about-the-high-court/more-about-the-high-court-of-justiciary accessed 21/10/2013.
[246] The sheriffdoms are Glasgow and Strathkelvin; Grampian, Highland and Islands; Lothian and Borders; North Strathclyde; South Strathclyde, Dumfries and Galloway and lastly Tayside, Central and Fife.
[247] More complex and difficult or higher monetary value cases are often heard in the Court of Session rather than the Sheriff courts.
[248] Scottish Courts (2013) "About Sheriff courts" available online at http://www.scotcourts.gov.uk/the-courts/sheriff-court/about-sheriff-courts accessed 21/10/2013. See in general, Part 2 and 3 of the Criminal Proceedings etc (Reform)(Scotland) Act 2007 (asp 6).

In 1975, District courts were introduced into the Scottish justice system. These courts sat locally but under summary procedure only. The court consisted of one or more Justice of the Peace, a lay Magistrate, who sat either alone or in threes along with either a qualified assessor or court clerk. The Criminal Proceedings etc (Reform)(Scotland) Act 2007[249] enabled the replacement of the District courts with Justice of the Peace courts and all District courts have now been abolished.[250]

Lastly, there are various special courts and tribunals acting as the lowest courts in Scotland. These function in specialised areas and often have appeals tribunals above them. Some of the matters which may be expected to fall under the authority of such specialist court or tribunal are asylum and immigration, employment, matters regarding children and land matters.

5.5 A DISTINCT JURISDICTION

The United Kingdom is a quasi-federal state that judicially consists of the three jurisdictions of England and Wales, Northern Ireland and Scotland.[251] The Acts of Union 1707, however, ensured the continued, separate existence of the Scottish legal system and therefore it is a different and distinct legal system. On the one hand, some similarities may be found in areas of national interest such as commercial law, consumer rights, tax, employment, as well as health and safety regulations.[252] The Human Tissue Act and Human Tissue Authority serve as examples of this and are discussed in greater detail in the course of this thesis.[253] On the other hand, various important differences exist between Scots law, Northern Irish law and English law in property law, criminal law, trust law, inheritance law, evidence law and family law. For example, the age of capacity is 16 in Scotland but 18 in England and Wales, criminal juries in Scotland are comprised of 15 members whereas juries in England and Wales have only 12 jurors who decide on simple majority.[254] In Scotland, the accused in a criminal trial does not have the right to elect a judge or jury trial.[255] Equity was never a distinct branch of Scots law as it was in English law[256]

[249] Criminal Proceedings etc (Reform)(Scotland) Act 2007.
[250] Section 59 of the Criminal Proceedings etc (Reform)(Scotland) Act 2007. See in general, Scottish Courts (2013) "About Justice of the Peace courts" available online at http://www.scotcourts.gov.uk/the-courts/jp-court/about-jp-courts accessed 2/10/2013.
[251] Black, Henderson *et al*. (eds)(1996) paragraph 4.
[252] Sutherland, Goodall *et al*. (eds)(2011) 9.
[253] See chapter 8 *infra*.
[254] Christie M & Jones T (eds)(2000) *The criminal law of Scotland, Volume 1 by Sir Gerald H Gordon*: 46.
[255] *Ibid*.
[256] Black, Henderson *et al*. (eds)(1996) paragraph 399.

and most interestingly, Scots law allows for a third verdict in criminal cases, that of "not proven."[257]

Further differences also exist regarding the terminology used in the different jurisdictions. For example, in Scotland there are Sheriff Courts and the College of Justice rather than Magistrates' Courts or Crown Courts. Public prosecution is administered by the Procurator Fiscal Service in Scotland and in England and Wales by the Crown Prosecution Service, while in Northern Ireland it is the responsibility of the Public Prosecution Service. This now brings the explanation of the different legal systems and jurisdictions of the UK to an end.

At this juncture a broad understanding of the complex and intertwined nature of the separate and cooperative jurisdictions in the UK has been established. Attention must, however, also be given to the case law related to consent as found in the UK.

6 UNITED KINGDOM CASE LAW PERTAINING TO CONSENT

In the previous section of this chapter the three separately identifiable legal systems at work in the UK were discussed to provide an overview, explanation and insight into the complexities of each system. In order to understand the dynamic consent model introduced in the course of this thesis, a holistic view of the regulatory environment of the United Kingdom must be provided. To this end some key cases pertaining to consent must be given some attention at this juncture. It must be mentioned that legislation plays a far more important role in context of this thesis but consent as found in case law requires attention for two reasons. Firstly, the Human Tissue Acts which are discussed in the following chapter are founded on this concept and as the cornerstone of the relevant legislation, the manifestation of consent as illustrated in case law ought not to be ignored. It must also be noted that no specific case law dealing pertinently with the Human Tissue Acts exists and case law pertaining to consent in general may therefore sufficiently serve the purpose of this thesis. Secondly, case law is discussed for the sake of completion and as part of the multi-layered approach followed in the methodology of this thesis. As was done in the course of the discussion of relevant South African case law, cases will be discussed chronologically.

[257] Christie & Jones (eds)(2000) 47. See in general, Bray S (2005) "Not proven: Introducing a third verdict" *University of Chicago Law Review* 72(4): 1299-1329.

6.1 BOLAM V FRIERN HOSPIAL MANAGEMENT COMMITTEE (1957)[258]

The *Bolam* case was of great importance and holds a special position in the case law of the United Kingdom. The claimant was receiving electro convulsive therapy as treatment for mental illness. The physician, however, neglected to provide him with relaxant drugs and he suffered a serious fracture. The claimant thus argued that the physician was in breach of his duty by not providing these drugs. Expert opinion among professionals regarding relaxant drugs were divided, as there is a small risk of death when taking them, and when not taking these drugs there exists a small risk of fractures.

McNair J stated where special skill is exercised, the test for negligence is not the test of the man on the Clapham omnibus as they do not possess this special skill.[259] The test is the standard of the ordinary skilled man exercising, or professing to have, that special skill. A professional man has the duty to exercise reasonable skill and care in the light of his actual knowledge and whether he exercised reasonable care cannot be determined by referencing a lesser degree of knowledge than he had since the ordinary competent practitioner would have had that lesser degree of knowledge. This is not to be construed as an amendment to the test of negligence as applied to a professional man which is only to be applied where the professional man causes damage due to his lack of knowledge or awareness. The test therefore establishes the degree of knowledge or awareness he ought to have in that context. However, where a professional man has knowledge, and in light of that knowledge acts or fails to act in a manner which he ought to reasonably foresee might cause damage, then he may be liable in negligence by virtue of the precedent set in Lord Atkins' original test in *Donoghue v Stevenson*.[260]

Further, the *Bolam* test was formulated for assessing the appropriate standard of reasonable care in negligence cases involving skilled professionals. The test holds that a medical professional is not guilty of negligence where he acted in a manner which is in accordance with the practice accepted as proper by a responsible body of medically skilled men in that particular art. This is similar to the South African position which compares physicians in the same field of medicine when determining negligence. *In casu* negligence on the part of the physician was not established.[261]

[258] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583.
[259] The man on the Clapham omnibus is a hypothetical ordinary and reasonable person as used in English law to determine whether a person has acted in the same way as a reasonable person would have in the circumstances.
[260] *Donoghue v Stevenson* [1932] UKHL 100.
[261] See in general, Stauch, Wheat *et al.* (2012) 153-154 &261-265.

6.2 SIDAWAY V BETHLEM ROYAL HOSPITAL GOVERNORS (1985)[262]

During an operation to release a trapped nerve, Mrs Sidaway's spinal cord was damaged and she was paralysed. She brought proceedings against the hospital on the grounds of not having been informed of the risk of paralysis due to the operation, rather than the grounds of negligence. During the course of the trial, expert witnesses testified that some, but not all, neurosurgeons would have regarded it acceptable to not inform Mrs Sidaway of the risks of paralysis. In the course of the trial the Lordships all agreed that the action should fail but each provided a different reason for their decision.

Lord Diplock held that the case before the court ought to be approached in the same manner as medical negligence cases and that a medical professional would not act negligently where they were acting in accordance with a respectable body of medical opinion as was established in the *Bolam* case.[263] In other words, a physician's failure to disclose information would only lead to negligence where all reasonable practitioners in the relevant speciality found such failure unacceptable. *In casu*, this was not the case and as such the doctor had not been negligent.

Lord Bridge also referred to *Bolam* but added two qualifications to his approach. Firstly, the court had to ascertain whether a body of medical opinion approved of non-disclosure. He emphasized that where experts were not in agreement, the court would have to decide which expert's views were preferable. Secondly, he stated that even where an established body of medical opinion in favour of non-disclosure existed, a court might find it unacceptable and thus not responsible. He therefore suggested that to not disclose a risk might be negligent even where it was acceptable by a respectable body of opinion. Lord Keith was in agreement with the decision of Lord Bridge.

Lord Templeman held the views of professional bodies of opinion irrelevant. He regarded the physician under a duty to inform the patient of the nature of the operation and of any risks which are special to the patient. The patient, however, being told of the operation, would have to ask about their particular concerns regarding the operation. Templeman argued that *in casu* the doctor's explanation of what the operation entailed would have clearly indicated the risk of spinal injuries and Mrs Sidaway had chosen to not ask for more information and so no duty to provide further existed. He pointed out that often patients do not wish to know much of the risks and choose to leave the decisions in the hands of the doctors. Lord Templeman argued that providing a patient with too much information may impair their ability to make a decision in the

[262] *Sidaway v Bethlem Royal Hospital Governors* [1985] 1 All ER 643. The *Sidaway* case was heavily relied on in the watershed South African case of *Castell v De Greef* 1994 (4) SA 408 (C). See chapter 3 paragraph 5.10 *supra*.
[263] *Bolam v Friern Hospital Management Committee supra.*

same way as too little information and that Mrs Sidaway had been given enough information to reach a balanced decision.

Lastly, Lord Scarman emphasized that patients have a right to decide to receive or refuse medical treatment.[264] In order to give effect to this right the patient must be given all material information necessary to make the decision. To decide whether information is material the "prudential patient test" was proposed. According to this test, if a reasonable person in the patient's shoes would regard the information as significant, the patient has a right to be informed thereof. However, a physician is entitled to rely on therapeutic privilege in instances where disclosure of information would seriously harm the health, which includes the mental health, of the patient. In applying this approach, Lord Scarman found that the doctor *in casu* was entitled to withhold information from Mrs Sidaway as it would cause her serious distress.[265]

6.3 GILLICK V WEST NORFOLK AND WISEBECK AREA HEALTH AUTHORITY (1986)[266]

The *Gillick* case dealt with the capacity of a child to consent and formulated the test in this regard.[267] Mrs Gillick was the mother of five daughters under the age of 16. She approached the court seeking a declaration that it would be unlawful for a doctor to prescribe contraceptives to girls under the age of 16 without the consent or knowledge of a parent. The declaration was refused and the court held that to suggest that a girl or a boy aged 15 could not effectively consent to have a medical examination was verging on the absurd. Normally, the consent of the parents should be obtained but they may not be immediately available. Provided the patient, whether a male or female child, is capable of understanding what is proposed and of expressing their own wishes, the court saw no reason for holding that they lack the capacity to express them and to authorise the physician to examine, treat or advise them. The court found that a minor is not incapable of giving consent merely due to their age and that a physician may proceed in treating a minor without the consent of a parent provided that he is satisfied that the minor, although below 16 years of age, will understand his advice; he is unable to persuade the minor to inform their parents or to allow him to inform the parents that the minor is seeking certain health services, *in casu*, contraceptive advice; the minor is likely to begin or to continue having sexual intercourse, with or without contraceptives; unless the minor receives contraceptives, her physical or mental health or both are likely to suffer and the best interests of

[264] See in general, *Mr Leslie Burke v GMC* [2005] EWCA Civ 1003 regarding the choice of treatment of a patient.
[265] See in general, Stauch, Wheat *et al*. (2012) 120-123.
[266] *Gillick v West Norfolk and Wisbeck Area Health Authority* [1986] AC 112 House of Lords.
[267] See chapter 8 paragraph 2.5.1 *infra*.

the minor require the doctor to give the contraceptive advice, treatment or both without parental consent.

To determine the competence of a child to consent, or differently stated to be *Gillick* competent, a child must therefore have sufficient understanding and intelligence to enable them to fully understand the proposed intervention. In determining the competence of the child the following will be considered: [268]

1. Whether the child understands the medical issues at hand;[269]
2. Whether the child understands the moral and family issues involved;
3. Whether the child is in fact mature enough to consent or merely repeating the views of other persons;[270]
4. The child need only have the maturity to consent to the particular issue; and
5. If the child seems to fluctuate between competent and incompetent the child ought to be deemed incompetent as a whole to make a decision.[271]

6.4 RE C (ADULT REFUSAL TO TREATMENT) (1994)[272]

C, a patient at Broadmoor High Security Hospital, had been diagnosed as suffering from paranoid schizophrenia. One of the delusions he suffered was that he was a great doctor who had a 100 percent success rate working with patients' damaged limbs. At a stage he injured his foot and it became gangrenous. He was informed that an 85 percent chance existed that he would die without an amputation. C opposed the opinion of the doctors, saying that he did not agree with them and that God did not want his foot to be amputated. He accepted that the doctors believed he would die but still did not agree.[273]

It was held by Thorpe J that competence has three aspects. The first is comprehension and retaining treatment information. The second is believing the information and the third is weighing the information in the balance and coming to a decision. Applying these aspects *in casu*, it was found that C had understood and retained the treatment information, had believed

[268] See in general, Wheeler R (2006) "Gillick or Fraser? A plea for consistency over competence in children: Gillick and Fraser are not interchangeable" *British Medical Journal* 332(7545): 807.
[269] See also *Re E* [1993] 1 FLR 386.
[270] See also *Re S* [1993] 1 FLR 376 and *Re L* [1998] 2 FLR 810.
[271] See in general, Stauch, Wheat *et al*. (2012) 160-162.
[272] *Re C (Adult Refusal to Treatment)* [1994] 1 WLR 290 (FD).
[273] The fact that C understood the prognosis is an interesting point of contrast to the case of *R (N) v Dr M, A Health Authority Trust and Dr O* [2002] EWHC 1911. In this case a patient believed that doctors wanted to drug her to induce her to believe she was a man.

it in his own way and come to a decision. The court therefore did not allow the hospital to operate on C's foot without his consent. C survived and his foot greatly recovered.[274]

6.5 PEARCE AND PEARCE V UNITED BRISTOL HEALTHCARE TRUST (1998)[275]

The *Pearce* case dealt with the information to be provided to a patient. The plaintiff was advised by her physician to delay childbirth but the child was then stillborn. She claimed that the doctor should have advised her of the risk of the child being born stillborn. It was held that in cases where it was being alleged that a plaintiff had been deprived of the opportunity to make a proper decision regarding the course they ought to take in relation to treatment, it seems that where a significant risk exists which may affect the judgment of a reasonable patient, it is in the normal course of events, the doctor's responsibility to inform the patient of the significant risk if the information is necessary for the patient to determine for themselves what course of action they ought to take.[276]

6.6 RE B (CONSENT TO TREATMENT: CAPACITY) (2002)[277]

The patient had a condition caused by malformation of blood vessels in the spinal cord. She executed a living will which stated that if she were unable to give instructions, treatment was to be withdrawn if she was suffering from a life threatening condition, permanent mental impairment or a state of permanent unconsciousness. She became tetraplegic and suddenly suffered complete paralysis from the neck down. She began to experience respiratory problems at which time the intensive care team in the hospital used a ventilator to treat her on which she became dependent. Since the doctors considered the terms of the living will as too vague to authorise withdrawal of the ventilation she was given surgery which allowed her some movement of the head and the ability to articulate words. She then asked for the ventilator to be switched off. She was assessed by two independent psychiatrists who at first assessed her as having capacity but who later concluded that she did not have capacity. She then underwent numerous rehabilitation assessments and in August 2001, was finally assessed as competent to make the decision to have treatment withdrawn. The hospital proposed a weaning process

[274] See also *A Local Authority v E* [2012] EWWHC 1639 (COP), *Re SB* [2013] EWHC 1417 (COP) and *PC v City of York Council* [2013] EWCA Civ 478.
[275] *Pearce and Pearce v United Bristol Healthcare Trust* [1998] EWCA Civ 865.
[276] See in general, Watt J (2002) "Pearce and Another v United Bristol Healthcare NHS Trust" *Clinical Risk* 8(4): 145-147. See also Stauch, Wheat *et al*. (2012) 123-124 and Grubb A & Kennedy I (1998) "Scope of consent" in Kennedy I & Grubb A (eds) *Principles of medical law*: 129-136.
[277] *Re B (Consent to Treatment: Capacity)* [2002] 1 FLR 1090.

which she refused as it would prolong her suffering and be painful. The patient then brought proceedings to the court and sought a declaration declaring that she had the capacity to choose to accept or refuse medical treatment even though her refusal would inevitably lead to her death. The court found that the hospital had been treating her unlawfully.

The court held that doctors may not allow their emotional reaction or strong disagreement with a patient's decision to cloud their judgment when considering if a patient has the capacity to make a decision. This means that a patient must not be found to lack capacity because their decisions seem irrational. When irrationality, however, is indicative of an inability to weigh up issues or appreciate the consequences of their decisions, it may indicate a lack of capacity.[278]

6.7 SIMMS V SIMMS (2003)[279]

Brothers JS, 18, and JA, 16, both suffered from variant Creutzfeldt-Jakob disease (v-CJD)[280] and were also incompetent to consent to treatment. The proposed treatment required surgery under general anaesthetic but was, however, new and had not been tested on humans. Medical evidence unanimously suggested that both brothers would die without treatment. Further unanimity existed regarding the effectiveness of the treatment as unproven and that it would be irresponsible to use it. Even experts were divided as to whether they would be willing to use the proposed treatment on patients. The parents of JS and JA thus approached the court seeking a declaratory order that the treatment was lawful to be administered.

Butler Sloss P held that it was lawful and since the brothers were both incompetent to make a decision regarding the matter, the issue was not consent related but rather whether or not the treatment would be in the best interests of the brothers. Again, Butler Sloss P held positively and decided that it would be. In coming to this decision, reference was made to the *Bolam* case[281] and since there was no responsible body of opinion according to which it would be irresponsible to provide the proposed treatment it was found to be beneficial to the brothers. A 5 percent risk of haemorrhage during the procedure did, however, exist but it was considered by the court to be within the reasonable bounds of risk in the circumstances. In other words, the treatment would be in the interests of the brothers despite there being no hope of recovery. The hope did, however, exist that the treatment might slow deterioration or prolong life. The court

[278] See Herring J (2014) *Medical law and ethics*: 158. Also see in general, Staunch M (2002) "Comment on Re B (Adult: Refusal of Medical Treatment) [2002] 2 All England Reports 449*" Journal of Medical Ethics* 28(4): 232-233.
[279] *Simms v Simms* [2003] 1 All ER 669.
[280] This is a rare and fatal neurodegenerative condition which has been strongly linked to Bovine Spongiform Encephalopathy, or as it is more commonly known, mad cow disease.
[281] *Bolam v Friern Hospital Management Committee supra.*

considered that although the chance of improvement was slight, it was worth taking and held that the concept of "benefit to a patient" included an improvement of their current state or a continuation of the illness without further deterioration. *In casu*, as v-CJD is fatal and progressive, it was therefore thought to be reasonable to administer experimental treatment with unknown risks and benefits.[282]

An important remark by Butler Sloss P in context of this thesis held that where a patient is unable to consent to a pioneering treatment, they ought not to be deprived of the opportunity to utilise it where, if the circumstances allowed it, they would have been competent to consent.

It is submitted, however, that perhaps an error was made in deciding that the proposed experimental treatment was in the best interests of the brothers. Considering that they had already deteriorated to such an extent that they were incapable of consenting it seems cruel and inhumane to subject them to treatment which would not lead to recovery but rather suspend the state of deterioration they had already achieved or prolong their lives, and therefore, their suffering. To merely push pause on a terrible illness is not a benefit. Then, knowing that either suspension or prolonging of suffering was the best hope, and consenting thereto seems unfit as it boils down to consenting to the use of a person, *in casu* your children, as human guinea pigs.[283] This case might have been decided differently if the *Montgomery* case were followed but this case only occurred years later and will be discussed in the course of this chapter.[284] *Montgomery* propagated a patient's rights approach and it is submitted this would have swayed Butler Sloss P to reach a different decision.[285]

6.8 CHESTER V AFSHAR (2004)[286]

Ms Chester suffered from persistent lower back pain and loss of bladder control at times for which she consulted Mr Afshar, a consultant neurosurgeon. During said consultation, Mr Afshar advised Ms Chester to undergo surgery which entailed the removal of three spinal disks which were protruding from her spinal column. The exact communication during the consultation was in dispute but Ms Chester claimed that all that Mr Afshar had mentioned regarding the risks involved were that he "had not crippled anyone yet." Normally, the risks of such a procedure and that it might cause paralysis with a risk margin of 1 to 2 percent, are explained to

[282] Jackson (2010) 441-442.
[283] See also *An NHS Trust v J* [2006] EWHC 3152 (Fam).
[284] See paragraph 6.9 *infra*.
[285] See in general, Stauch, Wheat *et al*. (2012) 463-465. See also Kennedy I (1998) "Research and experimentation" in Kennedy I & Grubb A (eds) *Principles of medical law*: 714-746.
[286] *Chester v Afshar* [2004] 4 All ER 587.

prospective patients. Mr Afshar conducted the operation a few days after the consultation, in a manner later found to be completely inappropriate and Ms Chester suffered severe motor impairment as a result, worsening her condition.

Before the House of Lords, Ms Chester claimed that had she been informed of the risks involved in the procedure, she would not have given her consent and would have taken more time to first seek other medical opinions. Mr Afshar argued that he had not acted negligently and that Ms Chester would still have undergone the procedure even if he had informed her of the risks. Ms Chester conceded that she would in fact have had the operation at some point in the future. The risk of the intervention would, at that time, have remained the same and as such, Mr Afshar claimed that Ms Chester was no worse off than she would have been had he informed her of the risks. This argument was not accepted by the majority of the House which held that Ms Chester has suffered a definite loss, in that she lost the opportunity of having the procedure at another time when she might not have developed the paralysis. The majority therefore focused on the rights of a patient to be informed and the corresponding duty of the doctor to respect that right. Further focus was given to the policy that where difficulty arose in establishing causation, a doctor who failed to properly inform his patient of the risks involved in an intervention was liable to pay damages to the patient.

This case is significant as it placed emphasis on the rights of the patient. The fact, however, that Ms Chester admitted that she would have undergone the operation at some point caused controversy as it meant that the crux of the matter, her loss of time and opportunity to make an informed decision, was of an ephemeral nature not recognised by tort law. Mr Afshar's disregard for her rights could not go unpunished, however. For this reason, the court held that the *Chester* case was not generally applicable to the law of negligence and was influenced by the special importance of a patient's rights in a medical context.[287]

6.9 MONTGOMERY V LANARKSHIRE HEALTH BOARD (2015)[288]

The *Montgomery* case is of great importance as it marks a clear departure from previously established law such as the principles and tests found in the *Bolam* and *Sidaway* cases.[289] It relates to the amount of information to be provided to a patient.[290]

[287] See in general, Hogg M (2005) "Duties of care, causation and the implications of Chester v Afshar" *The Edinburgh Law Review* 9: 156-167. See also Stauch M (2005) "Causation and confusion in respect of medical non-disclosure: Chester v Afshar" *Nottingham Law Journal* 14(1): 66-72.
[288] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.
[289] *Bolam v Friern Hospital Management Committee* and *Sidaway v Bethlem Royal Hospital Governors supra*. See in general, Sokol D (2015) "Update on the UK law on consent" *British Medical Journal* 350: h1481.

Ms Montgomery was in the late stages of pregnancy when some complications arose. She was not provided with information regarding the possibility of a Caesarean section nor was she warned that as a diabetic, a 9 to 10 percent risk of shoulder dystocia,[291] the inability of the shoulder of the infant to pass through the pelvis, existed should she proceed with natural birth. She proceeded with natural, vaginal birth and the risk of dystocia materialised, leaving her infant son with disabilities. Ms Montgomery stated that had she been informed of the option to rather undergo a C-section and of the risks involved in her giving vaginal birth, she would have decided to have the C-section. She thus claimed damages for negligence. The Supreme Court found in her favour.

It was held by Lords Kerr and Reed in writing on behalf of the court, that a doctor has a duty to take reasonable care to ensure that a patient is aware of the material risks involved in a treatment. The doctor must further inform the patient of reasonable alternative treatments or variations thereof.

The meaning of material risk was described as either a risk which a reasonable person in the position of the patient would be likely to attach significance to, or a risk which the doctor should be reasonably aware would have significance attached to by a particular patient.[292] Regarding the first aspect of risk it was found inappropriate to attach a percentage to risk as risk became material not at a certain numerical percentage but when considering a range of factors such as the nature of the risk, the effect it may have on the patient's life, available alternatives and even the risks involved in those alternatives. Thus, a contributory element found in this case is the requirement that a doctor must discuss reasonable alternative treatments with a patient.[293] Unfortunately, the meaning of a reasonable alternative is not clarified and it stands to reason that it is not possible to explain every alternative.

In applying this approach to the facts of the matter it was found that a reasonable woman in labour would in fact attach significance to a 9 to 10 percent risk and also that Ms Montgomery should have been informed of her option to undergo a C-section which carries a smaller risk to the mother and almost none to the infant. Two exceptions to this duty do, however, exist. The first is therapeutic privilege[294] and the second is an emergency medical situation.[295]

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[290] Herring J (2012) *Medical law and ethics*: 174.
[291] See also *Sibisi NO v Maitin* 2014 (6) SA 533 (SCA).in chapter 3 paragraph 5.13 *supra*.
[292] This is similar to the South African position as was shown previously. See chapter 3 paragraph 5.10 *supra*.
[293] See in general Grubb A & Kennedy I (1998) "Elements of consent" in Kennedy I & Grubb A (eds) *Principles of medical law*: 136-140.
[294] This is where information is withheld from a patient by a doctor who believes that it would be seriously detrimental to the health of the patient. This matter was addressed previously.
[295] In other words, there is no time to inform the patient of the risks.

As was mentioned, the *Montgomery* case marked a shift in law. Previously, such as in *Sidaway v Bethlem Royal Hospital Governors*,[296] the court found that the amount of information to be disclosed was determined by what a reasonable body of medical opinion would consider appropriate. This approach has now been rejected and in accordance to *Montgomery*, the patient and not the doctor(s) determines the amount of information which should be provided. This is a clear move in support of allowing patients to exercise their choices, in other words, away from a paternalistic model of decision making.[297] This means that a doctor must disclose a material risk.

6.10 SUMMARY OF UNITED KINGDOM CASE LAW

As was previously mentioned, consent has moral philosophical as well as legal origins which are often found in legal precedents.[298] The interpretation of aspects of consent as found in case law are therefore important as it helps to define the concept of consent and is insightful in understanding a jurisdiction's approach thereto.

The *Bolam* test was formulated in the case of *Bolam v Friern Hospital Management Committee*. It is used for assessing the appropriate standard of reasonable care in negligence cases involving skilled professionals. According to the test a medical professional is not liable where he acted in a manner in accordance to the practice accepted as proper by a responsible body of medically skilled men in that particular art. This test was also applied in the case of *Sidaway v Bethlem Royal Hospital Governors* which held that a physician's failure to disclose information only led to negligence where all reasonable practitioners in the relevant field of speciality found such failure to be unacceptable. This case further added that it was as detrimental to the decision making process to provide a patient with too much information as it is to provide too little information. Enough information must therefore be provided to allow for a balanced decision. It was emphasized in the *Sidaway* case that patients have a right to decide to receive or to refuse medical treatment, and to be able to give effect to this right the patient must be provided with all material information necessary to make a decision. In deciding whether information is material, the "prudential patient test" may be used meaning that if a reasonable person in the patient's shoes would deem the information significant, the patient has a right to be informed.

[296] *Sidaway v Bethlem Royal Hospital Governors supra*.
[297] This development is particularly significant as it shows that patients are regarded as persons holding rights rather than passive recipients of care provided by a medical professional. Patients are also widely treated like consumers exercising choices. This corresponds to the South African position regarding the NHA. See chapter 5 *supra*.
[298] See chapter 3 paragraph 5 *supra*.

Therapeutic privilege may, however, be used to protect the patient from disclosures which might seriously harm them.

Aspects regarding a child's competence to consent were addressed in the *Gillick* case and it was held that a child is not incapable of consenting merely due to age and that a doctor may proceed with treatment without the consent of a parent on the condition that he is satisfied that the child possesses the intelligence to enable them to fully understand the proposed intervention. As such the *Gillick* test was formulated to determine a child's competence to give consent. Adult consent aspects were discussed in the *Re C (Adult Refusal to Treatment)* case and it was found that competence has three aspects, namely comprehension and retaining treatment information; believing of the information, and weighing up of the information in coming to a decision.

The *Pearce and Pearce v United Bristol Healthcare Trust* case dealt with the information to be provided to a patient. It was shown that where there is a significant risk which may affect the judgment of a reasonable patient, it is considered to be in the normal course the physician's responsibility to inform the patient of the significant risk. The information is therefore seen as necessary as it allows the patient to determine for themselves which course of action to take. This aspect of patients making decisions for themselves was then also shown in the *Re B (Consent to Treatment: Capacity)* case wherein it was held that a doctor may not allow his emotional reactions or dislike of his patient's choice to cloud his judgment in the process of establishing whether or not a patient possesses the capacity to make decisions. This means that a patient who seems irrational ought not to be found to lack capacity merely on that basis. However, where irrationality indicates an inability to weigh up issues or to appreciate the consequences of decisions, it may show a lack of capacity. The *Simms* case was also discussed. It was found in the course of the decision of the court that where a person is incapable of consenting to a pioneering treatment, they ought not to be deprived of the opportunity to benefit from it where, if circumstances were different, they would have been able to.

The importance of patient rights was confirmed in *Chester v Afshar*. In particular, emphasis was placed on the right to be informed and the corresponding duty of the physician to respect that right. The case also focussed on causation and held that a physician who failed to inform a patient of the risks properly would be liable to pay damages. The *Montgomery* case was also discussed and also addressed aspects of risks and information. Material risk was described as either a risk which a reasonable person in the patient's position would be likely to attach significance to, or a risk which the doctor should be reasonably aware would have significance attached to by the specific patient. The *Montgomery* case is significant as it marks a shift in the

United Kingdom's consent law and breaks away from *Bolam* and *Sidaway*. Now, the patients and not the physicians determine the scope of information which ought to be provided. It indicates support in allowing patients to exercise their choices and a move away from paternalism.

In summary, when considering all the above discussed cases, it may be concluded that consent is a primary requirement in interventions involving humans, be it of a medical or experimental nature. This means that the person involved must have the capacity to make a competent decision. Competence has three facets, namely comprehension and retaining of information; belief or trust in the provided information and a process of weighing the information to reach a decision. Suitable intelligence enabling an understanding of the proposed intervention on the part of the consenting person must therefore exist. As such the mere youth of a child does not *prima facie* render them unable to provided consent. Furthermore, persons ought not to be excluded from receiving pioneering treatments on the mere basis of their incapacity to consent.

Also, the person who is to give consent must be provided with enough information to come to a balanced decision. The provision of information is, after all, regarded as a right of the patient and must be respected as such. The information which ought to be provided is that which is deemed material and therefore significant. Risk is then also included as an aspect which is material to decision making and should thus be disclosed.

Material risk is either a risk which a reasonable person in the patient's shoes would likely attach significance to, or a risk which a physician ought reasonably to be aware would carry significance to a patient. Due to the role of the patient in attaching significance to information, it is now the patient who determines the scope of information. This approach is in line with the dynamic consent model introduced in the course of this thesis.

7 CONCLUSION

In order to understand the specialised, the general must be understood, and so the aim of this chapter was to provide an overview and explanation of the various systems which together form the Law of the United Kingdom. In summary, it was discussed that although involving four different countries, the United Kingdom consists of three legal jurisdictions as England and Wales are considered as one since Wales was absorbed into the Kingdom of England by King Henry VIII. Some matters have devolved over time and this devolution now accords Wales the autonomy to enact some primary legislation. The legal system for the adjudication of civil and criminal matters, however, remains unified.

Although Welsh law operates separately, Wales is not considered a fourth and separate jurisdiction as it has no separate criminal law and the Parliament of the United Kingdom still greatly legislates for Wales and there are no separate Welsh courts and so the courts and judiciary of England are still followed.

Under the current devolutionary system, however, although English law applies to Wales regarding general and broad aspects, Welsh law governs local aspects. Scottish law, on the other hand has a civil and criminal system distinct from the English.

Since the Acts of Union 1707 ensured the continued, separate existence of the Scottish legal system, it is therefore a different and distinct entity. Some similarities may be found in areas of national interest but there do exist various important differences between Scots law, Northern Irish law and English law. Also, the principle of equity was never a distinct branch of Scots law as in English law and in criminal law, Scots law allows for a verdict of innocent, guilty and a third verdict of "not proven."

Although England and Wales together form one of the jurisdictions of the United Kingdom, some small distinction does exist. England has a system of combined statutory and common law and is derived from various primary sources of law such as legislation, case law, equity, custom, European law, treaties and other sources of law which include Canon law, Roman law, textbooks and legal writing. On the other hand, Welsh law, meaning both primary and secondary legislation generated by the National Assembly for Wales, is law made in terms of the devolved authority granted by the Government of Wales Act 2006.

Northern Irish law, like English law, is the system of statutory law and common law which has been used in Northern Ireland since the partition of Ireland in 1921. Statutory law in Northern Ireland consists of various different Acts which include Acts of the Parliament of the United Kingdom which have application in Northern Ireland, Acts of the Northern Ireland Assembly and statutory instruments as created and enacted by different departments of the Northern Ireland Executive and the Government of the United Kingdom. Legislative law in Northern Ireland is divided into primary and secondary legislation. Primary legislation is framework legislation while secondary legislation is usually legislation containing detailed provisions. The Scottish legal system is by far the most independent of the different jurisdictional systems and was granted this measure of autonomy by the Acts of Union 1707. It is therefore somewhat separate while co-existing with England, Wales and Northern Ireland. It draws from numerous sources including legislation, common law, custom, academic writing and European law.

The Parliament of the United Kingdom of Great Britain and Northern Ireland, also known as Westminster, is the legislature of the United Kingdom. It is sovereign and at its head sits Her Royal Highness Queen Elizabeth II. In other words, all Bills must be passed by all three Parliamentary components before it becomes law. The Westminster Parliament is also the legislature for England and Wales. The Welsh Assembly does, however, have devolved authority in terms of the Government of Wales Acts 1998 and 2006. The Act of 2006 provided the Assembly legislative powers over specified areas and where the Assembly does not have such powers it may request competence by way of a Legislative Competency Order.

Northern Ireland also has some devolved powers. The Northern Ireland Assembly is thus the devolved legislature for Northern Ireland and creates laws on “transferred matters” and monitors Ministers and Government Departments. The Assembly is a "mutually inter-dependent" institution as formed under the Good Friday Agreement of 1998. The Assembly is also, additionally to being the legislature for Northern Ireland, responsible for electing the Northern Irish Executive.

Scotland has two legal institutions. The first is the executive and the second institution is the Parliament which acts as the legislature of Scotland. The 1998 Scotland Act provides for devolved powers of the Parliament and also delineates the legislative competence of the Parliament by explicitly specifying "reserved" powers to the Parliament of the United Kingdom. Issues that are not explicitly reserved automatically fall to the Scottish Parliament. Scots Parliament legislates a vast number of areas of law as devolved from the Parliament of the United Kingdom. The 2012 Scotland Act extended the devolved competencies of the Scottish Parliament and enables it to enact primary legislation.

Attention was also given to the different courts in the United Kingdom. The English courts may be divided into a hierarchy ranking from higher, senior courts to lower subordinate courts. They are, in order from higher to subordinate courts, the Supreme Court of the United Kingdom, the Judicial Committee of the Privy Council, the Senior Courts of England and Wales, the subordinate courts and any special courts and tribunals. The Ministry of Justice known as Her Majesty’s Courts and Tribunals Service administer the Court of Appeal, High Court, Crown Court, Magistrates' courts and the county courts. There are no separate Welsh courts and so the courts of England also have authority over Wales.

Northern Ireland, like Scotland, has its own juridical system with both civil and criminal courts. The courts may be divided between higher and lower courts and include the Supreme Court of the United Kingdom, the Court of Judicature of Northern Ireland, County Courts and subordinate courts such as Magistrates’ courts.

In Scotland civil, criminal and heraldic courts take responsibility for the administration of justice. The Scottish courts may be ranked from the highest court to the lowest in the order of Supreme Court of the United Kingdom, Court of Session, the High Court of the Justiciary, the Court of the Lord Lyon, Sheriff courts which are unique to Scotland, Justice of the Peace courts and lastly some special courts and tribunals.

Due to the greater extent of independence historically held by Scotland, appeal processes and powers differ in Scotland. The courts in Scotland may be further divided and ranked according to the subject matter jurisdiction of each court. Civil courts rank from the Supreme Court of the United Kingdom, to the Court of Session and then down to the Sheriff courts. The Criminal Courts rank from highest to lowest as the High Court of Justiciary, the Sheriff courts and Justice of the Peace courts.

Numerous relevant United Kingdom cases were then also discussed in the course of this chapter. This was done in order to form a holistic picture of the regulatory regime and approach to certain issues in the United Kingdom. In the course of the discussion pertaining to case law it was found that the *Bolam* test, which is used for assessing the appropriate standard of care expected of skilled professionals, was formulated in the case of *Bolam v Friern Hospital Management Committee*. The test holds that a medical professional is not liable where they acted in accordance with the practice accepted as proper by a responsible body of medically skilled men in that particular art. This test was also applied in the case of *Sidaway v Bethlem Royal Hospital Governors* which held that failure of a physician to disclose information only leads to negligence where all reasonable practitioners in that same field of speciality find such failure unacceptable. It was further added in the *Sidaway* case that too much information is as detrimental to decision making as too little information. In other words, a patient must be provided with enough information to make a balanced decision. *Sidaway* then also emphasised that a patient has a right to decide whether or not to receive medical treatment. To give effect to this right, the patient must therefore be provided with all material information to make a decision. In determining the materiality of information, the "prudential patient test" is applied. It holds that if a reasonable person in the position of the patient might deem the information significant, the patient has a right to be informed.

Competence to consent was addressed in the *Gillick* and *Re C (Adult Refusal to Treatment)* cases. *Gillick* held that children are not incapable of consenting merely due to their young age and that physicians may proceed with treatment without parental consent provided that they are satisfied that the child concerned has the intelligence to fully understand the proposed intervention. *Re C (Adult Refusal to Treatment)* addressed adult competence and found that

competence entails three aspects. Firstly, comprehension and retaining treatment information. Secondly, believing of the information and lastly, weighing up of the information in the process of coming to a decision.

Aspects regarding the scope of consent or information to be provided to patients were discussed in the *Pearce and Pearce* case and it was shown that where a significant risk which may affect the judgment of a reasonable patient exists, it is a normal responsibility of the physician to inform the patient of such a risk. Information is therefore regarded as essential as it allows a patient to decide which course of action to take. *Re B (Consent to Treatment: Capacity)* also examined the need for patients to make their own decisions and it was held that physicians may not allow their emotional reactions or dislike of patients' choices to cloud their judgment when determining the patients' capacity to make decisions. In terms of this case, irrationality of a patient is therefore not a *prima facie* indication of incapacity.

The *Simms* case, which focuses on human research participation, was also discussed and it was held that where a person is not capable of consenting to a pioneering treatment, they ought not be deprived of the opportunity to be benefitted thereby where, in different circumstances they would have been able to. This decision already hinted at a patient orientated approach to matters of consent. Patient rights were then emphasised in the *Chester* case. Particular emphasis was placed on the right of a patient to be informed and the physician's corresponding duty to respect this right in the course of *Chester v Afshar*.

Lastly, the case of *Montgomery v Lanarkshire Health Board* was discussed which addressed issues regarding risk and information. *Montgomery* is an important case as it marks a shift in the United Kingdom's consent law and departs from the precedents set in *Bolam* and *Sidaway*. The case described material risk as either a risk which a reasonable person in the position of the patient would be likely to attach significance to, or a risk which the physician should reasonably be aware would have significance attached to by the patient in question. As a result of the decision made in *Montgomery* patients now determine the scope of information which ought to be provided, rather than physicians. It was found in the course of this chapter that the consent aspects as identified in the cases are in line with the dynamic consent model introduced in this thesis.

As a broad background has now been provided regarding the legal systems of the United Kingdom, attention may be turned towards specific Acts, legal documents and certain institutions or authorities. The following chapter will thus focus on the Human Tissue Acts 2004 and 2006, on certain policy documents applicable to this thesis as well as on the Human Tissue Authority. The 2004 Act was enacted by the UK Parliament and applies to England and Wales

while the 2006 Act, which was enacted by the Scots Parliament, applies to Scotland. Some mention will also be made of Northern Ireland where some measure of independent regulation regarding human material applies. The mentioned Acts illustrate how the separate jurisdictions and legal systems function in unison as well as independently on devolved issues in order to address certain matters.

CHAPTER 8
THE HUMAN TISSUE ACTS 2004 AND 2006, THE HUMAN TISSUE AUTHORITY AND OTHER RELEVANT REGULATORY INSTRUMENTS

1 INTRODUCTION

Part D of this thesis deals with the law and position as found in the United Kingdom. The previous chapter provided for an explanation as to the general functioning of the legal systems at play and their relationships towards each other. This was done in order to facilitate an understanding of the environment wherein the specialised legislation which is discussed in this chapter exists. Ultimately, this thesis seeks to introduce into South African law a novel model of obtaining consent and the Dynamic Consent and EnCoRe model which is introduced at the conclusion of this thesis, is being developed in the United Kingdom. To this end, an understanding of the specific legal environment at work in the UK is of obvious interest.

Human bodies, organs, tissues and cells may be used for various purposes which include treatments, transplants, research, education, post-mortem examinations and even public display. Since the use of human material is a highly emotional and controversial subject it is of paramount importance that trust exists between the public and the establishments which make use of the human material. One way in which such trust or confidence may be built, maintained and fostered is by proper regulation of any activities using or establishments dealing with human materials.[1]

Under the South African Constitution, an obligation exists to refer to foreign law and for this reason a study of the law of the United Kingdom is necessary. As discussed previously, the doctrine of informed consent was established and developed under the greater umbrella of ethics as well as medical law and South African medical law is influenced by English medical and common law.[2] As such, the regulatory regime found in the United Kingdom is of great

[1] Human Tissue Authority (2008) *A guide to our key message*: 6.
[2] This is confirmed by the heavy reliance on the case of *Sidaway v Bethlem Royal Hospital Governors* [1985] 1 All ER 643 by the watershed South African case of *Castell v De Greef* 1994 (4) SA 408 (C) which introduced the concept of informed consent into South African law.

informative and comparative value to any study rooted in medical law. After all, it stands to reason that should it be established that the South African and United Kingdom stem cell and consent regulatory regimes are sufficiently similar, the solutions to certain problems which may be encountered in South Africa, may be found in the United Kingdom. These solutions may then be applied in whatever possible extent, taking into account the unique characteristics of the South African legal system and society. The United Kingdom is also one of, if not the oldest, legislator of matters of biomedicine and so the importance of an examination of their laws and other legislative tools is essential to this thesis.

In the previous chapter an explanation was given on the broad and integrated system of law in the United Kingdom in order to illustrate the general and greater working thereof and of the manner whereby it is applied and developed within the different jurisdictions which together form the United Kingdom. This chapter focusses on specific laws, policy documents and other legislative instruments whereby the general topic of human tissues and cells, and particularly the relevant consent is regulated. Previously, the interplay between the different legal systems and legislative regimes in the UK was examined and it was mentioned that the Human Tissue Act 2004[3] and the Human Tissue (Scotland) Act 2006[4] illustrated this united yet sometimes separate system. The greater number of provisions of the 2004 Act applies to England, Wales and Northern Ireland while Scotland enacted a similar 2006 Act.[5]

This chapter will therefore examine the 2004 as well as 2006 Acts. From the onset of this discussion it must be noted that the consent concept or principle of consent is foundational and serves as the cornerstone on which various provisions in the respective Acts are built.[6] This discussion will be done with regard to the scope of the Acts, the activities permitted under the particular Acts, consent or authorisation provisions found within the Acts, the existence of any exemptions to the consent requirement, the offences under the Acts and a summary of the provisions regarding consent or authorisation. It will also be shown that additionally to the 2004 and 2006 Acts, numerous other legal instruments in force in the United Kingdom have an impact on the regulation of human tissue and cell related matters. These include the Human Tissue (Quality and Safety for Human Application) Regulations of 2007, the *Guide to Quality and Safety Assurance of Human Tissue and Cells for Patient Treatment*, the European Union Tissue

[3] Human Tissue Act 2004 (c.30). Hereafter referred to as the Human Tissue Act 2004 or the 2004 Act.
[4] Human Tissue (Scotland) Act 2006 (asp 4). Hereafter referred to as the Human Tissue Act 2006, the 2006 Act or the Scots or Scottish Act.
[5] Hardcastle R (2007) *Law and the human body: Property, rights, ownership and control*: 104. It should be noted however that section 45 of the 2004 Act pertaining to DNA analysis applies throughout the territory of the United Kingdom. See Department of Health (2004) *Human Tissue Act 2004-Explanatory notes*: 1.
[6] Department of Health (2004) 3. See in general Hardcastle (2007) 105-108.

and Cells Directives as well as certain Codes of Practice. The specific stem cell regulations in Northern Ireland are also discussed.

This chapter further examines the Human Tissue Authority by discussing the Authority's regulated activities, the mechanisms whereby the Authority regulates these activities, legislation relevant to the Human Tissue Authority and lastly the Codes of Practices issued by the Authority will be discussed.

A few notes on the terminology used in this chapter are, however, necessary in order to avoid confusion. The Human Tissue (Scotland) Act 2006 has at its core "authorisation" in the same manner as "consent" is at the core of the Human Tissue Act 2004. Both these terms denote the same principle and thus have the same meaning. The process of authorisation must be understood as the same process as obtaining consent and in the course of this chapter it will be shown that in essence, consent and authorisation may both be regarded as a positive act of granting permission. Also, the Scottish legislative documents refer to the Procurator Fiscal which is the same as the Coroner in the documents used in England, Wales and Northern Ireland. Finally, and keeping in mind the discussion in the previous chapter regarding the different legal systems in the United Kingdom, it must be noted that where reference is made to the Mental Capacity Act 2005,[7] the relevant Scottish legislation is the Adults with Incapacity (Scotland) Act 2000.[8]

Generally, consent may be understood as meaning permission to use human material for the purposes stipulated in the 2004 Act, the Regulations as well as the Directives.[9] A key aspect of the 2004 Act is thus that a person must grant permission for the use of their material whether they are dead or alive at the time of use. Consent, or authorisation in the case of the Scots Act, forms the core of the Act and the Acts themselves therefore stand as a starting point for the discussion in this chapter. The first of the Human Tissue Acts to be discussed is the 2004 Act which is applied in England, Wales and Northern Ireland. Thereafter the 2006 Act applicable to Scotland will be discussed.

2 HUMAN TISSUE ACT 2004

In the following section of this chapter, the 2004 Act will be analysed by paying attention to the scope of the Act, material to which the Act is applicable, the activities permitted under the Act,

[7] Mental Capacity Act 2005 (c.9).
[8] Adults with Incapacity (Scotland) Act 2000 (asp 4).
[9] Human Tissue Authority (2014) *A guide to our key message*: 11.

the consent provisions found in the Act and the exemptions thereto, the manner whereby the Act regulates certain activities and the offences created under the Act. Firstly, however, attention is given to the background and coming into force of the Act.

2.1 INTRODUCTION, COMING INTO FORCE AND BACKGROUND

Certain inquiries were held from 1999 to 2003 after the events at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey) came to light where organs and tissues had been removed, stored and used without consent. The *Kennedy*, *Redfern* and *Isaacs Report* as well as *Northern Irish Report of the Human Organs Inquiry* all reached a similar conclusion in that the storage and use of organs and tissues without proper consent had become widespread and that the current law existing at the time was not comprehensive, clear or consistent on the matter.[10] This was the catalyst that started a process of legislative reform which ultimately resulted in the Human Tissue Act 2004.

The Human Tissue Act 2004[11] was passed by the Parliament of the United Kingdom on the 15th of November 2004[12] and as a consolidation of various Acts, repealed the Human Tissue Act 1961, the Anatomy Act 1984, the Corneal Tissue Act 1986 and the Human Organ Transplants Act 1989 in both England and Wales.[13] It furthermore repeals the Human Tissue Act (Northern Ireland) 1962, the Human Organ Transplants (Northern Ireland) Order 1989 and the Anatomy (Northern Ireland) Order 1992 as far as the jurisdiction of Northern Ireland is concerned.[14]

The Act attempts to make provision regarding the activities involving human tissue, to make provision regarding the transfer of human remains from museum collections and for connected purposes.[15] The Act contains numerous provisions which cover a large variety of subjects. The Act is divided into three parts, each addressing different facets of regulation. Broadly speaking, the 2004 Act provides for the removal, storage and use of human organs and other tissue for

[10] Department of Health (2004) 1-2.
[11] Human Tissue Act 2004.
[12] At the time, it was required that the Secretary of State make an order by way of statutory instrument stating when different sections of the Act would come into force and full implementation of the Act was not expected prior to April 2006, meaning at least two years after assent. See Kaye J (2004) "A guide to the Human Tissue Act 2004" available online at http://www.ethox.org.uk/education/teach/HTAguide.htm accessed 5/8/2013.
[13] Human Tissue Act 1961 (c.54), the Anatomy Act 1984 (c.14), the Corneal Tissue Act 1986 (c.18) and the Human Organ Transplants Act 1989 (c.31).
[14] Human tissue Act (Northern Ireland) 1962 (c.19), the Human Organ Transplants (Northern Ireland) Order 1989 No.2408 (NI 21) and the Anatomy (Northern Ireland) Order 1992 No.1718 (NI 11).
[15] See in general McLean S, Campbell A, Gutridge K & Harper H (2006) "Human tissue legislation and medical practice: A benefit or a burden?" *Medical Law International* 8(1): 1-21.

scheduled purposes in Part 1;[16] the regulation of activities involving human tissue in Part 2;[17] and miscellaneous and general provisions in Part 3[18] of the Act. It is also further supplemented by schedules.[19] The discussion of the 2004 Act in this chapter will focus mostly on Parts 1 and 2 of the Act. It thus becomes necessary to introduce Part 1 of the Act at this juncture.

Part 1 of the Act pertains to consent and sets out the requirements for obtaining appropriate consent for the activities regulated under the Act. In brief, it defines appropriate consent with reference to the person who may grant such consent and provides for a nominated representative to make decisions on behalf of another person after their death. Part 1 also creates offences where any regulated activity is carried out without the appropriate consent, provides for existing holdings, exempts coroners from certain consent requirements and permits storage and use of human material from living persons for particular purposes. Part 1 of the Act, however, does not apply to the removal of human material, as opposed to the storage and use, from living persons.[20]

As mentioned above, certain aspects of the Act which are of importance to this thesis will be discussed in greater detail and specific attention will be given to consent related to these aspects.[21] The 2004 Act will therefore be discussed in the following section of this chapter, starting with the scope of the Act.

2.2 SCOPE

The Human Tissue Act makes a distinction between living and deceased persons and provides for the removal, storage and use of "relevant material" from deceased persons and also provides for the transplantation of human organs. Where living persons are concerned, however, the 2004 Act only provides for the storage and use of "relevant material." This means that common law principles still guide the removal of tissue from a living person and therefore, any intervention or interference with the body of a person must be preceded by consent in order to be lawful. The Act furthermore prohibits the use of bodies or human material which was

[16] This includes *inter alia* the authorisation of activities, appropriate consent, representatives, prohibition of activities without consent and the activities utilising material from incapacitated persons. See Part 1 of the 2004 Act, sections 1-12.
[17] This includes *inter alia* the Human Tissue Authority, licensing, codes of practice, anatomy, trafficking, transplants and exceptions. See Part 2 of the 2004 Act, sections 13-41.
[18] Part 3 of the 2004 Act, sections 42-61.
[19] Schedule 1: Scheduled Purposes; Schedule 2: The Human Tissue Authority; Schedule 3: Licences for the Purposes of Section 16; Schedule 4: Section 45 Supplementary; Schedule 5: Powers of Inspection, Entry, Search and Seizure; Schedule 6: Consequential Amendments and Schedule 7: Repeals and Revocations.
[20] Department of Health (2004) 2.
[21] See in general Hardcastle (2007) 103-105.

donated for purposes other than the purposes sanctioned under the Act and provides for penalties for any non-compliance with the Act.

2.3 MATERIAL

The application of the Human Tissue Act is limited to "relevant material" only and this is defined in section 53 of the Act as "material, other than gametes, which consists of or includes human cells."[22] This definition expressly excludes embryos outside of the human body as well as hair and nails from the body of a living person.[23] All materials, other than that which has been expressly excluded, which thus consists of or includes cells will, fall under the ambit of the Act. For example, blood or a tissue sample, which consist of cells or contains cells, will qualify as "relevant material" in terms of the 2004 Act. DNA is, however, provided for specifically as it would not qualify under the more general definition of relevant material.[24] "Relevant material" used or stored regarding genetic testing devices is also not included under this definition and will fall under the remit of the European Union Directive on *in vitro* diagnostic medical devices.[25]

It may be mentioned here that gametes and embryos outside of the human body fall under the regulatory ambit of the Human Fertilisation and Embryology Act 2008[26] and Human Fertilisation and Embryology Authority (HFEA). For the purposes of this thesis, this Act and Authority is not relevant and will not be discussed in further detail.[27]

[22] Section 53(1) of the 2004 Act.
[23] Section 53(2) of the 2004 Act.
[24] It must be mentioned that when it comes to matters of DNA, the Human Tissue Act 2004 finds application in Scotland as well, despite devolution. Devolution was explained in the previous chapter.
[25] European Union Directive 98/79/EC on *in vitro* diagnostic medical devices.
[26] Human Fertilisation and Embryology Act 2008 (c.22).
[27] The Human Fertilisation and Embryology Act of 2008 (HFE Act) regulates matters related to stem cells derived from embryos which includes unused IVF embryos; embryos created by IVF for research purposes; embryos created by SCNT; so-called "admixed embryos" including hybrids created from human and animal gametes; "cytoplasmic hybrids" created by SCNT using a human nucleus and animal oocytes, transgenic human embryos created by introducing animal DNA into human cells; chimeric human embryos created by introducing one or more animal cells into human embryos or any other embryos that contain both human and animal DNA. The Human Fertilisation and Embryology Authority (HFEA) enforces the Regulations made in terms of the HFE Act and licences IVF clinics and scientists undertaking human embryo research. Section 13 and Schedule 3 of the HFE Act relate to consent for the use or storage of gametes, embryos, human admixed embryos etc. The HFE Act and the HFEA fall outside the ambit of this thesis as it is argued that the use of stem cells derived from embryos will be obsolete in the near future and as such attention ought rather to be given to the Human Tissue Acts which will then serve as the dominant legislative tools for stem cell regulation. See in general, Jackson E (2010) *Medical law: text, cases and materials*: 631-652.

2.4 ACTIVITIES PERMITTED UNDER THE ACT

The Human Tissue Act stipulates certain permitted activities related to human material and bodies. These activities may further only be undertaken for specified purposes. Not all activities may be conducted for all purposes and as a result of this, four categories of activities may be identified as found in Schedule 1 of the Act and throughout the Act itself. These four categories are:[28]

1. Activities permitted for all lawful purposes specified under both Parts 1 and 2 of Schedule 1;
2. Activities permitted only for the purposes under Part 1 of Schedule 1;
3. Activities permitted only for the purposes under Part 2 of Schedule 1; and
4. Activities specified within the Act.

The first category, all lawful purpose activities under Schedule 1, allows for the storage of a deceased person's body but excludes anatomical examination[29] and the removal of any relevant material from the body of a deceased person.[30] In both instances "appropriate consent" must be obtained prior to the activity being undertaken. These activities may be undertaken for the purposes of anatomical examination,[31] to determine cause of death, to establish the efficacy of an administered drug or other treatment after the death of a person, to obtain scientific or medical information about a living or deceased person which could be relevant to another person or future person, public display, to conduct research regarding disorders or the functioning of the human body, transplantation, clinical auditing, education or training in human health, to conduct performance assessments, for the purpose of monitoring public health, or for quality assurance.[32]

The second identified category relates to activities for the purposes as specified in Part 1 of Schedule 1. As long as the "appropriate consent" has been obtained, any relevant material which has come from a human body may be stored or used[33] for the purposes of anatomical examination, determination of cause of death, establishing drug or treatment efficacy, to obtain any scientific or medical information about a living or deceased person which could be relevant to any other person or future person, to display in public, for research connected to any disorders or the functioning of the body, and transplantation.

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[28] Kaye (2005) online.
[29] Section 1(1)(a) of the 2004 Act.
[30] Section 1(1)(c) of the 2004 Act.
[31] Anatomical examination is "macroscopic examination by dissection for anatomical purposes," according to section 54 of the 2004 Act.
[32] Parts 1 and 2 of schedule 1 of the 2004 Act.
[33] Sections 1(1)(d) and 1(1)(f) of the 2004 Act.

Thirdly, activities which are only permitted in terms of Part 2 of Schedule 1 may be identified. These are the storage and use of relevant material from the body of a deceased person[34] for the purpose of clinical audits, health education or training, performance assessments, public health monitoring and quality assurance. The "appropriate consent" is also required in these circumstances.

Lastly, a fourth category of activities and purposes may be found when reading through the text of the Act itself. These are activities which are specifically provided for in the Act itself. An example of such a provision is section 1(1)(b) wherein the possibility of other activities is acknowledged by stating "the use of the body of a deceased person for a purpose so specified, other than anatomical examination." Once again, as with each of the previous categories of activities which have been discussed, "appropriate consent" is required unless an exemption is applicable.[35]

From the above it may therefore be noted that consent plays an important role in determining the permissibility of certain activities. The concept of consent and the provision thereof as found in the 2004 act must thus receive some attention at this juncture.

2.5 CONSENT

Consent is the cornerstone of the 2004 Act and as such it is the foundation of the various provisions found in Act.[36] In terms of the Human Tissue Act, two forms of consent are relevant, namely "appropriate consent" and "qualified consent." For the sake of of completion, and since stem cell therapy and research fall under the greater umbrella of biomedical sciences including DNA related matters, both forms of consent will be discussed here. The discussion will first turn towards "appropriate consent."[37]

Any removal and use of tissue should be carried out with the "appropriate consent." No definition is provided for what constitutes "appropriate consent" and it is suggested that this alludes to consent as flexible, yet essential requirement for legitimate activities conducted under the Act. In context of this thesis, it may be suggested that Dynamic Consent may be suitably appropriate to qualify as a legitimate consent format in terms of the 2004 Act. Various factors such as age and capacity may influence consent and for this reason the consent requirement may differ from situation to situation. A distinction is also made in the Act

[34] Sections 1(1)(e) and 1(1)(g) of the 2004 Act.
[35] See paragraph 2.6 *infra* for more on the exemptions to consent.
[36] Department of Health (2004) 3. See in general Hardcastle (2007) 105-108.
[37] "Qualified consent" is discussed in paragraph 2.8.5.1 *infra*.

regarding the required consent in instances concerning a living person *versus* those concerning a deceased person. Appropriate consent could therefore be understood as the form of consent which is most appropriate in the circumstances of the case.[38] As mentioned previously, consent is an essential requirement but it is also flexible. This flexibility is also contributed to by the Codes of Practice issued by the Human Tissue Authority.[39] The codes provide for consent requirements such as the type of information which should be made available to the person giving their consent.[40] This thesis argues that consent should be flexible enough to accommodate the changing science as well as the preferences of the patient-participant and as such introduces and promotes a dynamic consent model.

Firstly, however, the law as it currently stands must be discussed. To this end the provisions regarding appropriate consent, as it relates to children[41] and adults, as well as instances where a person other than the concerned person grants consent to an activity, will now be discussed.

2.5.1 Children

A child is, except in the context of qualifying relationships,[42] a person who is below the age of 18 years, according to the general interpretation provisions of the Act.[43] Section 2 of the 2004 Act[44]

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[38] See in general Bell MDD (2006) "The UK Human Tissue Act and consent: Surrendering a fundamental principle to transplantation needs?" *Journal of Medical Ethics* 32(5): 283-286.
[39] See paragraph 6 *infra* for a discussion of the relevant Codes of Practice.
[40] See paragraph 5 *infra* for a discussion on the Human Tissue Authority. See in general, Stauch M, Wheat K & Tingle J (2012) *Text, cases and materials on medical law and ethics*: 502 & 526-529.
[41] See in general Holm S (2005) "Informed consent and the bio-banking of material from children" *Genomics, Society and Policy* 1(1): 16-26.
[42] See paragraph 2.5.4 *infra* for the discussion pertaining to qualifying relationships.
[43] Section 54 of the 2004 Act. The definition of "child" is provided for in section 54(1) of the 2004 Act.
[44] Section 2: **" 'Appropriate consent': Children-**
(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material from the body, of a person who is a child or has died a child ("the child concerned").
(2) Subject to subsection (3), where the child concerned is alive, "appropriate consent" means his consent.
(3) Where-
(a) the child concerned is alive,
(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force, and
(c) either he is not competent to deal with the issue of consent in relation to the activity or, though he is competent to deal with that issue, he fails to do so,
"appropriate consent" means the consent of a person who has parental responsibility for him.
(4) Where the child concerned has died and the activity is one to which subsection (5) applies, "appropriate consent" means his consent in writing.
(5) This subsection applies to an activity involving storage for use, or use, for the purpose of-
(a) public display, or
(b) where the subject-matter of the activity is not excepted material, anatomical examination.
(6) Consent in writing for the purposes of subsection (4) is only valid if-
(a) it is signed by the child concerned in the presence of at least one witness who attests the signature, or
(b) it is signed at the direction of the child concerned, in his presence and in the presence of at least one witness who attests the signature.
(7) Where the child concerned has died and the activity is not one to which subsection (5) applies, "appropriate consent" means -

makes provision for the interpretation of "appropriate consent" as it is used and required in section 1 of the Act, in relation to the activities involving the body or material taken from the body of a child or a person who was a child at the time of their death. It also makes provision for living children who must then be competent in order to make their own decision and grant consent themselves.[45] Competence is not defined by the 2004 Act but may be determined by common law principles, or then the *Gillick* test.[46] This person is then referred to as "the child concerned"[47] and a distinction may be drawn between living and deceased children in terms of the 2004 Act.[48]

2.5.1.1 Living children

Section 2(2) of the Act states that where a child is alive, the appropriate consent is the consent of that child. Where a child is alive but unable to give their consent due to incompetence or another reason and no decision has been made,[49] the Human Tissue Act also permits a person who has a "parental responsibility" towards the child to make decisions on behalf of the child.[50] "Parental responsibility" is a somewhat complex issue as it is not defined in the 2004 Act and reference is made to two other Acts wherein the meaning of this concept must be sought.

The Human Tissue Act, in section 54, states that parental responsibility carries the same meaning as it does in the Children Act 1989[51] concerning England and Wales and has the same meaning as the meaning ascribed to it in the Children (Northern Ireland) Order 1995[52] concerning Northern Ireland.[53] In terms of these two Acts parental responsibility means "all the rights, duties, powers, responsibilities and authority which by law a parent of a child has in relation to the child and his property," according to both section 3(1) of the Children Act of 1989

(a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
(b) if paragraph (a) does not apply-
(i) the consent of a person who had parental responsibility for him immediately before he died, or
(ii) where no person had parental responsibility for him immediately before he died, the consent of a person."

[45] See in general, Munby J (1998) "Consent to treatment: Children and the incompetent patient" in Kennedy I & Grubb A (eds) *Principles of medical law* 179-282.
[46] The *Gillick* test was laid down in the case of *Gillick v West Norfolk and Wisbech Area Health Authority* (1985) 3 All ER 402. It is used to determine whether a child, 16 years or younger, is capable of consenting to his own medical treatment. See Staunch M, Wheat K & Tingle J (2002) *Sourcebook on medical law*: 136-140 and Jackson (2010) 263-267. See also chapter 7 paragraph 6.3 *supra*.
[47] Section 2(1) of the 2004 Act.
[48] Department of Health (2004) 4. See in general, Jackson (2010) 254-273.
[49] This could be a decision either to give or to withhold consent.
[50] Section 2(3) of the 2004 Act.
[51] Children Act 1989 (c.41).
[52] Children (Northern Ireland) Order 1995 No.755 (NI 2).
[53] See paragraph 4 *infra* for a discussion on Stem Cell Regulation in Northern Ireland.

and section 6(1) of the Children (Northern Ireland) Order 1995.[54] The person who carries parental responsibility differs depending on the circumstances. Where the mother and father of a child were married at the time of the child's birth, both parents share parental responsibility.[55] Where the mother and father of the child were not married at the time of birth, the mother of the child will have parental responsibility,[56] meaning that the rule of law that the father of a child is its natural guardian is abolished.[57] It should be noted that the Children Act 1989 has been amended by the addition of section 2(1A) which makes provision for section 42 and 43 of the Human Fertilisation and Embryology Act 2008. Section 42 is related to women in a civil partnership who receive fertility treatment and section 43 provides for women who receive fertility treatment but have agreed that another woman will be the parent of the child.[58]

Parental responsibility may also be acquired. According to the Children Act of 1989 the father,[59] a second female parent[60] or a step-parent[61] may acquire parental responsibility. The Children (Northern Ireland) Order 1995, however, only makes provision for the acquisition of parental responsibility by the father of the child.[62]

[54] This includes the rights, powers and duties which a guardian of the child's estate would have had regarding the child and his property according to sections 2(2) of the Children Act 1989 and 6(2) of the Children (Northern Ireland) Order 1995. Furthermore, according to sections 2(3) and 6(3) of the same Acts, the guardian may receive or recover, in his own name for the benefit of the child, property of whatever description and wherever situated which the child is entitled to. Sections 2(4) and 6(4) respectively state that whether or not a person has parental responsibility or not does not affect any obligation towards the child such as a statutory obligation to maintain the child or any rights which they may have in the event of the child's death. Lastly, a person who does not have parental responsibility for a child but has care of the child may do what is reasonable to protect and promote the welfare of the child in terms of sections 2(5) and 6(5) of the Acts.
[55] Section 2(1) of the Children Act 1989 and section 5(1) of the Children (Northern Ireland) Order 1995.
[56]Section 2(2) of the Children Act 1989 and section 5(2) of the Children (Northern Ireland) Order 1995.
[57] Sections 3 of both the Children Act and Children (Northern Ireland) Order 1995.
[58] Section 42 of the Human Fertilisation and Embryology Act 2008 reads: "(1) If at the time of the placing in her of the embryo or the sperm and eggs or of her artificial insemination, W was a party to a civil partnership, then subject to section 45(2) to (4), the other party to the civil partnership is to be treated as a parent of the child unless it is shown that she did not consent to the placing in W of the embryo or the sperm and eggs or to her artificial insemination (as the case may be). (2) This section applies whether W was in the United Kingdom or elsewhere at the time mentioned in subsection (1)." Section 43 of the Human fertilisation and Embryology Act 2008 reads: "If no man is treated by virtue of section 35 as the father of the child and no woman is treated by virtue of section 42 as a parent of the child but - (a) the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, in the course of treatment services provided in the United Kingdom by a person to whom a licence applies, (b) at the time when the embryo or the sperm and eggs were placed in W, or W was artificially inseminated, the agreed female parenthood conditions (as set out in section 44) were met in relation to another woman, in relation to treatment provided to W under that licence, and (c) the other woman remained alive at that time, then, subject to section 45(2) to (4), the other woman is to be treated as a parent of the child."
[59] Section 4 of the Children Act 1989.
[60] Section 4ZA of the Children Act 1989.
[61] Section 4A of the Children Act 1989.
[62] Section 7 of the Children (Northern Ireland) Order 1995.

2.5.1.2 Deceased children

In the event of a child's death, a distinction is made between the activities which will be undertaken with the relevant material or the body of the child. Either the material will not be used or stored for public display or anatomical examination or it will. In the event of the former, appropriate consent will be the decision of the child immediately prior to dying, to consent or not to consent to a proposed activity.[63] Where the child had not made any decisions while still alive, a parent or a person in a qualifying relationship with the child may decide and give consent in accordance with such decision.[64] Where the relevant material or child's body will, however, be used and stored for public display and anatomical examination, the child's consent is required in writing.[65]

2.5.2 Adults

An adult is a person who has attained the age of 18 years according to section 54, the general interpretation provision, of the Human Tissue Act.[66] Appropriate consent in context of adults is provided for in section 3 of the Act.[67] It provides for the interpretation of "appropriate consent"

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[63] Section 2(7)(a) of the 2004 Act.
[64] Section 2(7)(b) of the 2004 Act.
[65] Section 2(5) and (6) of the 2004 Act.
[66] The definition of "adult" is provided for in section 54(1).
[67] Section 3: " **'Appropriate consent': Adults -**
(1) This section makes provision for the interpretation of "appropriate consent" in section 1 in relation to an activity involving the body, or material from the body, of a person who is an adult or has died an adult ("the person concerned").
(2) Where the person concerned is alive, "appropriate consent" means his consent.
(3) Where the person concerned has died and the activity is one to which subsection (4) applies, "appropriate consent" means his consent in writing.
(4) This subsection applies to an activity involving storage for use, or use, for the purpose of-
(a) public display, or
(b) where the subject-matter of the activity is not excepted material, anatomical examination.
(5) Consent in writing for the purposes of subsection (3) is only valid if-
(a) it is signed by the person concerned in the presence of at least one witness who attests the signature,
(b) it is signed at the direction of the person concerned, in his presence and in the presence of at least one witness who attests the signature, or
(c) it is contained in a will of the person concerned made in accordance with the requirements of-
(i) section 9 of the Wills Act 1837 (c. 26), or
(ii) Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 (S.I. 1994/1899 (N.I. 13)).
(6) Where the person concerned has died and the activity is not one to which subsection (4) applies, "appropriate consent" means-
(a) if a decision of his to consent to the activity, or a decision of his not to consent to it, was in force immediately before he died, his consent;
(b) if-
(i) paragraph (a) does not apply, and
(ii) he has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, consent given under the appointment;
(c) if neither paragraph (a) nor paragraph (b) applies, the consent of a person who stood in a qualifying relationship to him immediately before he died.

as used and required in section 1 of the Act in relation to the activities involving the body or material from the body of an adult or an adult person who has died. This person is then referred to as "the person concerned."[68] Once again the 2004 Act distinguishes between living and deceased adults but a further distinction is also made between capacitated and incapacitated persons.[69] These subdivisions of adult concerned persons will now be discussed.

2.5.2.1 Living adults

Living adults may consent themselves where the proposed activity relates to their body or material taken from their body. Appropriate consent is therefore understood as their consent.[70] An adult is also at liberty to appoint one or more persons in terms of section 4 of the Act as a nominated representative to make decisions and consent to activities on his behalf after his death.[71] Such an appointment may be made either orally[72] or in writing[73] and may be ended by revocation[74] or renunciation.[75]

2.5.2.2 Deceased adults

When dealing with situations where an adult has died and where the body or tissue from the body will be stored for use or used for the purposes of public display or anatomical examination there must be written consent of the deceased person.[76] Additionally, for anatomical examination, the death must be registered and a death certificate must be signed.[77]

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(7) Where the person concerned has appointed a person or persons under section 4 to deal after his death with the issue of consent in relation to the activity, the appointment shall be disregarded for the purposes of subsection (6) if no one is able to give consent under it.
(8) If it is not reasonably practicable to communicate with a person appointed under section 4 within the time available if consent in relation to the activity is to be acted on, he shall be treated for the purposes of subsection (7) as not able to give consent under the appointment in relation to it."

[68] Section 3(1) of the 2004 Act. See See in general, Stauch, Wheat *et al*. (2012) 526.
[69] Department of Health (2004) 4. See in general, Munby (1998) in Kennedy & Grubb (eds) 179-282.
[70] Section 3(2) of the 2004 Act.
[71] Department of Health (2004) 5. Suggested further reading, Foster CM (2001) "International regulation, informed consent and medical research" in Doyal L & Tobias JS (eds) *Informed consent in medical research*: 141-165.
[72] Section 4(4) of the 2004 Act states that where the appointment is made orally it will only be valid if it was made in the presence of at least two present witnesses.
[73] Section 4(5) of the 2004 Act provides that where such an appointment is made in writing it will only be valid if (a) it is signed by the person making the appointment in the presence of at least one witness who attests the signature, (b) it is signed at the direction of the person making the appointment and in his presence and in the presence of at least one witness who attests the signature, and (c) it is contained in a will of the person making the appointment and the will is made in accordance with the requirements of either section 9 of the Wills Act 1837 (c. 26) for England and Wales or Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994 No.1899 (NI 13).
[74] Section 4(7) of the 2004 Act.
[75] Section 4(9) of the 2004 Act.
[76] Section 3(3) of the 2004 Act.
[77] Section 1(2) and (3) of the 2004 Act.

Regarding storage and use in a public display, the Act requires only that there must be a decision to consent or not to consent to the activity, and this decision must have been in force immediately prior to the person's death.[78] It is very interesting to note that the Act states that it must be a decision rather than formal consent. This decision may also be made on behalf of the deceased person by a nominated representative as long as this representative was, orally or in writing, appointed in accordance to section 4 of the Act. Where no such appointment was made, or it was revoked or renounced, a person who immediately before the death of the deceased person, stood in a qualifying relationship with the deceased may make such a decision and give their consent to the proposed activity.[79]

2.5.3 Incapacitated Persons

Provisions regarding an adult person who does not possess the capacity to consent may be found in section 6 of the Human Tissue Act.[80] The Act states that in the case of such an incapacitated adult person, neither a decision to consent to an activity nor a decision not to consent is in force.[81] This relates to relevant material which is to be used or stored for use in terms of the purposes outlined in Part 1 of Schedule 1 of the Act.[82] Consent will, however, be assumed to have been decided upon in circumstances such as a clinical trial, for example, that have been specified in Regulations made by the Secretary of State.[83]

It is interesting to note that consent is presumed rather than to seek proxy consent from another person who may act on behalf of the incapacitated person. At first glance, this may create the perception that such proxy consent is not permitted under the 2004 Act.[84] However, certain persons who stand in a particular relationship towards another person may make decisions on their behalf and as such, attention must now be given to these specially qualified relationships.

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[78] Section 3(6) of the 2004 Act.
[79] Section 3(6)(b) of the 2004 Act. See paragraph 2.5.4 *infra* for more on the qualifying relationship.
[80] Section 6: "**Activities involving material from adults who lack capacity to consent -**
Where—
(a) an activity of a kind mentioned in section 1(1)(d) or (f) involves material from the body of a person who-
(i) is an adult, and
(ii) lacks capacity to consent to the activity, and
(b) neither a decision of his to consent to the activity, nor a decision of his not to consent to it, is in force,
there shall for the purposes of this Part be deemed to be consent of his to the activity if it is done in circumstances of a kind specified by regulations made by the Secretary of State."
[81] Section 6(b) of the 2004 Act.
[82] See paragraph 2.4 *supra* for these purposes.
[83] Keep in mind that any such Regulations will overlap with the Mental Capacity Act 2005.
[84] Department of Health (2004) 5. See also See in general, Stauch, Wheat *et al*. (2012) 136-199. See also Munby (1998) in Kennedy & Grubb (eds) 179-282.

2.5.4 Qualifying relationships

As mentioned previously, qualifying relationships may entitle a person to make decisions and give proxy consent on behalf of another person. Section 27 of the Human Tissue Act provides the following ranked order list of persons who share a relationship with the person or child concerned and whose relationship will be deemed as a qualifying relationship:[85]

(a) A spouse or partner;
(b) A parent or child;
(c) A brother or sister;
(d) A grandparent or grandchild;
(e) A child of a person falling within paragraph (c);[86]
(f) A stepfather or stepmother;
(g) A half-brother or half-sister; or
(h) A longstanding friend.

Qualifying relationships will be relevant in two instances. Firstly, either section 2(7)(b)(ii) which provides for activities other than storage for use or use in a public display or anatomical examination of a deceased child, where the child had not made a decision to consent or not to the proposed activities immediately prior to dying and there is no person with parental responsibility. Secondly, a qualifying relationship could become relevant in terms of section 3(6)(c). Here, the person concerned is deceased and the proposed activity is not for public display or anatomical examination purposes and no decision was made immediately before dying regarding whether to give consent or not. Also, no person had been appointed prior to dying to act as a nominated representative and make such decisions on behalf of the deceased person.

From the above it is clear that proxy consent via a qualified person is permitted in certain circumstances but it is not preferable. Making use of a person in a qualifying relationship is therefore regarded as a last resort when it comes to decision making and obtaining consent. As such, while recognising the importance of consent, it becomes possible to excuse this requirement in certain scenarios.[87] The consent exemptions are therefore examined in the following section of this chapter.

[85] Section 27(4)(a)-(h) of the 2004 Act.
[86] This means a niece or a nephew of the concerned person or child.
[87] See in general Hardcastle (2007) 108-113.

2.6 EXEMPTIONS FROM CONSENT

According to the Act there are two exceptions where consent is not required specifically for research. These exceptions regarding research concern research using existing holdings[88] and research using material manufactured outside of the human body.[89] The 2004 Act then makes further provision for various scenarios wherein consent may be dispensed with regarding the storage and use of relevant material and human bodies. These scenarios may be found mostly in section 7 of the Act and further exemptions are found throughout the rest of the Act. The exemptions relevant to this thesis include those related to dispensing of consent by the Human Tissue Authority, dispensing of consent by the High Court, where consent is not required for storage for research purposes, excluded activities not requiring consent, instances of surplus tissue, in cases of importation, existing holdings, and activities by a coroner.[90] Each will now be discussed briefly.

2.6.1 Dispensing of Consent by the Human Tissue Authority

There are two distinctly identifiable scenarios wherein the Authority may dispense with consent. The first is where it is not possible to trace the material to the donor thereof and the second situation is where a decision has not been made by the donor. Each of the identified scenarios will now be discussed.

2.6.1.1 Untraceable donor

In the first scenario, where the donor cannot be traced, the Human Tissue Authority has the power to dispense with consent, or at least to direct that consent is deemed to exist for the use of the material.[91] There are, however certain requirements which must be met. Before this exemption to consent will apply, the Authority must be satisfied firstly, that the material has been removed from the body of a living person,[92] secondly that it is not reasonably possible to trace the donor of the material,[93] thirdly, it is in the interests of another person[94] that the material must be used in order to obtain medical or scientific information regarding the

[88] See paragraph 2.6.7 *infra*.
[89] Cell lines for example.
[90] Department of Health (2004) 5-6.
[91] In accordance to section 7(3) of the 2004 Act.
[92] Section 7(1)(a) of the 2004 Act.
[93] Section 7(1)(b) of the 2004 Act.
[94] Or future person. See section 7(1)(c) of the 2004 Act.

donor,[95] and lastly, that no reason exists to believe that the donor has died or has decided to not consent to the use of the specific material for the proposed purpose or that the donor does not possess the capacity to consent to making use of the material for the proposed purpose.[96]

2.6.1.2 Undecided donor

The second scenario wherein the Human Tissue Authority may dispense with consent of the donor is where the donor has not yet made a decision whether or not to consent to the proposed activities related to their donated material. The Human Tissue Act states that if "reasonable efforts" have been made to elicit a decision from the donor as to whether or not to consent to the use of his material for a specific purpose, the Human Tissue Authority may direct that consent is deemed to have been given to the use of the material. Certain requirements must, however, also be met before this exemption will apply. Once again, the Authority must be satisfied firstly, that the material comes from the body of a living person,[97] secondly that reasonable efforts were made to get the donor to decide whether to consent to the use of the material for the proposed purpose,[98] thirdly that it is in the interests of another person in order to obtain medical or scientific information about the donor[99] and fourthly, that there is no reason to believe that the donor is now dead or that the donor has since made a decision not to consent to the use of the material or that the donor lacks the capacity to consent.[100] A last and very important requirement states that the Authority must be satisfied that the donor of the material received notice that the Authority has been requested to make such a direction.[101]

It must be noted that this section seems to be in contrast and perhaps even in violation of the principle of autonomy. In South Africa this would most probably be found to be unconstitutional and directly in violation of section 12(2)(c) of the Constitution.[102] The essence of the principle is to ensure that persons have freedom and security in themselves and that no interference whatsoever from whomever will be allowed. This section, for all intents and purposes, overrides autonomy since it provides for a mechanism whereby decisions are taken out of the hands of the person whom it concerns. The only viable justification of this may perhaps be altruism due to the fact that this dispensing of consent by the Human Tissue Authority must be to the benefit of another person. This direction of the Authority whereby consent is deemed to exist is provided

[95] Section 7(1)(c) of the 2004 Act.
[96] Section 7(1)(d)(i)-(iii) of the 2004 Act.
[97] Section 7(2)(a) of the 2004 Act.
[98] Section 7(2)(b) of the 2004 Act.
[99] Section 7(2)(c) of the 2004 Act.
[100] Section 7(2)(d)(i)-(iii) of the 2004 Act.
[101] Section 7(2)(e) of the 2004 Act.
[102] See chapter 3 paragraph 6.1.1 *supra* for more on section 12(2)(c) of the South African Constitution.

for in section 7(3) of the Act which states that there shall be "deemed to be consent of the donor to the use of the material for the purpose of obtaining scientific or medical information about him which may be relevant to the person for whose benefit the direction is given." It may be noted that this is suggestive of an "opting out" system of consent. Opting out, according to Slabbert, is not a preferable model of consent as it creates a reversed burden of proof on the donor.[103] This therefore creates an obligation, rather than protects a right such as the right to dignity or autonomy which is, or ought to be, protected under consent.

2.6.2 Dispensing of Consent by Order of the High Court

According to section 7(4) of the Human Tissue Act, the Secretary of State may enable the High Court to make an order whereby appropriate consent will be deemed to exist. This exemption applies to the following specified activities:[104]

(a) Storage of the body of a deceased person;
(b) The use of the body of a deceased person;
(c) Removal of relevant material from the body of a deceased person;
(d) Storage of any relevant material taken from the body of a deceased person; and
(e) The use of any relevant material from the body.

All the above activities are for use in research related to disorders or the functioning of the human body.

2.6.3 Storage for Research Purposes

According to section 1(7) and 1(8) of the Act, consent is not required for the storage of relevant material which is intended for use in research in connection with disorders or the functioning of the human body. However, the material must come from the body of a living donor and fall within the ambit of section 1(9). Section 1(9) requires that the research must be ethically approved in accordance with any Regulations made by the Secretary of State and that the donor of the material must not be identified.

[103] Slabbert M (2016) *An analysis of organ donation in SA* presented at the Centre for Law and Medicine, University of Pretoria, Pretoria, 15March.
[104] Section 7(4)(a)-(e) of the 2004 Act.

2.6.4 Activities Where Consent is Not Required

Section 1(10) provides for further circumstances where appropriate consent is not required. Consent may be waived where material is to be stored[105] or used[106] for the purposed listed in Part 2 of Schedule 1 of the Act. These have been discussed previously.[107]

2.6.5 Surplus Tissue

Any material which is removed from a person's body during either medical treatment, while undergoing diagnostic testing or while a person participates in research, is lawfully considered and thus dealt with as waste in terms of section 44(1) and (2) read together. This section applies to relevant material which comes from the body of a human person and which ceases to be used or stored for the purposes provided for in Schedule 1 of the Act. As Schedule 1 provides for the purposes requiring consent this means that if the material is no longer used for these purposes, consent is no longer required.

2.6.6 Importation

Consent is not required where a body[108] or relevant material is imported,[109] whether it has been removed from a living or deceased donor, or where material has come from an imported body.[110] The exemptions regarding importation also apply to material or bodies of which the donor died prior to the Human Tissue Act coming into force or where a century has passed since the donor person's death.[111] The Act, however, prohibits the exportation followed by subsequent re-importation of material which would allow whomever to take advantage of this exemption.[112]

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[105] Section 10(1)(a) of the 2004 Act.
[106] Section 10(1)(b) of the 2004 Act.
[107] They are clinical audit, education and training relating to human health, performance assessment, public health monitoring, or quality assurance. Also, note that according to the Explanatory Notes of the Human Tissue Act this includes "evaluations of *in vitro* diagnostic devices." *In vitro* diagnostic devices and genetic tests are covered by Directive 98/79/EC and would include genetic tests. This does not fall under the definition of "relevant material."
[108] Section 1(5)(a) of the 2004 Act.
[109] Section 1(6)(a) of the 2004 Act.
[110] Section 1(6)(b) of the 2004 Act.
[111] Sections 1(5)(b) and 1(6)(c) of the 2004 Act.
[112] Section 1(13) of the 2004 Act.

2.6.7 Existing Holdings

The Human Tissue Act provides the following definition of existing holdings:[113]

> "In this section, 'existing holding' means—
> (a) the body of a deceased person, or
> (b) relevant material which has come from a human body,
> held, immediately before the day on which section 1(1) comes into force, for use for a purpose specified in Schedule 1."

No appropriate consent is required for the use or storage of existing holdings as long as the holdings are used for the purposes as provided for in Schedule 1 and as long as the holdings are not anatomical specimens.[114]

2.6.8 Coroners' Activities

The Act amended the Coroners Act 1988[115] in various ways according to Schedule 6.[116] Coroners and their activities are now provided for in section 11 of the Human Tissue Act[117] and the functions of the Coroner are exempt from the requirements of the Act.

Although the offences which are discussed in the course of this chapter and which are created under the Act fall under Part 1 of the 2004 Act, this concludes the greater part of the discussion of Part 1. Attention may therefore now be given to Part 2 of the Act. In brief, Part 2 pertains to the regulatory system which enables the proper carrying out of the regulated activities. It creates the Human Tissue Authority which has a mandate which covers various activities related to human tissue and for which licenses are required. Penalties are then also created under Part 2 of the Act for contravention of such a licence and certain provisions are made

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[113] Section 9(4) of the 2004 Act.
[114] Sections 9(1) and (2) of the 2004 Act. See also Department of Health (2004) 6.
[115] Coroners Act 1988 (c.13).
[116] Schedule 6 paragraph 3 reads as follows: "(1) The Coroners Act 1988 is amended as follows. (2) In section 19 (post-mortem examination without inquest), after subsection (1)(which confers power to direct a person to make a post-mortem examination) there is inserted- "(1A) No direction under subsection (1) above shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act). (3) In section 21 (which confers powers to direct a person to make a post-mortem examination in connection with an inquest), after subsection (4) there is inserted- "(4A) No direction under this section shall have effect to require a person to make a post-mortem examination if the making of the examination by him would contravene section 16(1) of the Human Tissue Act 2004 (under which a person may make a post-mortem examination only under the authority of a licence under that Act)."
[117] Section 11: "**Coroners -**
(1) Nothing in this Part applies to anything done for purposes of functions of a coroner or under the authority of a coroner.
(2) Where a person knows, or has reason to believe, that-
(a) the body of a deceased person, or
(b) relevant material which has come from the body of a deceased person, is, or may be, required for purposes of functions of a coroner, he shall not act on authority under section 1 in relation to the body, or material, except with the consent of the coroner."

relating to the licence holder. The Human Tissue Authority is then further tasked with issuing Codes of Practice as well as Directions. These aspects will now be addressed in more detail.[118]

2.7 REGULATION OF ACTIVITIES

As stated, Part 2 of the Human Tissue Act provides for the regulation of activities involving human tissue. Here, the Human Tissue Authority is established and the requirement for licensing under the Authority is provided for. The Human Tissue Authority is discussed in greater detail later in this chapter and the discussion here merely serves to illustrate that it is established in terms of the Act and functions under the ambit of the Human Tissue Act.[119]

2.7.1 The Human Tissue Authority

The Human Tissue Authority was established in terms of the 2004 Act to oversee the removal, use, storage, import and export and disposal[120] of relevant material and bodies.[121] The Authority is also tasked with providing Codes of Practice and guidance, to ensure compliance with the Act,[122] provide information to the public or other interested parties, monitor developments within its field of knowledge, and to advise the Secretary of State thereon.[123] The Authority may further issue, revoke, review and suspend licences as well as specify the conditions applying to individual licences. Also, the Tissue Authority has the power to inspect, enter, search and seize as provided for in Schedule 5 of the Act.

The Tissue Authority will be examined in greater detail in the course of this chapter and as such the following discussion will focus on the regulation of the activities permitted under the 2004 Act by way of licensing.[124]

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[118] Department of Health (2004) 2-3.
[119] See paragraph 5 *infra*.
[120] The activities which fall within the remit of the Human Tissue Authority include carrying out of anatomical examinations and post-mortem examinations. An activity is, however, excluded from the remit of the Authority if it relates to the body of a person who died before the day on which section 14 of the Act came into force or to material which has come from the body of such a person and at least a hundred years have passed since the date of the person's death. See sections 14(2) and (3) of the 2004 Act.
[121] Section 14 of the 2004 Act.
[122] According to section 28 of the Act noncompliance with a Code does not in itself render the person liable to any proceedings.
[123] Section 15 of the 2004 Act.
[124] See paragraph 5 *infra*.

2.7.2 Licences

Under the Human Tissue Act, the Tissue Authority has the power to issue licences for lawful activities and unless such a licence has been granted, the following activities may not be undertaken:[125]

(a) The carrying out of an anatomical examination;
(b) Conducting a post-mortem examination;
(c) Removal of relevant material from the body of a deceased person for use other than transplantation;
(d) Storage of an anatomical specimen;
(e) Storage of the body of a deceased person or relevant material from a human body; and
(f) Use of the body of a deceased person or relevant material in a public display.

A licence is, however, not required for the body of a person who died before the day on which section 16 came into force or for material which comes from the body of a person who has been dead for a hundred years.[126] Storage for transplantation is also excluded from the licensing provisions. Part 2 of the Act also provides for numerous other matters in connection with licensing. These include *inter alia* persons to whom licences apply,[127] duties of persons who receive licences,[128] conduct of licensed activities,[129] changes to licence circumstances[130] and breach of licence requirements.[131]

The last aspect of the 2004 Act in need of discussion pertains to the offences created under the Act and as such, before concluding this discussion, attention may now be given to this aspect.

2.8 OFFENCES

In terms of the Act, five situations may be identified wherein it constitutes an offence to use or store relevant material without the appropriate consent. Section 5 of the Human Tissue Act provides for the prohibition of activities without consent but further offences are provided for in individual sections in the course of the Act.[132] If a person is found to be guilty of an offence in

[125] Section 16(2)(a)-(f) of the 2004 Act.
[126] This exemption excludes many museum collections from the licence requirement.
[127] Section 17 of the 2004 Act.
[128] Section 18 of the 2004 Act. These persons are referred to as "designated individuals" or DI's.
[129] Section 23 of the 2004 Act.
[130] Section 24 of the 2004 Act.
[131] Section 25 of the 2004 Act. See in general Department of Health (2004) 7-9.
[132] Section 5: "**Prohibition of activities without consent etc. -**
(1) A person commits an offence if, without appropriate consent, he does an activity to which subsection (1), (2) or (3) of section 1 applies, unless he reasonably believes-

terms of the 2004 Act, they will be liable to a fine or imprisonment or both.[133] The offences in terms of the Act are discussed briefly.

2.8.1 Failure to Obtain Appropriate Consent

Any activity specified under the Act which requires appropriate consent, which is done in the absence of such consent will constitute a punishable offence in terms of the 2004 Act. However, where a person reasonably believes that the activity is undertaken with the appropriate consent or that the concerned activity does not require consent, the absence of consent will not render the activity unlawful.[134] For example, a person working with the relevant material as a laboratory assistant has no contact with the donor of the material and therefore assumes that the appropriate consent was obtained earlier in the donation, removal or withdrawal process. If it were to come to light that the appropriate consent was not obtained, the laboratory assistant will not be held liable in terms of the Act. Questions do, however, arise regarding the liability of

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(a) that he does the activity with appropriate consent, or
(b) that what he does is not an activity to which the subsection applies.
(2) A person commits an offence if-
(a) he falsely represents to a person whom he knows or believes is going to, or may, do an activity to which subsection (1), (2) or (3) of section 1 applies-
(i) that there is appropriate consent to the doing of the activity, or
(ii) that the activity is not one to which the subsection applies, and
(b) he knows that the representation is false or does not believe it to be true.
(3) Subject to subsection (4), a person commits an offence if, when he does an activity to which section 1(2) applies, neither of the following has been signed in relation to the cause of death of the person concerned-
(a) a certificate under section 22(1) of the Births and Deaths Registration Act 1953 (c. 20), and
(b) a certificate under Article 25(2) of the Births and Deaths Registration (Northern Ireland) Order 1976 (S.I. 1976/1041 (N.I. 14)).
(4) Subsection (3) does not apply-
(a) where the person reasonably believes-
(i) that a certificate under either of those provisions has been signed in relation to the cause of death of the person concerned, or
(ii) that what he does is not an activity to which section 1(2) applies, or
(b) where the person comes into lawful possession of the body immediately after death and stores it prior to its removal to a place where anatomical examination is to take place.
(5) Subject to subsection (6), a person commits an offence if, when he does an activity to which section 1(3) applies, the death of the person concerned has not been registered under either of the following provisions-
(a) section 15 of the Births and Deaths Registration Act 1953, and
(b) article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.
(6) Subsection (5) does not apply where the person reasonably believes-
(a) that the death of the person concerned has been registered under either of those provisions, or
(b) that what he does is not an activity to which section 1(3) applies.
(7) A person guilty of an offence under this section shall be liable-
(a) on summary conviction to a fine not exceeding the statutory maximum;
(b) on conviction on indictment-
(i) to imprisonment for a term not exceeding 3 years, or
(ii) to a fine, or(iii) to both.
(8) In this section, "appropriate consent" has the same meaning as in section 1."
See also Department of Health (2004) 5.

[133] Section 5(7) of the 2004 Act.

[134] Section 5(1) of the 2004 Act.

the person who was initially responsible for obtaining consent and for the removal of the material.

2.8.2 False Representation

Where a person falsely represents to another person that appropriate consent exists or that the proposed activity is lawful, such a person will be guilty of an offence in terms of the Act. The person to whom the false statement is made must either be going to or may be going to undertake an activity described in the Act. The person making the statement must be aware of the falsehood thereof or must not believe the statement to be true.[135]

2.8.3 Failure to Obtain a Certificate of Death

Use or storage of a human body for the purpose of anatomical examination without a signed certificate of death stating the cause of death of the deceased will constitute an offence in terms of the Act[136] unless the person involved believes that such a death certificate does exist[137] or that the activity they are performing or have performed is not an activity in terms of the Human Tissue Act.[138]

2.8.4 Activities Regarding Donated Material

Where a person uses or stores donated material for a purpose which is not a "qualified purpose," such a person will be guilty of an offence.[139] This prohibition relates to the body of a person or to material which was taken from a human body and which has been donated.[140] A person will, however, not be prosecuted in terms of this provision if they reasonably believed that the material was not donated in other words, that it is not donated material as such, or where the activity was a specified lawful purpose which includes the purposes as provided for under Schedule 1 of the Act, for medical or diagnostic treatment, for decent disposal or for purposes specified in Regulations made by the Secretary of State.[141]

[135] Section 5(2) of the 2004 Act.
[136] Section 5(3) of the 2004 Act.
[137] Section 5(5) of the 2004 Act.
[138] Section 5(4) of the 2004 Act.
[139] Section 8(1) of the 2004 Act.
[140] Section 8(5) of the 2004 Act.
[141] Section 8(4) of the 2004 Act.

2.8.5 Non-Consensual Analysis of DNA

A person is guilty of an offence in terms of section 45 of the Act where they have any bodily material[142] and intend to analyse any human DNA without "qualifying consent" and to use the results of such analysis for other purposes than "excepted purposes."[143] This means that there are two elements to this offence. The first relates to "qualified consent," which was previously mentioned, and the second to "excepted purposes." These concepts require some explanation.

2.8.5.1 "Qualified consent"

A distinction is made between "qualified consent" in relation to adults and children.[144] In the case of an adult, qualified consent is the consent of the adult[145] unless they are deceased in which case a decision, as opposed to formal consent, to consent or not to consent, will be deemed as qualified consent.[146] Where no decision had been made by the deceased person, a person in a qualified relationship[147] with the deceased may give qualifying consent.[148] Where a living child is concerned, a person with parental responsibility may consent on behalf of the child where the child has not made a decision to consent or not to consent to the activity, the child is not competent to make a decision or where the child has failed to make a decision even though he is competent to do so.[149] In the case of a deceased child, a decision of the child not to consent or to consent to the activity will constitute appropriate consent. Where no such decision was made, a person with parental responsibility or in a qualifying relationship may consent on behalf of the child if the child had not made a decision immediately before dying.

2.8.5.2 "Excepted purpose"

Part 2 of Schedule 4 of the Human Tissue Act provides for various excepted purposes, listed as follows:

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[142] Bodily material, for purposes of this section and Schedule 4 of the Act which supplements section 45, means "material which (a) has come from a human body, and (b) consists of or includes human cells," according to section 45(5) of the 2004 Act.
[143] Section 45(1) of the 2004 Act.
[144] It is important to point out a difference regarding the application of this provision in Scotland where an adult is "a person who has attained the age of 16 years," and a child is "a person who has not yet attained the age of 16 years," according to Schedule 4 paragraph 3(3). Elsewhere in the United Kingdom the age of majority is 18 for purposes of the distinction between child and adult for purposes of this Act.
[145] Schedule 4 paragraph 2(1) of the 2004 Act.
[146] Schedule 4 paragraph 2(3) of the 2004 Act.
[147] See paragraph 2.5.4 *supra*.
[148] Schedule 4 paragraph 2(3)(b) of the 2004 Act.
[149] Schedule 4 paragraph 2(2) of the 2004 Act.

1. Purposes for general application;[150]
2. Purposes of research in connection with disorders or functioning of the human body;[151]
3. Purposes relating to existing holdings;[152]
4. Purposes relating to material from the body of a living person;[153]
5. Purposes authorised under section 1;[154] and
6. Purposes relating to DNA of adults who lack capacity to consent.[155]

2.9 SUMMARY OF PROVISIONS REGARDING CONSENT

The main focus of study of this thesis is that of consent and for this reason it becomes pertinent to emphasise by way of summary the provisions found in, and thus the lessons learnt from, the Human Tissue Act 2004.

The Human Tissue Act 2004 legally requires consent for research in three situations.[156] These situations are where the tissue to be utilised is firstly, from a living person and the sample is identifiable, secondly from a living person and the sample has been anonymised but the research project has not been approved by a NHS Research Ethics Committee, and thirdly where the tissue, anonymised or identifiable, is from a deceased person and collected after 1 September 2006. Regarding adults with capacity, the individual concerned must consent themselves. Where an adult, however, lacks the capacity to consent, consent must be obtained in accordance with the Mental Capacity Act 2005 and may be deemed to exist in certain instances. In the case of a deceased adult who had not given consent before death, consent may be obtained from a nominated representative or from a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half-sibling or longstanding friend in this order.

A person with parental responsibility may consent on behalf of a living child below the age of 16 who is not competent or cannot decide whether or not to consent. Where a child is deceased and was below the age of 16 and did not decide to consent or was not competent, a person with

[150] These are: (a) medical diagnosis or treatment of the person whose body manufactured the DNA, (b) functions of a coroner, (c) for the functions of a Procurator Fiscal in connection with the investigation of deaths, (d) the prevention or detection of crime, (e) conduct of prosecution, (f) for purposes of national security and (g) implementing an order or direction of a court or tribunal, including one outside the United Kingdom. See Schedule 4 paragraph 5(1) of the 2004 Act.
[151] Schedule 4 paragraph 6 of the 2004 Act.
[152] Such as clinical audit, determining cause of death, public health monitoring or transplantation. See Schedule 4 paragraph 7(a)-(j) of the 2004 Act.
[153] These purposes may include *inter alia* education or training relating to human health or performance assessment or quality assurance. See Schedule 4 paragraph 8(a)-(e) of the 2004 Act.
[154] Schedule 4 paragraph 11 of the 2004 Act.
[155] Schedule 4 paragraph 12 of the 2004 Act.
[156] It is interesting to note that the South African National Health Act provides for three different types of research which require consent. See chapter 5 *supra*.

parental responsibility may grant consent, or where there is no such person, a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half-sibling or longstanding friend may do so. Existing holdings and material created outside of the body such as cell lines are exempt from the consent requirement.

The position as set out by the Human Tissue Act 2004 as it pertains to this thesis has now been discussed. It must be mentioned that it is very similar to the South African as well as the international legal position on the matter of consent in instances where novel medical treatment borders on research involving human subjects. It is also noteworthy that although, once again, consent is heralded as a primary and pivotal principle, the consent process of format is not specified nor prescribed in particular detail.[157] The Human Tissue Authority Codes of Practice becomes relevant in this regard and is discussed in the course of this chapter.[158]

As mentioned previously the Human Tissue (Scotland) Act 2006 will now also be discussed and the same format as was utilised in the examination of the 2004 Act will be followed. What follows is therefore a discussion of the background, scope, material as defined under the Scots Act, the activities permitted and the required consent or authorisation for these activities, the exempted activities, regulation of the permitted activities, and the offences where the provisos of the Act have not been met.

Before continuing with the discussion of the Scottish Human Tissue Act of 2006, it is important to note that research using human tissue is regulated by two pieces of legislation in Scotland. The Human Tissue (Scotland) Act is the primary legal document when it comes to Scotland but the Human Tissue Act 2004, which is mainly applied in England, Wales and Northern Ireland, is also applicable regarding DNA analysis.[159] Section 45(1) of the 2004 Act created the offence of "DNA theft" which entails analysing DNA without consent or possessing bodily material with the intention of analysing the DNA without qualifying consent.[160] Exceptions to this offence do, however, exist. Lack of consent is therefore not an offence where the results of DNA analysis are to be used as follows:[161]

1. Medical diagnosis or treatment;
2. The research involves adults who lack capacity and in certain specific circumstances such as a clinical trial;

[157] See in general, Jackson (2010) 219.
[158] See paragraph 6 *infra*.
[159] The Scottish Act uses the term "authorisation" rather than "consent." In terms of DNA related matters however the term "consent" is also used in Scotland. In Scotland, DNA analysis requires explicit consent though it need not be written.
[160] See paragraph 2.8.5.1 *supra*.
[161] Medical Research Council (2006) "Summary of legal requirements for research with human tissue in Scotland" *Research and Human Tissue Legislation Series*: 2.

3. The material which is used in Research Ethics Committee approved research is from a living person and has been anonymised; or
4. The bodily material is from a living person and is used for:
   a. Performance assessments;
   b. Clinical audit;
   c. Monitoring of public health;
   d. Quality assurance; or
   e. Training related to human health.

As mentioned, the primary legislative document regulating human tissue and the activities related thereto is the Human Tissue (Scotland) Act 2006. This Act will now be discussed in the same manner as the Human Tissue Act 2004 was discussed above in order to provide a comparative illustration of the provisions relevant to this thesis and the subject of consent, or authorisation as it is referred to in the Scots Act.

3 HUMAN TISSUE (SCOTLAND) ACT 2006

In the following section of this chapter, similar to the examination of the 2004 Act, the Scots Human Tissue Act 2006 will be analysed with reference to the scope of the Act, material to which the Act applies, the activities permitted under the Act, the authorisation provisions found in the Act and any exemptions thereto, the manner whereby the Act regulates certain activities and the offences created under the Act.

3.1 INTRODUCTION, COMING INTO FORCE AND BACKGROUND

As mentioned in the previous chapter, Scotland has certain devolved legislative powers and as such may create legislation of its own on certain matters.[162] The Human Tissue (Scotland) Act 2006[163] was passed by the Scottish Parliament and came into force on the 1st of September 2006[164] to consolidate and override legislation previously in force on the subject of human tissue.[165] The Act replaces the Human Tissue Act 1961 which regulated transplantations and

[162] See chapter 7 paragraph 5 *supra*.
[163] Human Tissue (Scotland) Act 2006.
[164] The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 thus came into effect on the same day. The Bill for this Act of the Scottish Parliament was passed by the Parliament on 2 February 2006 and received Royal Assent on the 16th of March 2006.
[165] See in general Scottish Executive (2006) *Human Tissue (Scotland) Act 2006-Revised explanatory notes*: 32-33.

post-mortem examinations and it modernises the Anatomy Act of 1984.[166] It is the devolved Scottish counterpart of the United Kingdom's Human Tissue Act 2004 and aims to make provision regarding activities involving human tissue. The Human Tissue Act 2006 may be divided into 7 Parts which pertain to three main elements,[167] namely provisions relating to hospital post-mortem examinations, provisions regarding organ donations and transplantation and modernising the Anatomy Act 1984.[168] This Act thus covers a wide variety of subjects which includes transplantation;[169] post-mortem examinations;[170] tissue samples or organs which are no longer required for Procurator Fiscal purposes;[171] supplementary provisions for Parts 1 to 3 of the Act;[172] amendments to the Anatomy Act 1984;[173] miscellaneous and general provisions[174] as well as the schedule to the Act.[175] The 2006 Act is comprehensively supplemented by various Regulations and Orders.[176] The aspects of the Scottish Act which are of importance to this thesis will be discussed in greater detail.

3.2 SCOPE

The 2006 Act distinguishes between living and deceased persons as well as adults, children and incapacitated persons. The 2006 Act further deals with the mechanisms whereby the wishes of a person regarding donation and transplantation may be expressed. It is suggested by the

166 Scottish Government Health Directorate NHS HDL (2006) 46.
167 See in general Scottish Executive (2006) 1-2.
168 The Scottish Government (2006) "Human Tissue Act comes into force" available online at www.scotland.gov.uk/News/Releases/2006/08/31125311 accessed 28/10/2013.
169 This includes *inter alia* the general functions of the Scottish Ministers; use of part of the body of a deceased person for transplantation or research; restrictions on transplants involving a live donor; records and information and trafficking. See Part 1 of the 2006 Act, sections 1-22.
170 This includes *inter alia* the meaning of a post-mortem examination; disapplication; consent provisions; authorisation of various actions and offences. See Part 2 of the 2006 Act, sections 23-37.
171 This includes *inter alia* samples which become part of the medical record of a deceased person; uses and authorisation of various actions. See Part 3 of the 2006 Act, sections 38-48.
172 These include *inter alia* conditions attached to authorisation. See Part 4 of the 2006 Act, sections 49-52. Conditions may be attached to authorisation in respect of research, education, training or audit but not transplantation. See Scottish Executive (2006) 22.
173 Anatomy Act 1984.
174 These include *inter alia* the amendment of the Adults with Incapacity (Scotland) Act 2000; ancillary provisions; interpretation and repeals. See Parts 6 and & of the 2006 Act, sections 54-62.
175 Schedule: Repeals.
176 These are the Human Tissue (Removal of Body Parts by an Authorised Person)(Scotland) Regulations 2006 (SSI 2006 No.327); the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (SSI 2006 No.390); the Adults with Incapacity (Removal of Regenerative Tissue for Transplantation)(Form of Certificate)(Scotland)(No.2) Regulations 2006 (SSI 2006 No.368); the Human Tissue (Scotland) Act 2006 (Maintenance of Records and Supply of Information Regarding the Removal and Use of Body Parts) Regulations 2006 (SSI 2006 No.344); the Approval of Research on Organs No Longer Required for Procurator Fiscal Purposes (Specified Persons)(Scotland) Order 2006 (SSI 2006 No.310); the Human Tissue (Specification of Posts)(Scotland) Order 2006 (SSI 2006 No.309); the Anatomy (Specified Persons and Museums for Public Display)(Scotland) Order 2006 (SSI 2006 No.328); the Anatomy (Scotland) Regulations 2006 (SSI 2006 No.334); and the Human Tissue (Scotland) Act 2006 (Anatomy Act 1984 Transitional Provisions) Order 2006 (SSI 2006 No.340). These Regulations and Orders provide mostly for administrative matters and provide standardised formats for certain documents and will therefore not be discussed in further detail in this thesis.

National Health System (NHS) that in future, electronic health records may offer a convenient vehicle of recording such wishes as well as a person's wishes regarding their bodies after their death.[177] It is recommended, however, that the system of dynamic consent as discussed in the course of this thesis may perhaps be more suitable as it will better protect a person's privacy since it does not entail a record of past and current health issues, procedures and treatments.[178]

3.3 MATERIAL

Section 28 of the 2006 Act stipulates the body parts which may be removed during a post-mortem examination and retained for the purpose of providing information about, or confirming, the cause of death, investigating the effect and efficacy of any medical or surgical intervention which was carried out on the person, for obtaining information which may be relevant to the health of another person, and for audit, education, training or research.[179] These parts are organs, tissue samples, blood or any material derived from blood and other bodily fluids. A tissue sample may include any derivative of skin, including hair and nails in accordance with section 60 of the 2006 Act.[180]

3.4 ACTIVITIES PERMITTED UNDER THE ACT

The Human Tissue (Scotland) Act 2006 provides for three distinct uses for human tissue: firstly, the donation of tissue for the purposes of transplantation,[181] research, education or training and audit;[182] secondly, the removal, retention and use of tissue after a post-mortem examination; and thirdly for the purposes as specified in the Anatomy Act 1984.[183]

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[177] In the interim, the most effective manner of making one's wishes known, especially if it is that a person does not wish to donate any part of their body for transplantation after their death, is to make them known to one's GP. This is due to the reason that transplant co-ordinators will contact the GP where there is any possibility of a person becoming an organ donor. These wishes may be conveyed either verbally or in writing and they are then added to a person's medical record. This also applies to objections to post-mortem examinations. See Human Tissue Authority (2006) "Human Tissue (Scotland) Act 2006: A guide to its implications for NHSScotland" available online at http://www.hta.gov.uk/_db/_documents/Information_about_HT_(Scotland)_Act.pdf accessed 1/10/2013: 3.
[178] See chapter 9 *infra*.
[179] Section 23(a)-(d) of the 2006 Act.
[180] The distinction between tissue samples and organs indicate the differing emotional significance attached to these materials. Tissue samples automatically form part of the deceased's medical record and so do any tissue samples taken from organs removed and retained at a post-mortem examination. See HTA (2006) online 8.
[181] This is the primary use.
[182] Section 3 of the 2006 Act.
[183] The Anatomy Act 1984 as amended for Scotland by the Human Tissue (Scotland) Act 2006. The key amendment concerns authorisation for the donation of a body. The 1984 Act originally provided therefore that a person was permitted to grant verbal authorisation to donate their body during their final illness. As amended by the 2006 Act, this is no longer permissible under the 1984 Act. Authorisation leaving the body to medical science must now be in writing and also countersigned by two witnesses. Where the deceased is a child aged 12 years or over, the

Children below 16 years of age and adults with incapacity are only permitted two forms of donation under the 2006 Act. The first form is that of regenerative tissue which is defined as "tissue which is able to be replaced in the body of a living person by natural processes if the tissue is injured or removed."[184] Tissue includes skin, cornea and bone marrow in terms of section 60(1) of the 2006 Act. In terms of the 2006 Act an adult with incapacity and a child will be allowed to donate bone marrow, peripheral blood stem cells and skin. These donations will, however, be scrutinised by the Human Tissue Authority.[185]

The second form of donation open to adults with incapacity and children is that of an organ or part of an organ as part of a domino organ transplant operation. This is "a transplant operation performed on a living person by a registered medical practitioner (a) which is designed to safeguard or promote the physical health of the person by transplanting organs or parts of organs into the person; and (b) by so doing, necessitates the removal of an organ or part of an organ from the person which in turn is intended to be used for transplantation in respect of another living person."[186]

Section 23 of the 2006 Act provides for the purposes for which a post-mortem examination may be undertaken. They are:[187]

(a) To provide information about or to confirm cause of death;
(b) To investigate the effect and efficacy of any medical or surgical intervention the deceased was subject to;
(c) To obtain information which may be relevant to the health of another person; and
(d) Audit, education, training or research purposes.

3.5 AUTHORISATION

The Scottish Act is based on the concept of "authorisation."[188] This is the principle that a person has the right to determine what their bodies may be used for after their death while they are

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authorisation must be witnessed by two adults. They must confirm that the child understood the effect of the authorisation and was not acting under any undue influence. Where the person granting authorisation is illiterate and thus unable to write, the authorisation must be signed by an adult person, acting on behalf of the illiterate person and this must be witnessed by a second adult. Both persons must then be able to confirm that the illiterate person expressed their intention to grant authorisation and that they requested the signatory to sign on their behalf.

[184] Section 17(10) of the 2006 Act.

[185] HTA (2006) online 6.

[186] Section 17(10) of the 2006 Act.

[187] Section 23(a)-(d) of the 2006 Act. See also HTA (2006) online 7.

[188] The 2006 Act, similar to the 2004 Act, strengthened the "opting in" system and so it is clearly based on the principle of authorisation. Authorisation, as was previously mentioned, is the Scots equivalent of consent. According to McLean consent is the golden thread which runs through the Human Tissue Acts. McLean as mentioned in Gillot J (2014) *Bioscience, governance and politics*: 120.

still alive.[189] It is the Scottish equivalent of the concept of consent as used in the 2004 Act applying to England, Wales and Northern Ireland. Authorisation is also the foundational principle of the 2006 Act.

The use of the word "authorisation" intends to convey that people have the right to make known their wishes regarding their bodies after their death while they are still alive, and to have these wishes respected. Authorisation is therefore a positive concept and represents a positive attitude which replaces the approach demonstrated in the Human Tissue Act 1961[190] known as the "lack of objection" approach. It must be noted that the concept of "authorisation" is equal to that of "consent" as used in the 2004 Act and in the same manner as the 2004 Act is founded on the concept of consent, so too is the 2006 Act based on the concept of authorisation. The equivalence of these two concepts is essential to the continued existence of arrangements of the sharing of organs, and other materials or information, across the United Kingdom.[191]

The provisions regarding authorisation as determined by the 2006 Act apply to both transplantations and hospital post-mortem examinations and relate to three categories, namely children 12 years of age or over at the time of their death, children below the age of 12 at the time of their death[192] and adults.[193] Each category will be discussed, starting with children, after which the authorisation provisions relating to adults will be discussed as well as those of persons unable to grant authorisation due to incapacity.

For a post-mortem examination and the retention of any tissues and organs obtained during such examination to be lawful, the proper authorisation must be obtained. In context of post-mortem examinations, the principle of authorisation is the same as set out regarding transplantation. This means that the same three categories as those mentioned above may be identified. Due to these similarities, largely the same arrangements apply to post-mortem examinations as to transplants. A key difference, however, is that an adult or a child aged 12 years or over can, during their life, nominate representatives to make decisions regarding post-mortem examinations. Where no wishes were indicated, no person has been nominated and there is no nearest relative or person with parental rights or responsibilities, authorisation is not possible and thus it will be unlawful to perform a hospital post-mortem examination.[194]

[189] The Scottish Government (2006) online. See also Scottish Government Health and Social Care Directorates (2006) "Human Tissue (Scotland) Act 2006: A guide to its implications for NHSScotland" *Directorate* (2006) 46.
[190] Human Tissue Act 1961. This Act was repealed for Scotland by the 2006 Act.
[191] HTA (2006) online 2.
[192] HTA (2006) online 3.
[193] This is a person aged 16 years or over who has the capacity to make his own decisions.
[194] HTA (2006) online 8.

3.5.1 Children

It should be noted from the start of this discussion that the child must be capable of making their own decisions and granting their own authorisation. In Scotland, this determination is done in accordance to the Age of Legal Capacity (Scotland) Act 1991.[195] In terms of the Age of Legal Capacity (Scotland) Act 1991, a person below the age of 16 has no legal capacity to act.[196] However, certain exceptions to the general rule may be found in section 2 of this Act and as such, subsection (4) states that a person under the age of 16 has the legal capacity to consent on their own behalf to medical treatment.[197]

The 2006 Act distinguishes between children who die at 12 years of age or over and children who die before reaching this age and are therefore below the age of 12. Both groups of children are discussed here.

3.5.1.1 Children aged 12 years of age or over at the time of their death

A child over the age of 12 years may authorise the removal and use of a part of their body after their death for any of the activities permitted under section 8 the 2006 Act.[198] This authorisation must be in writing and if it were to be withdrawn, this withdrawal must also be in writing. Where such a child is blind or not able to write, an adult referred to as a "signatory" may grant

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[195] Age of Legal Capacity (Scotland) Act 1991 (c.50).
[196] Section 1 of the Age of Legal Capacity (Scotland) Act 1991.
[197] Interestingly, section 2(AZA) of the Age of Legal Capacity (Scotland) Act provides that the storage of gametes in accordance to the Human Fertilisation and Embryology Act 1990 qualifies as a medical procedure.
[198] Section 8: "**Authorisation: child 12 years of age or over -**
(1) A child who is 12 years of age or over may authorise the removal and use of a part of the child's body after the child's death for one or more of the purposes referred to in section 3(1).
(2) Subject to subsections (3) to (5), authorisation by virtue of subsection (1)-
(a) must be in writing;
(b) may be withdrawn in writing.
(3) If the child is blind or unable to write, authorisation by virtue of subsection (1) and withdrawal of such authorisation may be signed by an adult (a "signatory") on the child's behalf and if it is so signed it must be witnessed by one witness.
(4) Authorisation by virtue of subsection (1), or withdrawal of such authorisation, which is signed by a signatory on behalf of a child by virtue of subsection (3) must contain a statement signed by both the signatory and the witness in the presence of the child and of each other that the child, in the presence of them both, expressed the intention to give the authorisation or, as the case may be, withdraw the authorisation and requested the signatory to sign the authorisation or, as the case may be, the withdrawal on behalf of the child.
(5) Authorisation by virtue of subsection (1) which is signed by a signatory on behalf of a child by virtue of subsection (3) must contain or be accompanied by-
(a) certification in writing signed by the signatory that, in the opinion of the signatory;
(b) certification in writing signed by the witness that, in the opinion of the witness, the child understands the effect of the authorisation and is not acting under undue influence in giving it.
(6) Nothing in subsection (3) prevents a child who is blind from giving authorisation by virtue of subsection (1) in accordance with subsection (2)(a) or withdrawing, in accordance with subsection (2)(b), any authorisation by the child by virtue of subsection (1)(including authorisation signed by a signatory in accordance with subsection (3)).
(7) In subsection (2)(a), "writing" includes, in relation to the requirement there for authorisation to be in writing, but only where the authorisation in writing is not signed by a signatory on behalf of the child, representation of a character in visible form."

authorisation on behalf of the child and any signing of authorisation must be witnessed by one witness. Both the signatory as well as the witness must express the intention to act on behalf of the child, whether it is in granting authorisation or in withdrawing it.[199]

Where there is no authorisation for the removal of any part of the body in force immediately before the death of a child aged 12 years or over, section 9 applies.[200] It states that a person who immediately before the death of such a child had parental rights and parental responsibilities in relation to the child, may authorise removal and use of any part of the body of the deceased child for the permitted activities under the 2006 Act.[201] Where authorisation was given by a

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[199] Scottish Executive (2006) 4.

[200] Section 9: "**Authorisation as respects child who dies 12 years of age or over by person with parental rights and responsibilities -**

(1) If there is in force immediately before the death of a child who died 12 years of age or over no authorisation by the child by virtue of section 8(1) of removal and use of any part of the child's body for transplantation, a person who, immediately before the death, had parental rights and parental responsibilities in relation to the child (but who is not a local authority) may, subject to subsection (4), authorise removal and use of any part for one or more of the purposes referred to in section 3(1).

(2) If-

(a) there is in force immediately before the death of a child who died 12 years of age or over authorisation by the child by virtue of section 8(1) of removal and use of a part of the child's body for transplantation;

(b) the authorisation does not expressly include removal and use of the part for a particular purpose referred to in paragraphs (b) to (d) of section 3(1),

a person who, immediately before the death, had parental rights and parental responsibilities in relation to the child (but who is not a local authority) may, subject to subsection (4), authorise the removal and use of the part for the particular purpose in question which is not included in the authorisation.

(3) If-

(a) there is in force immediately before the child's death authorisation by the child by virtue of section 8(1) of removal and use of a particular part of the child's body for transplantation;

(b) the authorisation does not expressly include removal and use of another particular part,

a person who, immediately before the death, had parental rights and parental responsibilities in relation to the child (but who is not a local authority) may, subject to subsection (4), authorise the removal and use of the other particular part which is not so included for one or more of the purposes referred to in paragraphs (b) to (d) of section 3(1).

(4) A person may not give authorisation under-

(a) subsection (1) if the person has actual knowledge that the child was unwilling for any part of the child's body, or the part in question, to be used for transplantation;

(b) subsection (2) if the person has actual knowledge that the child was unwilling for the part to be used for the purpose in question;

(c) subsection (3) if the person has actual knowledge that the child was unwilling for any other part of the child's body or, as the case may be, the other particular part in question, to be used for transplantation.

(5) For the purposes of-

(a) subsection (4)(a), the mere fact that there is no authorisation by the child in force is not to be regarded as unwillingness by the child referred to in that subsection;

(b) subsection (4)(b), the mere fact that the authorisation by the child does not include a particular purpose referred to in paragraphs (b) to (d) of section 3(1) is not to be regarded as unwillingness by the child referred to in that subsection;

(c) subsection (4)(c), the mere fact that there is no authorisation by the child in force as respects the removal and use of other parts, or the other particular part in question, for transplantation is not to be regarded as unwillingness by the child as referred to in that subsection.

(6) Authorisation by virtue of subsection (1), (2) or (3)—

(a) must be–

(i) in writing and signed; or

(ii) expressed verbally,

by the person who gives the authorisation in accordance with that subsection;

(b) subject to subsection (7), may be withdrawn in writing signed by the person.

(7) To the extent that authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn."

[201] Section 9(1) of the 2006 Act. Interestingly, such authorisation for transplantation may not be withdrawn in terms of section 9(7) of the 2006 Act.

child over the age of 12 but it does not expressly include removal and use for a particular purpose, a person who had parental rights and responsibilities immediately before the death of the child may also authorise the removal and use for the particular proposed purpose. This is also the case where authorisation was given but it did not expressly include a specific part of the body.[202] Such authorisation by a person with parental rights and responsibilities may, however, not be given where such a person has actual knowledge that the child was unwilling to grant authorisation for any of the purposes or body parts in question. Authorisation must be in writing and signed or expressed verbally and if it were to be withdrawn it would have to be done so in writing and this withdrawal would have to be signed.[203] Where no person with parental rights and responsibilities exists, the "nearest relative" provisions do not apply and no transplantation may be undertaken using parts of the body of the child since the necessary authorisation is not attainable. This is also the case in circumstances regarding a child below the age of 12 years at the time of their death.

3.5.1.2 Children below the age of 12 at the time of their death

In terms of section 10, when a child below the age of 12 dies, a person with parental rights and responsibilities is tasked with granting authorisation for the purposes permitted under the 2006 Act.[204] This may include a person appointed as guardian of the child in terms of section 7 of the Children (Scotland) Act 1995.[205] The authorisation of only one such person with rights and responsibilities is sufficient and this is then also consistent with the provisions of the Children (Scotland) Act 1995 in regards to parental consent for medical treatments.[206] Local authorities with parental rights are, however, excluded from the 2006 Act.[207]

Where the child, above or below the age of 12 years, is not survived by any parents it becomes necessary to established whether or not any guardians were appointed in terms of section 7 of

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[202] See section 9(2) and (3) of the 2006 Act.
[203] Section 9(6)(a) and (b) of the 2006 Act. See also Scottish Executive (2006) 5.
[204] Section 10: **"Authorisation as respects child who dies under 12 years of age -**
(1) A person who immediately before the death of a child who died under 12 years of age had parental rights and parental responsibilities in relation to the child (but who is not a local authority) may authorise removal and use of a part of the body of the child for one or more of the purposes referred to in section 3(1).
(2) Authorisation by virtue of subsection (1)-
(a) must be–
(i) in writing and signed; or
(ii) expressed verbally,
by the person who gives the authorisation in accordance with that subsection;
(b) subject to subsection (3), may be withdrawn in writing signed by the person.
(3) To the extent that authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn."
[205] Children (Scotland) Act 1995 (c.36).
[206] Scottish Executive (2006) 5.
[207] HTA (2006) online 4.

the Children (Scotland) Act 1995. If no such appointment was made and there are therefore no persons with parental rights and responsibilities, the nearest relative hierarchy does not apply and no transplantation would be permitted since the required authorisation would not be attainable.[208] The last mentioned category of persons relevant to authorisation is adults which will now be discussed.

3.5.2 Adults

Section 6 of the 2006 Act provides that adults may authorise the removal and use of a part of their own body after their death for the purpose of transplantation and also for the purposes of research, education or training and audit.[209] Usually authorisation is in the context of transplantation and for this reason it more often than not takes the form of an organ donor card or registration on the NHS Organ Donor Register. Other forms of authorisation will of course also be valid. These may include authorisation which has taken place in writing or verbally.[210]

Any wishes of an adult regarding transplantation made before 1 September 2006 will be deemed to have been made as if authorised under the new legislation, no matter the process of registration in terms of section 15 of the 2006 Act. This means that renewal of previous authorisation, like a donor card for example, is not necessary. Any authorisation in favour of transplantation will take precedence over the authorisation made for any other permitted purpose in terms of the Act.[211]

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[208] *Ibid*.
[209] Section 6: "**Authorisation: adult -**
(1) An adult may authorise the removal and use of a part of the adult's body after the adult's death for one or more of the purposes referred to in section 3(1).
(2) Authorisation by virtue of subsection (1)-
(a) must be-
(i) in writing; or
(ii) expressed verbally;
(b) subject to subsections (3) and (4), may be withdrawn in writing.
(3) If the adult is blind or unable to write, withdrawal of authorisation by virtue of subsection (2)(b) may be signed by another adult (a "signatory") on the adult's behalf and if it is so signed it must be witnessed by one witness.
(4) Withdrawal of authorisation which is signed by a signatory on behalf of an adult by virtue of subsection (3) must contain a statement signed by both the signatory and the witness in the presence of the adult and of each other that the adult, in the presence of them both, expressed the intention to withdraw the authorisation and requested the signatory to sign the withdrawal on behalf of the adult.
(5) Nothing in subsection (3) prevents an adult who is blind from withdrawing, in accordance with subsection (2)(b), any authorisation by virtue of subsection (1).
(6) In subsection (2)(a)(i), "writing" includes, in relation to the requirement there for authorisation to be in writing, representation of a character in visible form."
See also Scottish Executive (2006) 3.
[210] HTA (2006) online 3. Interestingly, section 6 has been drafted in such a manner that it allows for online registration as well as telephonic registration. This indicates a move towards health 2.0 measures and the convergence of health matters and new technology. See again chapter 4 paragraph 6.1.1 *supra*.
[211] Section 22 of the 2006 Act. See also HTA (2006) online 3.

An adult may withdraw their authorisation for transplantation, research, education or training and audit[212] at anytime. Such withdrawal of consent must, however, be done in writing.[213]

3.5.3 Incapacitated Persons

Provisions regarding adult donors with incapacity and children donors are set out in Parts 3 and 4 of the 2006 Human Organ and Tissue Live Transplants (Scotland) Regulations which supplement the 2006 Act.[214] An adult with incapacity is a person who, in the opinion of the Scottish Minister who issues a certificate to the effect, is incapable[215] of making a decision regarding the removal of regenerative tissue for transplantation.[216] The Human Tissue Authority acts on behalf of the Scottish Minister and must be satisfied that:[217]

1. The donor is an adult with incapacity[218] or a child;
2. That the organ is being removed as part of a domino transplant operation[219] or that the tissue being removed is regenerative tissue;[220]
3. That the donor, be that an incapacitated adult or child, is not unwilling;
4. That the donor has been given the necessary information; and
5. That there is no evidence of reward.[221]

The donor will be interviewed as well as the proxy person, in the case of an incapacitated adult, or person with parental rights and responsibilities in the case of a child, to determine their

[212] As provided for in section 3(1)(a)-(d) of the 2006 Act.
[213] Section 6(2)(b) of the 2006 Act. Where the adult is blind or unable to write, withdrawal may be signed by another adult in terms of section 6(3). According to section 6(4), this must then contain a statement signed by both the signatory and the witness to the signing in the presence of the adult on whose behalf the withdrawal is signed, expressing the intention to withdraw the authorisation.
[214] Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.
[215] "Incapable" has the same meaning as in section 1(6) of the Adults with Incapacity (Scotland) Act 2000 which means "incapable of- (a) acting; or (b) making decisions; or (c) communicating decisions; or (d) understanding decisions; or (e) retaining the memory of decisions, as mentioned in any provision of this Act, by reason of mental disorder or of inability to communicate because of physical disability; but a person shall not fall within this definition by reason only of a lack or deficiency in a faculty of communication if that lack or deficiency can be made good by human or mechanical aid (whether of an interpretative nature or otherwise)." Incapacity is then construed accordingly.
[216] Section 18(1) of the 2006 Act.
[217] HTA (2006) online 6.
[218] Section 17(10) defines an adult with incapacity as "(a) for the purposes of subsections (1)(c) and (2)(c), an adult to whom section 18 applies; (b) for the purposes of subsection (6)(a)(ii), an adult in respect of whom section 47 of the Adults with Incapacity (Scotland) Act 2000 applies in relation to the domino organ transplant operation in question." See also Scottish Executive (2006) 10-11.
[219] See paragraph 3.4 *supra* for the definition of domino organ transplantation.
[220] See paragraph 3.4 *supra* for the definition of regenerative tissue.
[221] Section 17(10) defines reward as "any description of financial or other material advantage, but does not include any payment in money or money's worth for defraying or reimbursing- (a) the cost of removing, transporting, preparing, preserving or storing the organ (or part) or tissue; (b) any liability incurred in respect of expenses incurred by a third party in, or in connection with, any of the activities referred to in paragraph (a); (c) any expenses or loss of earnings incurred by the person from whose body the organ (or part) or tissue comes so far as reasonably and directly attributable to the person's supplying it from the person's body."

views regarding the adult or child's past wishes and feelings on the issue of donation for transplantation. At this juncture the provisions regarding the nearest relative or person with parental responsibilities become relevant as they pertain to the power of a so-called proxy person.

3.5.4 Nearest Relative or Person with Parental Rights and Responsibilities

In the same manner as the 2004 Act provides for "qualifying relationships,"[222] the 2006 Act provides for the nearest relative or person with parental rights and responsibilities to make decisions as the proxy of the concerned deceased person.[223] The 2006 Act focuses greatly on the wishes of a person themselves regarding what is permissible after their death. Sometimes, however, a different person must make decisions regarding the relevant person's body, and so provision is made for a nearest relative or person with parental rights and parental responsibilities to make decisions. Previously, a relative could refuse transplantation using the relevant person's body parts even where the person themselves had authorised it. In effect, a relative could therefore *veto* a decision to donate material for transplantation. Currently, a nearest relative must be approached in order to query any medical reasons for transplantation to be refused. However, where a person was an adult or 12 years of age or over at the time of their death and they had authorised transplantation, their authorisation is the only requirement for lawful transplantation.[224]

Where a person, however, left no formal wishes regarding their bodies after their death, the nearest relative where the deceased was an adult or, person with parental rights and responsibilities where the deceased was a child aged 12 years or over, may be approached and asked to consider authorising transplantation of parts of the body in accordance with what they believe the deceased would have wished in terms of section 7 of the 2006 Act.[225] This means

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[222] See paragraph 2.5.4 *supra*.
[223] Scottish Executive (2006) 4 & 23.
[224] HTA (2006) online 4.
[225] **Section 7: "Authorisation by adult's nearest relative -**
(1) If there is in force immediately before an adult's death no authorisation by the adult by virtue of section 6(1) of removal and use of any part of the adult's body for transplantation, the nearest relative of the deceased adult may, subject to subsection (4), authorise the removal and use of any part for one or more of the purposes referred to in section 3(1).
(2) If-
(a) there is in force immediately before an adult's death authorisation by the adult by virtue of section 6(1) of removal and use of a part of the adult's body for transplantation;
(b) the authorisation does not expressly include removal and use of the part for a particular purpose referred to in paragraphs (b) to (d) of section 3(1), the nearest relative of the deceased adult may, subject to subsection (4), authorise the removal and use of the part for the particular purpose in question which is not included in the authorisation.
(3) If-

that they must not have actual knowledge that a person would not have authorised the proposed use of the specified body part.[226] A nearest relative or person with parental rights and responsibilities may, however, authorise the use for a different purpose or the use of a different part of the body of a person where no express wishes regarding the purpose or part were made.[227] An adult or person of 12 years of age or over may then also nominate a person to make decisions regarding a post-mortem examination of their body after their death in terms of the 2006 Act.[228]

Section 50 of the 2006 Act sets out the hierarchy of persons to be considered the nearest relative where they were immediately before the death of the deceased:[229]

(a) The adult's spouse or civil partner;
(b) Living with the adult as husband or wife or in a relationship with the characteristics of the relationship between civil partners and they had been living in this manner for a period of no less than 6 months;
(c) The adult's child;
(d) The adult's parent;
(e) The adult's siblings;
(f) The adult's grandparent;

(a) there is in force immediately before an adult's death authorisation by the adult by virtue of section 6(1) of removal and use of a particular part of the adult's body for transplantation;
(b) the authorisation does not expressly include removal and use of another particular part, the nearest relative of the deceased adult may, subject to subsection (4), authorise the removal and use of the other particular part which is not so included for one or more of the purposes referred to in paragraphs (b) to (d) of section 3(1).
(4) The nearest relative may not give authorisation under-
(a) subsection (1) if the relative has actual knowledge that the adult was unwilling for any part of the adult's body, or the part in question, to be used for transplantation;
(b) subsection (2) if the relative has actual knowledge that the adult was unwilling for the part to be used for the purpose in question;
(c) subsection (3) if the relative has actual knowledge that the adult was unwilling for any other part of the adult's body or, as the case may be, the other particular part in question, to be used for transplantation.
(5) For the purposes of-
(a) subsection (4)(a), the mere fact that there is no authorisation by the adult in force is not to be regarded as unwillingness by the adult referred to in that subsection;
(b) subsection (4)(b), the mere fact that the authorisation does not include a particular purpose referred to in paragraphs (b) to (d) of section 3(1) is not to be regarded as unwillingness by the adult referred to in that subsection;
(c) subsection (4)(c), the mere fact that there is no authorisation by the adult in force as respects the removal and use of other parts, or the other particular part in question, for transplantation is not to be regarded as unwillingness by the adult referred to in that subsection.
(6) Authorisation by virtue of subsection (1), (2) or (3)-
(a) must be–
(i) in writing and signed; or
(ii) expressed verbally, by the nearest relative;
(b) subject to subsection (7), may be withdrawn in writing so signed.
(7) To the extent that authorisation by virtue of subsection (1) is for the purposes of transplantation, it may not be withdrawn."

[226] Section 7(4) of the 2006 Act.
[227] Section 7(2) & (3) of the 2006 Act.
[228] Sections 30 & 31 of the 2006 Act.
[229] Section 50(10)(a)-(k) of the 2006 Act.

(g) The adult's grandchild;
(h) The adult's uncle or aunt;
(i) The adult's cousin;
(j) The adult's niece or nephew; or
(k) A longstanding friend of the adult.

The nearest relative or the person with parental rights and responsibilities may not withdraw authorisation for transplantation once it has been granted as this would open the door to last minute withdrawal which would put the recipient at risk. Authorisation for other permitted activities under the 2006 Act may, however, be withdrawn at any time provided that it is done in writing.[230]

3.6 EXEMPTIONS FROM CONSENT

Similar to the Human Tissue Act 2004,[231] organs or tissue samples removed post-mortem prior to 1 September 2006 when the 2006 Act came into force, may be used for research purposes without authorisation. This means that Procurator Fiscal organs may be held for future NHS research which has been approved by Research Ethics Committees and all human material which is currently utilised in research projects may continue to be utilised without authorisation.[232]

3.7 REGULATION OF ACTIVITIES

The following discussion briefly illustrates the establishments in place to regulate the activities permitted under the 2006 Act. Take note, however, that the Human Tissue Authority is discussed in greater detail in the course of this chapter.[233]

3.7.1 The Human Tissue Authority

Despite Scotland having its own Human Tissue Act, the 2006 Act as discussed in this chapter, and the fact that the Human Tissue Authority was established under the 2004 Act, the Human Tissue Authority is also a competent authority in Scotland.[234]

[230] HTA (2006) online 4.
[231] See paragraph 3.6 *supra* for the exemptions to consent under the Human Tissue Act 2004.
[232] Medical Research Council (2006) 1.
[233] See paragraph 5 *infra*.

This is due to an agreement which was reached between the Scottish Ministers and the Human Tissue Authority that the Authority will act as the Competent Authority for Scotland under the European Union Directive on the Safety of Tissue and Cells which came into force on the 6th of April 2006 and which regulates the storage of tissue intended for human application.[235] This agreement was reached in order to preserve the system of accreditation in operation across the UK.[236]

The Scottish Executive and the Authority have further agreed that the arrangements for living donation provided for by the Authority's *Codes of Practice on Donation of Organs and Tissue and Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells* (PBSC) will apply to Scotland in order to promote uniform regulation across the UK. The 2006 Act does not provide for tissue donation by living adults who have the capacity to make decisions and such cases will therefore also be overseen by Codes of Practice by the Human Tissue Authority.[237]

Previously, the Unrelated Living Transplants Regulatory Authority (ULTRA) dealt with situations of living donation where the donor and recipient were unrelated. The power of scrutiny over such cases has, as of 1 September 2006, been transferred to the Human Tissue Authority under both the 2004 and 2006 Acts in order to preserve a uniform approach across the UK. The Human Tissue Authority now has the power to deal with related and unrelated donations and applications involving parts of, as well as whole, organs.[238]

Certain Regulations were also drafted under the European Communities Act 1972 with detailed requirements to be met by Scotland in regulating certain activities related to donation and transplantation of human materials.[239]

3.7.2 Ministers

As mentioned in the preceding paragraph, the Human Tissue Authority has authority over Scotland by agreement with the Scots Ministers. The Human Tissue Authority is thus the primary regulatory establishment. The Minsters do, however, have certain functions to fulfil.

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[234] The Human Tissue Authority, however, does not regulate the storage of tissue samples for research purposes in Scotland. The remit of the Authority in Scotland is described in the Scottish Health Department letter issued on 20 July 2006 Ref: NHS HDL (2006).
[235] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells.
[236] Currently operated by the Medicines and Healthcare Products Regulatory Authority (MHRA).
[237] HTA (2006) online 5. The relevant Codes of Good Practice are discussed in the course of this chapter. See paragraph 6 *infra*.
[238] HTA (2006) online 5.
[239] European Communities Act 1972 (c.68). See chapter 7 footnote 26 *supra* regarding the possible implications of Brexit on the laws of the UK.

Part 1 of the 2006 Act places the following duties on the Scottish Ministers: to promote, support and develop programmes of transplantation; to promote information and awareness regarding donation for transplantation of parts of the body; and to promote the taking of any required measures relating to the quality and safety, the storage and use of any body part which has been donated for transplantation purposes.[240] The Ministers are further permitted to give assistance and support, which includes financial assistance, to anyone who provides or is proposing to provide a transplantation related service.[241] Ministers are also in a position to make Regulations in terms of the Act regarding the provision of information and the maintenance of records related to transplantations.[242]

3.8 OFFENCES

The 2006 Act continued the approach followed in the Human Organ Transplants Act 1989,[243] associated Regulations and the Human Tissue Act 2004. The removal of organs, parts of organs or tissue from the body of a living person for use in transplantation constitutes an offence unless certain conditions are met.[244] Detailed conditions are provided for in the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. For removal of any of the mentioned materials to be lawful, the following requirements must be met:

1. The donor must have authorised the removal and use for transplantation;
2. The donor has not been subject to coercion; and
3. No reward has been or will be given.[245]

The 2006 Act provides for legal sanctions which underline the importance of authorisation and ensures that the exact terms of the authorisation are respected and adhered to. In terms of section 16 of the 2006 Act, it is an offence to remove or use part of a body of a deceased person for transplantation, research, education or training and audit without the required authorisation. In context of a post-mortem examination, it is an offence to carry out a post-mortem examination, remove an organ during such an examination and retain such an organ

[240] Section 1 of the 2006 Act.
[241] Section 2 of the 2006 Act.
[242] HTA (2006) online 7.
[243] Human Organ Transplants Act 1989.
[244] See section 17 of the 2006 Act.
[245] See section 20 of the 2006 Act as it relates to contravention of the prohibition on commercial dealings in parts of a human body for transplantation. See in general Herring J (2014)"Why we need a statute regime to regulate bodily material" in Goold I, Greasley K, Herring J & Skene L (eds) *Persons, parts and property: How should we regulate human tissue in the 21st century?*: 213-229. See also the cases of *Evans v United Kingdom* (2006) 42 EHRR 21 and *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37 regarding property rights in human material.

where the necessary authorisation was not granted.[246] Conditions attached to authorisation must be adhered to where reasonably practicable.[247]

3.9 SUMMARY OF PROVISIONS REGARDING AUTHORISATION

The Scottish Act regulates research using organs, tissues and samples from deceased persons but not research using tissue from living donors. It is therefore of informative value in the context of the person from whom authorisation or consent must be obtained. As mentioned above, the focus of this thesis is that of consent and in order to understand this concept as found in the United Kingdom, the Human Tissue (Scotland) Act 2006 was examined similarly to the 2004 Act. It is therefore also necessary to summarise the provisions regarding authorisation as found in the Human Tissue Act 2006.

In terms of the Human Tissue (Scotland) Act 2006 authorisation is required for the removal and use of post-mortem tissue samples intended for research. Adults, meaning persons over the age of 16, may authorise the removal, use and storage of organs, tissue or samples for research purposes themselves or in the event of an incapacitated person, they may nominate a person or a nearest relative in order of priority. Authorisation may be written or verbal.

A child over the age of 12 may give authorisation themselves where they are competent. A nominated person or person with parental responsibility may give authorisation on behalf of such a child. Authorisation by the child or by a representative person, as well as any withdrawal thereof must be written and signed. Where the child is not able to sign the authorisation, a signatory must sign it on behalf of the child. In the case of a child below the age of 12, only a person with parental responsibility may grant authorisation. While existing holdings are exempt from the requirement of authorisation, good practice dictates that authorisation and/or consent should, where practical, be obtained for use of all tissue samples for research.

After discussing the specific legislation in operation in England and Wales and in Scotland it becomes necessary at this juncture to discuss the Northern Irish position briefly.

[246] Section 37 of the 2006 Act.
[247] Section 49 of the 2006 Act.

4 STEM CELL REGULATION IN NORTHERN IRELAND

As was mentioned in the previous chapter of this thesis, the legal system of the United Kingdom is a complex web of legislation and devolved powers. As the Northern Irish legal system was discussed in general, it is relevant to mention briefly the specific legal position as it pertains to this thesis.

To date, Northern Ireland has no specific legislation providing for stem cell research and related matters.[248] Previously, embryo research was thought to have been banned under the Constitution but the current situation is unclear due to the case of *MR v TR*[249] wherein the Irish Supreme Court agreed with the 2006 Irish High Court judgement[250] that cryopreserved embryos which had been created outside of the womb do not enjoy constitutional protection. The Irish government has, however, stated its intention to regulate stem cell research in future.[251]

The Human Tissue Act 2004 is, however, in force in Northern Ireland and superseded the Anatomy (Northern Ireland) Order 1992[252] which previously regulated matters related to bequests of human remains after the death of the donor, the retention of parts of the human body at the conclusion of anatomical examinations, and the requirement of written donor and witness signatures for any donation.[253] The Human Tissue Authority is also the competent authority dealing with matters regarding human materials and tissues in Northern Ireland. Once again the Human Tissue Authority comes to the foreground and, as the Authority has been mentioned numerous times throughout the course of this chapter, it becomes imperative to examine this regulatory body in further detail.

5 THE HUMAN TISSUE AUTHORITY

In 2005, after it came to light that hospitals had developed a culture of removing and retaining human organs and tissues during the 1990's,[254] the Human Tissue Authority (HTA) was

[248] In 2008 a Bill was introduced to the Irish parliament which attempted to ban embryonic research in Northern Ireland but this Bill was never passed. Also, the Human Tissue Bill 2008 which aimed at regulating the removal, use and storage of human tissue and materials never became law. Then, in 2009, the Irish Medical Council banned the creation of embryos for research purposes.
[249] *MR v TR* [2009] IESC 82.
[250] *MR v TR* [2006] IESC 359.
[251] Small S (2012) "Regulation of stem cell research in Ireland" available online at www.eurostemcell.org/regulations/regulation-stem-cell-research-ireland accessed 14/10/2013.
[252] Anatomy (Northern Ireland) Order 1992.
[253] Taylor SJ & Wilson DJ (2007) "The Human Tissue Act (2004), anatomical examinations and the importance of body donation in Northern Ireland" *Ulster Medical Journal* 76(3): 124-125.
[254] Human Tissue Authority (2014) "About us" available online at http://www.hta.gov.uk/about-us accessed 25/5/2015. See also Bell (2006) 283.

established by section 13 of the Human Tissue Act 2004.[255] The HTA came into being on the 1st of April 2005 with its statutory functioning beginning on the 1st of April 2006.[256]

The HTA is a non-departmental public body under the Department of Health. It is responsible for the regulation of removal, storage, use and disposal of human bodies, organs and tissue intended for various scheduled purposes which include *inter alia* research, transplantation, education and training. The HTA also approves organ and bone marrow donations from living persons. It further acts as the Competent Authority under the European Union Tissue and Cells Directives.[257] The Authority strives toward and ensures the safe and ethical use of human tissues and organs and requires that any activity involving these materials is preceded by the granting of the proper consent.[258] The general functions of the HTA are all supervisory in nature and range from maintaining general principle statements to be followed in the activities permitted under the remit of the Authority, to providing the public with information.[259] It is not surprising then that with "confidence maintenance" declared as the Authority's strategic goal, the HTA is sometimes described as a watchdog protecting public trust.[260]

The main function of the Authority is to inspect and license establishments which store and use human cells and tissues for the following purposes which will be discussed in somewhat more detail in this section of this thesis:[261]

1. Education regarding the human body;
2. Post-mortem examinations;
3. Patient treatment utilising human tissue and cells;
4. Research on human tissue and cells; and
5. Public display of human bodies.

The HTA is comprised of a Chair and eleven Members,[262] nine of whom are appointed by the Secretary of State for Health, one by the National Assembly for Wales and one by the Department of Health, Social Services and Public Safety in Northern Ireland. The Members of the HTA are medical and scientific professionals as well as lay persons with the necessary business or commercial and public service experience.[263] In order to ensure that the HTA itself functions

[255] Read with Schedule 2 to the 2004 Act.
[256] Department of Health (2004) 7.
[257] See paragraph 5.3.3 *infra* for more on the Directives.
[258] HTA (2014) "About us" online.
[259] Section 15 of the 2004 Act. See paragraph 5.1 and 5.2 *infra* for more on the general functions of the Human Tissue Authority.
[260] HTA (2008) 6.
[261] HTA (2014) 6.
[262] Baroness Hayman was the Chair of the Authority from 2006 until 2010 when Baroness Diana Warwick became the Chair.
[263] Schedule 2 of the 2004 Act.

in a manner that is well regulated and controlled, it is accountable to the Secretary of State for Health[264] and as of April 2014, the Authority itself must adhere to the *Regulators' Code*.[265]

It must be mentioned that the HTA is only one of the United Kingdom's Competent Authorities and has the responsibility of regulating tissues and cells intended for human application but not tissues and cells derived from gametes and embryos. In such cases, the Human Fertilisation and Embryology Authority (HFEA) is the Competent Authority and bears responsibility for the regulation of gametes and embryos intended for human application.[266] As mentioned above, the activities as regulated by the HTA will be discussed somewhat at this juncture.

5.1 REGULATED ACTIVITIES

The Authority regulates research, public displays, tissue used in treatment, post-mortem examinations, organ transplantation as well as bone marrow and peripheral blood stem cell donations from living persons.[267] Each of these aspects of regulation will be discussed shortly.

5.1.1 Research

By studying human tissue, it is possible to improve our understanding of illness and disease. The HTA believes that good regulation supports good science which then leads to improved healthcare. The term "research"[268] is often used to describe a wide variety of laboratory- or treatment-based activities. The Authority regulates mostly laboratory based research and thus ensures that tissue is removed and stored in a manner that is appropriate and well managed.

The HTA licenses organisations for the removal and storage of tissue intended for research in England, Wales and Northern Ireland. This licensing role for research purposes is, however, limited to licensing premises and storing tissue from living and deceased persons. The Authority also licenses all establishments where tissue is removed from deceased persons for research purposes. The HTA does, however, not license the use of tissue for research purposes or

[264] HTA (2014) 2.
[265] For the self-assessment to which the HTA is subject, see Human Tissue Authority (2014) "HTA self-assessment against the Regulators' Code" available online at http://www.hta.gov.uk/about-is/how-we-do-it/hta-self-assessment-agianst-regulators%E2%80%99-code accessed 25/5/2015.
[266] Human Tissue Authority (2014) "EU Tissue and Cells Directives" available online at http://www.hta.gov.uk/about-us/how-we-do-it/legislation/eu-tissue-and-cells-directives accessed 25/5/2015.
[267] Department of Health (2004) 7.
[268] Research is not defined in the Human Tissue Act 2004.

approve any individual research projects or clinical trials. The Authority also does not play a role in ethical approval of research.[269]

Although the 2004 Act requires the licensing of removal of tissue from deceased persons for research, its storage is exempt from licensing. Various tissues that have been stored for research are automatically exempted as they are removed from living persons and project-specific approval from a recognised Research Ethics Committee is undertaken.[270]

5.1.2 Public Display

Human bodies and body parts may be publicly displayed in exhibitions and museums.[271] Any person wishing to donate their body for display must give prior consent while they are still alive and the HTA then assures the public that bodies or tissue from the deceased are carefully handled and treated with respect. Any organisation involved in such public display must be licensed, unless the remains were removed from persons who have been dead for more than 100 years.[272]

5.1.3 Tissue Used in Treatment

Under the direction of European Union law, the HTA licenses organisations across the United Kingdom in order to ensure the quality and the safety of all tissue and cells used in treating patients. The Authority has a similar licensing role regarding organs.

Since stem cells have the potential to become a wide variety of medicines, the HTA works closely with other regulatory bodies to achieve this goal. The Authority, however, only licenses establishments and not individual clinicians or healthcare professionals.[273]

5.1.4 Post-Mortem Examinations

Post-mortem examinations are studies of bodies after death and are usually undertaken where the cause of death is unknown, suspicious, sudden or unexpected and ordered by a coroner. In

[269] For more on the licensing role of the HTA, see paragraph 5.2.1 *infra*.
[270] HTA (2014) "About us" available online at http://www.hta.gov.uk/about-us accessed 25/5/2015.
[271] The Body Worlds Exhibition is an example of such public display of human bodies or body parts. For more on Body Worlds and the process of "plastination" see Gunter von Hagens' Body Worlds (2015) "The original exhibition of real human bodies" available online at http://www.bodyworlds.com/en.html accessed 27/5/2015.
[272] HTA (2014) "About us" online.
[273] *Ibid*.

England, Wales and Northern Ireland mortuaries are licensed and inspected by the Authority. Post-mortem regulations are provided by the 2006 Act and supplementary Regulations in the territory of Scotland.[274]

5.1.5 Organ Transplantation

Organs are transplanted into patients in an attempt to save and improve the quality of their lives.[275] Under European Union law the HTA licenses organisations to ensure the quality and safety of organs intended for transplantation in humans. As mentioned previously, the Authority has a corresponding role regarding the removal of tissue for treatment.[276] Once again, the HTA licenses establishments and not individual clinicians or healthcare professionals.[277]

5.1.6 Bone Marrow and Peripheral Blood Stem Cell Donations from Living Persons

The HTA regulates all donations of bone marrow and peripheral blood stem cells from living child and adult donors who do not have the capacity to give their consent. This is done through an independent assessment process. The Authority is greatly concerned with the task of ensuring that valid consent has been given, that the donors understand any risks involved, that donors donate of their own free will and that no reward is offered or sought for any donations.[278]

There are two ways or mechanisms whereby the HTA regulates the abovementioned activities which will now be discussed.

5.2 MECHANISMS OF REGULATION

The Human Tissue Authority regulates the abovementioned activities by making use of two methods or exercising regulatory power: firstly, by licensing the establishments which practise these activities and secondly by issuing legal documents referred to as Directions. Each of these methods or mechanisms of regulation will now be discussed.

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[274] *Ibid.*
[275] This includes the kidneys, liver, lungs and pancreas.
[276] See paragraph 5.1.3 *supra*.
[277] HTA (2014) "About us" online.
[278] *Ibid.*

5.2.1 Licensing

Under Part 2 of the 2004 Act[279] as well as the Human Tissue (Quality and Safety for Human Application) Regulations 2007,[280] the Authority licenses and inspects establishments active in the procurement, testing, processing, storage, distribution, import and export of tissues and cells intended for human application.[281] These establishments include hospitals, stem cell laboratories and tissue banks as well as privately established companies such as cord blood banks, acellular material[282] suppliers and any establishment which procures material for Advanced Therapy Medicinal Products (ATMPs).[283] The establishments which are licensed by the HTA under the direction of the Human Tissue (Quality and Safety for Human Application) Regulations 2007[284] work with various cell and tissue types which include bone, skin, heart valves, bone marrow, stem cells, chondrocytes[285] and pancreatic islets.[286]

The HTA's licensing procedure is based on the five principles of "Better Regulation," namely: transparency, accountability, proportionality, consistency and being targeted.[287] A licence will be issued to an establishment which is able to indicate that it will comply with the essential standards as set by the Authority. When an establishment applies for a licence, is must first asses itself against the standards set by the HTA. The Authority will then evaluate the information and, if need be, more information may be requested. A licence will then be issued.

Licences may be granted for the following activities according to section 16 of the Human Tissue Act 2004:[288]

(a) Carrying out of an anatomical examination;
(b) Post-mortem examinations;
(c) Removal of relevant material from the body of a deceased person for use in a scheduled purpose other than transplantation;
(d) Storage of anatomical specimens;

[279] Specifically sections 16-25 of the 2004 Act.
[280] See paragraph 5.3.2 *infra* for a discussion of these Regulations.
[281] Department of Health (2004) 7-9.
[282] Meaning material which is not made up of cells or contains no cells.
[283] ATMPs are medicines intended for human application and are based on gene therapy, somatic cell therapy or tissue engineering. For more on ATMPs see European Medicines Agency (2015) "Advanced therapy medicinal products" available online at http://www.ema.europa.eu/ema/index.jsp and European Commission (2015) "Medicinal products for human use" available online at http://ec.europa.eu/health/human-use/advanced-therapies/index_en.htm accessed 12/6/2015.
[284] See paragraph 5.3.2 *infra* for an in depth discussion of the Regulations.
[285] These are the cells found in cartilage.
[286] Human Tissue Authority (2014) "Human application" available online at https://www.hta.gov.uk/regulated-sectors/human-application accessed 25/5/2015.
[287] HTA (2014) 10.
[288] Section 16(2)(a)-(f) of the 2004 Act.

(e) Storage of the body of a deceased person or relevant material derived from a human body; and
(f) Public display of the body of a deceased person or relevant material removed from the body of such a deceased person.

A licence may however not be required in certain instances as provided for in section 16(4)(a) and (b). Furthermore, licences may be issued conditionally and dependent on the meeting of such conditions within a certain period of time.[289] The HTA may also inspect establishments to ensure that good standards are maintained and that the appropriate procedures are followed.[290] Where the licence circumstances change, the Authority may also amend the conditions attached to the specific licence in question.[291]

All licensed establishments are required to nominate an individual who will be responsible for supervising the activities carried out by the establishment. This person is known as the Designated Individual or DI and is trained by the Authority to be able to accomplish this task.[292] The DI has the duty of securing and ensuring that the other persons to whom the licence applies are suitable to participate in the activity for which the licence has been granted, that proper practices are followed in carrying out the relevant activity and that the licence conditions are complied with.[293]

The licensed establishments are required to meet the standards as set out and detailed in the Authority's *Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment*[294] which was implemented by Directions 003/2010.[295] Should a person contravene any section of the 2004 Act regarding aspects of the licensing provisions, this will constitute an offence punishable by imprisonment, a fine or both.[296]

The second mechanism of regulation as mentioned above pertains to the issuing of legal documents referred to as Directions and these will now also be discussed.

[289] Section 23 of the 2004 Act.
[290] High risk establishments are inspected before any other.
[291] Section 24 of the 2004 Act.
[292] HTA (2014) 10.
[293] Section 18 of the 2004 Act.
[294] See paragraph 5.2 *infra* for a discussion on the HTA's *Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment.*
[295] Direction 003/2010 consolidate and clarify the required standards under the 2007 Regulations. See paragraph 5.3.3 *infra* for more on the HTA Directions.
[296] Section 25 of the 2004 Act.

5.2.2 Human Tissue Authority Directions

Policy-making powers have been bestowed upon the HTA by the 2004 Act by providing the Authority with the power to create and issue Codes of Practice as well as Directions.[297] These Directions could be best described as the standards expected by the Authority from establishments. The Authority may therefore issue general Directions to establishments which take into account any changes in legislation or policy which might affect the establishment, its functioning or licensing. The Authority may also issue Directions which are establishment-specific or will only influence aspects of that particular establishment.[298] In this manner, the Authority is able to prescribe the essential requirements to be met by establishments which have been licensed by the HTA and in so doing, the HTA exercises regulatory control over the activities practised by the establishments.

The HTA has issued various Directions which cover a broad range of subjects all of which are not specifically relevant to this thesis. Some of these Directions include, but are not limited, to:[299]

1. Directions implementing the requirements of the European Union Tissue and Cells Directive as well as the First Technical Directive;
2. Directions bringing into force certain HTA Codes of Practice;
3. Directions provided under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which in turn implement the European Union Tissue and Cells Directive's Parent Directive requirements as well as those of the First and Second Technical Directives;
4. Further Directions bringing into force HTA Codes of Practice;
5. The Directions which consolidate and clarify the standards set under the Human Tissue (Quality and Safety of Tissues and Cells for Human Application) Regulations 2007;
6. Directions on the removal of tissue from the body of a deceased person;[300]
7. Directions which bring into force compliance reporting for establishments with a certain licence such as public display, anatomy or research licences for example;
8. Directions on licensing fee structures for certain financial years;
9. Directions on post-mortem storage of relevant material; and
10. Directions on research.

[297] See paragraph 5.3.2 *infra* for the discussion of the relevant Codes of Practice.
[298] Human Tissue Authority (2015) "HTA legal directions" available online at https://www.hta.gov.uk/policies/hta-legal-directions accessed 12/6/2015.
[299] HTA (2015) "HTA legal directions" online. See also HTA Directives 001/2006; 002/2006; 003/2007; 002/2009; 003/2010; 002/2012; 005/2013; 004/2013; 003/2013; 004/2013; 002/2015; 003/2015; 006/2015 and 007/2015.
[300] HTA Direction 002/2012.

5.3 LEGISLATION

The Authority works under the empowerment of the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The HTA attempts to ensure adherence to these legislative documents by setting standards in practice which are clear and reasonable and wherein both the public and the relevant professions will have confidence. These laws ensure that human cells and tissues are used safely and ethically and with the required necessary consent. The following is therefore an explanation of the relevant legislation under which the HTA functions. The mentioned Regulations were brought into force by the European Union Tissue and Cells Directives which will therefore also be discussed.

5.3.1 Human Tissue Act[301]

The Human Tissue Act 2004, which created the HTA and underpins most of the Authority's remit, governs England, Wales and Northern Ireland while Scotland is governed by the Human Tissue (Scotland) Act 2006. The HTA does, however, have certain powers and performs certain tasks on behalf of the Scots Government such as approving transplants from living donors and licensing the organisations using human tissue in patient treatments.[302]

As stated above, the HTA was created by the 2004 Act which prescribes the establishment, remit and general functions of the Authority in sections 13 to 15. Schedule 2 to the Act provides for further, more detailed provisions regarding the administration and running of the HTA.

The Authority covers the removal, use, storage, import and export of a human body as well as any relevant material of which the body consists or contains, such as organs or cells, for any of the scheduled purposes.[303] These scheduled purposes include *inter alia* research, transplantation, education and training.

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[301] As mentioned previously, the Human Tissue Act 2004 repealed the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 in England and Wales as well as the Northern Irish Orders.
[302] HTA (2014) 8.
[303] Section 14: "**Remit -**
(1) The following are the activities within the remit of the Authority-
(a) the removal from a human body, for use for a scheduled purpose, of any relevant material of which the body consists or which it contains;
(b) the use, for a scheduled purpose, of-
(i) the body of a deceased person, or
(ii) relevant material which has come from a human body;
(c) the storage of an anatomical specimen or former anatomical specimen;
(d) the storage (in any case not falling within paragraph (c)) of-
(i) the body of a deceased person, or
(ii) relevant material which has come from a human body, for use for a scheduled purpose;
(e) the import or export of-
(i) the body of a deceased person, or

The general functions of the HTA include maintaining a statement of general principles which are to be followed in carrying out the activities within the remit of the Authority; providing oversight and guidance to those whom the HTA regulate; superintending; providing information to the public and those who practise any of the activities regulated by the Authority; monitoring any developments in the field, and advising the Secretary of State, the National Assembly of Wales and the relevant department for Northern Ireland.[304]

As previously mentioned, Schedule 2 to the 2004 Act provides for administrative matters related to the HTA. For the sake of completion, these matters will be briefly listed here. They are: membership of the HTA; disqualification of person as chairperson; tenure of office of the chair; remuneration and pension of members; staff; the proceedings of the Authority; members' interests; finance as well as accounts and audits; the instruments of the HTA; status of the Authority and supplementary powers; the application of Statutory Instruments Act 1946;[305] public records; investigation by a Parliamentary Commissioner; the disqualification of the House of Commons and of the Northern Ireland Assembly and freedom of information.

5.3.2 Human Tissue (Quality and Safety for Human Application) Regulations 2007

The Human Tissue (Quality and Safety for Human Application) Regulations of 2007, hereafter referred to as the Q&S Regulations, fully implemented the European Union Tissue and Cells

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(ii) relevant material which has come from a human body, for use for a scheduled purpose;
(f) the disposal of the body of a deceased person which has been-
(i) imported for use,
(ii) stored for use, or
(iii) used, for a scheduled purpose;
(g) the disposal of relevant material which-
(i) has been removed from a person's body for the purposes of his medical treatment,
(ii) has been removed from the body of a deceased person for the purposes of an anatomical, or post mortem, examination,
(iii) has been removed from a human body (otherwise than as mentioned in subparagraph (ii) for use for a scheduled purpose,
(iv) has come from a human body and been imported for use for a scheduled purpose, or
(v) has come from the body of a deceased person which has been imported for use for a scheduled purpose.
(2) Without prejudice to the generality of subsection (1)(a) and (b), the activities within the remit of the Authority include, in particular-
(a) the carrying out of an anatomical examination, and
(b) the making of a post-mortem examination.
(3) An activity is excluded from the remit of the Authority if-
(a) it relates to the body of a person who died before the day on which this section comes into force or to material which has come from the body of such a person, and
(b) at least one hundred years have elapsed since the date of the person's death.
(4) The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority.
(5) In this section, "relevant material", in relation to use for the scheduled purpose of transplantation, does not include blood or anything derived from blood."

[304] Section 15 of the 2004 Act.
[305] Statutory Instruments Act 1946 (c.36).

Directive (EUTCD) on 5 July 2007. It extended the remit of the HTA by including thereto the regulation of procurement, testing, processing, storage, distribution as well as import and export of cells and tissues. Establishments where any of these activities are carried out will thus need to be licensed by the HTA under the Q&S Regulations. These establishments will also be required to meet the standards as set out by the *Guide to Quality and Safety Assurance of Human Tissue and cells for Patient Treatment*,[306] hereafter referred to as the Q&S Guide, which was implemented by HTA Direction 003/2010. This Direction consolidates as well as clarifies the required standards in terms of the Q&S Regulations.[307]

The Q&S Regulations cover a vast number of matters but do not specifically provide for consent. The Q&S Guide therefore supplements the Regulations in this regard. Both these instruments will now be discussed with attention given to the aspects most relevant to this thesis.

The Q&S Regulations are divided into seven parts and have three schedules. Part 1 stipulates the citation, commencement, extent and interpretation of the Regulations. Provision is made for the citation and commencement, extent and application, and designation of competent authorities; reference is made to the Directives and to the interpretation of other terms which provide definitions and references to third party agreements. Here it is interesting to note that the whole of the Regulations apply to England, Wales and Northern Ireland while only Parts 1 to 5 and 7 and the relevant schedules thereto apply to Scotland. The Regulations then do not apply to the processing, preservation, storage, distribution, import and export of human tissues and cells or the manufacture of products made from these materials where these activities are regulated by other specified legislative documents.[308]

Part 2 covers aspects of licensing of activities relating to the use of tissue for human application. This includes licensing requirements; the application of the 2004 Act; the extension of certain provisions of the 2004 Act to Scotland; breach of the requirement to hold a licence or to act under a third party agreement; the preconditions to granting of licence to an establishment; the duties of the designated individual; information and confidentiality aspects and provisions for the breach of the confidentiality requirement. Licensed activities with specific reference to the import and export of tissue and cells and compliance with the Parent, First Technical and Second Technical Directives are regulated by Part 3.

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[306] Human Tissue Authority (2010) *Guide to quality and safety assurance of human tissue and cells for patient treatment*.
[307] These Directions revoke Directions 001/2006, 002/2007 and 004/2007.
[308] These are the Medicines (Homeopathic Medicinal Products for Human Use) Regulations 1994; the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994; the Medical Devices Regulations 2002 or the Medicines for Human Use (Clinical Trials) Regulations 2004.

Part 4 stipulates the obligations of the Authority. These are, according to the Q&S Regulations: the requirement for the Authority to provide information; the obligation to keep a register of licences as well as a register of serious adverse events and serious adverse reactions and it provides for the duties of the Authority in relation to serious adverse events and serious adverse reactions. Part 5 elaborates on the obligations of the Human Tissue Authority by providing for inspection, entry, search and seizures.

Part 6 regulates amendments to the 2004 Act to the extent of the remit of the Authority, and any exclusion from licensing requirements and Part 7 deals with general provisions such as offences by the bodies corporate and transitional arrangements regarding storage licences. The three Schedules to the Q&S Regulations deal with licences;[309] directions for securing compliance with the EUTCD[310] and certain appropriate statements.[311]

The Q&S Guide explains the requirements for licensing for the storage of tissues and cells for human application as well as licensing of third party agreements for the procurement, testing, processing, distribution, import and export of tissues and cells intended for human application. The Guide is based on the Q&S Regulations as well as the standards set by the EUTCD. The consent requirements are set out in accordance with these documents but also take into account the 2004 Act. The Scottish tissue and cell establishments therefore need to refer to the 2006 Act.[312]

The Q&S Guide states that any tissue or cell establishment must comply with the Human Tissue Act 2004 as well as the HTA Codes of Practice.[313] The establishment must further ensure that consent information is provided to a donor prior to any donation and then in a manner compliant with the 2004 Act and the Code.[314] It must also be ensured by the establishment that:[315]

1. The donor is given information by trained personnel in a manner and using terms which are easily understood;
2. The information covers at least the following:
   a. The purpose and nature of the donation;
   b. The consequence and risks thereof;
   c. Any analytical tests that are to be performed;

[309] Schedule 1 of the Q&S Regulations.
[310] Schedule 2 of the Q&S Regulations.
[311] Schedule 3 of the Q&S Regulations.
[312] HTA (2010) 2.
[313] See paragraph 6 *infra* for the discussion of the Code of Practice on consent.
[314] HTA (2010) 22.
[315] This overlaps with the provisions of the Parent Directive. See paragraph 5.3.3.1 *infra*.

d. The manner of recording and protection of donor data and medical confidentiality;
e. Any therapeutic purposes and potential benefits of the donation; and
f. All information on the applicable safeguards intended to protect the prospective donor.

3. The prospective donor must be informed that they have the right to receive the confirmed results of any analytical tests which have been performed on their donations; and
4. The prospective donor must be informed of the necessity for obtaining their consent prior to the procurement of the donation.

In the event of deceased donors, the results of any tests must be communicated and explained to the person who consented to the donation. The Q&S Guide also states that no tissues or cells may be procured without lawfully obtained prior consent and this thus reiterates the importance of this principle.

5.3.3 European Union Tissue and Cells Directives

The European Union Tissue and Cells Directives (EUTCD) were adopted by the Council of Ministers on 2 March 2004 and published in the Official Journal of the European Union on 7 April 2004. Member States, which include the United Kingdom, were obliged to comply with the provisions thereof from 7 April 2006. In order to comply with the EUTCD the Human Tissue Authority commenced licensing the storage of human tissue and cells. The Authority also issued two further Directives which will be discussed below.

The EUTCD attempts to establish a harmonised approach in the manner wherein tissues and cells are regulated across the European continent. The Directives therefore provide a benchmark for the standards which are to be met in undertaking any activity which involves cells and tissues intended for human application or patient treatment. The Directives also require that a tracing system be in place whereby the donor and the recipient may be connected.[316]

[316] HTA (2014) "EU Tissue and Cells Directives" online.

The EUTCD is comprised of three separate Directives, namely the Parent Directive which sets framework legislation,[317] as well as the First Technical Directive[318] and the Second Technical Directive[319] which provide certain detailed requirements.

The EUTCD were fully incorporated into the law of the United Kingdom on 5 July 2007 by the Human Tissue (Quality and Safety for Human Application) Regulations. The three Directives which make up the EUTCD will now be discussed briefly. Emphasis will be placed on provisions related to consent as it is the focus of this thesis.

5.3.3.1 Parent Directive of 31 March 2004

The Parent Directive commences by reiterating that the quality and safety of human tissues and cells must be ensured in order to prevent transmission of diseases and to safeguard public health. It further states that it is necessary to promote information and awareness of these matters. Also, strikingly, it emphasises that as a matter of principle, tissue and cell application programmes must be founded on a philosophy of voluntary and unpaid donations, anonymity of both the donor and the recipient, altruism of the donor and solidarity between the donor and recipient. According to this Directive, this is a contributory factor to high safety standards for tissues and cells and so in the protection of human health.

The Parent Directive provides for various matters. Firstly, general provisions as contained in Chapter I of the Directive are dealt with.[320] The objective of the Directive is stated as laying down standards of quality and safety for human tissues and cells intended for human application in order to ensure a high level of protection of human health. The Directive then applies to all donations, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human application and the manufacture of products derived from human tissues and cells intended for human application. The general provisions

[317] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells.
[318] Directive 2006/17/EC of 8 February 2006 Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards Certain Technical Requirements for the Donation, Procurement and Testing of Human Tissues and Cells.
[319] Directive 2006/86/EC of 24 October 2006 Implementing Directive 2004/23/EC of the European Parliament and of the Council as regards Traceability Requirements, Notification for Serious Adverse Reactions and Events and Certain Technical Requirements for the Coding, Processing, Preservation, Storage and Distribution of Human Tissues and Cells.
[320] Articles 1-4 of the Parent Directive.

also include relevant definitions and the provisions regarding the implementation of the Directive.[321]

Chapter II of the Directive then makes provision for the obligations on member states which comprise the supervision of human tissue and cell procurement; accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes; inspection and control measures; traceability; provisions related to import and export of human tissues and cells; a register of tissue establishments and reporting obligations and notification of serious adverse events and reactions.[322]

Donor selection and evaluation provisions are regulated in Chapter III of the Directive and include provisions regarding the principles governing tissue and cell donations; consent which will be discussed in more detail below;[323] data protection and confidentiality and selection, evaluation and procurement.[324]

Chapter IV pertains to provisions on the quality and safety of tissues and cells and provides for quality management; the responsible person; personnel; tissue and cell reception; tissue and cell processing; tissue and cell storage conditions; labelling, documentation and packaging; distribution and the relationships between tissue establishments and third parties.[325] Chapter V deals with the exchange of information, reports and penalties as well as coding of information[326] while Chapter VI regulates the consultation of committees[327] and lastly Chapter VII deals with the final provisions.[328]

As stated above, the issue of consent deserves further attention. Article 13 contains the consent requirement of the Directive and must be read with the Annexure to the Directive. According to this article, the procurement of human tissue or cells may be authorised only after all

[321] Article 3 of the Parent Directive. Some of these definitions which are also relevant to this thesis include: "cells" which means individual human cells or a collection of human cells when not bound by any form of connective tissue; "tissue" meaning all constituent parts of the human body formed by cells; "donor" which means every human source, whether living or deceased, of human cells or tissues; "donation" meaning donating human tissues or cells intended for human applications; "procurement" which means a process by which tissue or cells are made available; "storage" meaning maintaining the product under appropriate controlled conditions until distribution; "distribution" which means transportation and delivery of tissues or cells intended for human applications; "human application" meaning the use of tissues or cells on or in a human recipient and extracorporeal applications; and "tissue establishment" which means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells.
[322] Articles 5-11 of the Parent Directive.
[323] Article 13 of the Parent Directive.
[324] Articles 12-15 of the Parent Directive.
[325] Articles 16-24 of the Parent Directive.
[326] Articles 25-27 of the Parent Directive.
[327] Articles 28-30 of the Parent Directive.
[328] Articles 31-33 of the Parent Directive.

mandatory consent or authorisation requirements are met.[329] The donor, a relative of the donor or any person granting consent on behalf of the donor must, in keeping with the national legislation, be provided with all the appropriate information as required by the Annexure.

The Annexure to the Directive establishes the information to be provided in the donation of cells and tissues and distinguishes between living and deceased donors. In the event of a living donor, the donor must, prior to the procurement of the donation, be furnished with the following information by the person who is in charge of the donation process:

1. The necessity of consent must be explained to the donor in order to proceed with the procurement;
2. The purpose and nature of the procurement;
3. The consequences and risks thereof;
4. The possibility of analytical tests if they are to be performed;
5. Aspects regarding the recording and protection of donor data and medical confidentiality;
6. The therapeutic purpose and potential benefits which may be derived from the donation;
7. Information on the applicable safeguards intended to protect the donor; and
8. The donor must be informed that they have the right to receive the confirmed results of the analytical tests and to have these tests clearly explained to them.

This information must be given to the donor by a trained person who is able to transmit it in a clear and appropriate manner and by making use of terms easily understood by the donor.

In the event of a deceased donor, all information must be given and consent obtained in accordance with national legislation, and the confirmed result of any evaluation of the donor must be communicated and clearly explained to the person who granted consent. The Parent Directive is implemented by the First and Second Technical Directives and so a discussion of these Directives is also important at this juncture.

5.3.3.2 First Technical Directive of 8 February 2006

The First Technical Directive implements the Parent Directive and covers aspects regarding donation, procurement and testing of human tissues and cells. This Directive also contains provisions aimed at promoting the quality and safety of human tissues and cells but further also

[329] Article 13(1) of the Parent Directive.

contains provisions related to reproductive cells as these cells have specific qualities and characteristics which need to be taken into account.[330]

As the First Technical Directive to an extent supplements the Parent Directive, it contains certain definitions which are omitted in the Parent Directive.[331] It further provides for the requirements for the procurement of human tissues and cells;[332] the selection criteria for donors of tissues and cells;[333] laboratory tests required of donations;[334] tissue and cell donation and procurement procedures and the reception thereof at the tissue establishment;[335] the requirements for direct distribution to the recipient of specific tissues and cells;[336] and transposition.[337] The First Technical Directive also has 4 annexes which provide detailed practical guidelines for the above mentioned provisions.

5.3.3.3 Second Technical Directive of 24 October 2006

The Second Technical Directive is also a supplementary Directive to the Parent Directive and deals with matters regarding traceability requirements, notification for serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells. It therefore lays down the quality and safety standards for donation, procurement, testing, coding, processing, preservation, storage and distribution of human tissues and cells intended for human applications and the manufacture of products derived from such tissues and cells to be used in human applications. This Directive calls for the establishment of specific technical requirements for each of the steps in the process of human application. The Directive applies to coding, processing, preservation, storage and distribution of human tissues and cells and the

[330] For example, donations of reproductive cells between partners who have an intimate physical relationship are subject to less stringent biological testing.
[331] Article 1 of the First Technical Directive. These include: "reproductive cells" which means all tissues and cells intended to be used for the purpose of assisted reproduction; "partner donation" meaning the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship; "direct use;" "quality system;" "standard operating procedures;" "validation (or 'qualification' in the case of equipment or environments;" "traceability" and "procurement organisation." Only the definitions of most relevance to the current discussion and which are of interest here have been provided.
[332] Article 2 of the First Technical Directive. These requirements include *inter alia* that procurement be done at an accredited, designated, authorised or licensed establishment; that it be done by a person who has successfully completed a specific training programme; that standard operating procedures must be in place and that any procurement must take place in an environment which ensures safety and privacy.
[333] Article 3 of the First Technical Directive.
[334] Article 4 of the First Technical Directive.
[335] Article 5 of the First Technical Directive.
[336] Article 6 of the First Technical Directive.
[337] Article 7 of the First Technical Directive.

manufacture of products from these materials but does not extend to the application of tissues and cells.[338]

The content of this Directive includes definitions;[339] requirements for the accreditation, designation, authorisation or licensing of tissue establishments;[340] requirements for the accreditation, designation, authorisation or licensing of tissue and cell preparation processes;[341] notification of serious adverse reactions;[342] notification of serious adverse events;[343] annual reports;[344] communication of information between competent authorities and the European Commission;[345] traceability;[346] the European Coding System,[347] and transposition.[348] Annexes I to VI of the Directive provide detailed practical guidance regarding the above.

At the conclusion of the discussion of the legislation which underpins the Human Tissue Authority, the last section of this chapter will now focus on the HTA Codes of Practice as they illustrate the practical advisory and supervisory function of the HTA.

6 CODES OF PRACTICE

The Human Tissue Authority produced nine Codes of Practice which provide professionals with practical guidance on human tissue legislation such as the 2004 and 2006 Acts.[349] The Codes were last updated in 2014 in order to reflect the most recent policy decisions and legal advice.[350] The Codes were, however, set to be more significantly reviewed during 2015, and in 2016, Draft Codes of Practice were made available.[351] Although the Codes are not strictly

[338] Such as insemination, implantation, perfusion, surgery or embryo transfer.
[339] Article 2 of the Second Technical Directive.
[340] Article 3 read with Annexure I of the Second Technical Directive.
[341] Article 4 read with Annexure II of the Second Technical Directive.
[342] Article 5 read with Annexure III of the Second Technical Directive.
[343] Article 6 read with Annexure IV of the Second Technical Directive.
[344] Article 7 read with Annexure V of the Second Technical Directive.
[345] Article 8 of the Second Technical Directive.
[346] Article 9 read with Annexure VI of the Second Technical Directive.
[347] Article 10 of the Second Technical Directive.
[348] Article 11 of the Second Technical Directive.
[349] Department of Health (2004) 9.
[350] HTA (2014) "Codes of practice" available online at http://www.hta.gov.uk/codes-practice accessed 25/5/2015.
[351] The Draft Code offers professionals guidance on informing persons of their options and seeking consent for the use of tissue, organs and cells. It differs from the previous Code in that it introduces four new guiding principles which must inform the actions of any person working under the HTA. These principles are consent, dignity, quality as well as honesty and openness. The Draft Code further brings together generic information regarding consent; provides general guidance to all sectors rather than provide sector-specific guidance; includes advanced information regarding the remit of the HTA; explains the relationship between the Codes; explains the legal position on limiting consent; provides some clarity on the legal position regarding donated material and removes all information regarding DNA. See in general Human Tissue Authority (2016) *A-Guiding principles and fundamental principle of consent: Draft code of practice* available online at https://www.hta.gov.uk/sites/default/files/files/Code%20A.pdf accessed 7/7/2016. See also Human Tissue Authority (2016) *Code A: Principles and consent* available online at https://www.hta.gov.uk/sites/default/files/General%20Code%20A%20principles%20and%20consent%20for%20website.pdf accessed 7/7/2016.

speaking law, any person who fails to observe the provisions thereof may be held liable to any legal proceeding, and any non-adherence to a Code may also be taken into account by the HTA in carrying out its licensing functions.[352]

The discussion which is to follow will be divided into two sections. The first will deal with the provisions regarding the Codes of Practice as found in the 2004 Act and the second will deal with the content of the most relevant Code namely the *Code of Practice: Consent*.

Sections 26 to 29 of the 2004 Act provide for the preparation of the Codes, provisions with respect to consent within the Codes, the effect of the Codes, and their approval.[353] According to section 26 of the 2004 Act, the HTA may prepare Codes of Practice for the purpose of giving practical guidance to persons involved in carrying out the activities permitted by the Act and laying down the standards expected in carrying out such activities. These Codes may deal with certain varied matters[354] but an express obligation is placed on the Authority to issue a Code dealing with consent.[355]

Specified provisions regarding consent are then set out in section 27. These provisions focus mainly on the person in a qualifying relationship to the donor who may grant consent on behalf of the donor of any material and ranks these persons in a specific order.[356] Instances of persons of the same rank are also dealt with as well as those circumstances wherein a person's relationship to the donor may be left out of account.[357]

The HTA issued nine Codes which were originally brought into force by HTA Directions in September 2009.[358] Only the Consent Code as the most relevant to this study will be discussed here. The Human Tissue Act 2004 specifies whose consent is necessary in all relevant circumstances but it does not provide the details surrounding when and how consent should be sought or what information should be provided. The Consent Code therefore offers advice on

[352] Section 28 of the 2004 Act. The Codes of Practice remain in force until the new, updated Codes are finalised. At the date of publication of this thesis, this had not been done. See in general Human Tissue Authority (2016) "Launch of draft HTA Codes of practice and standards" available online at https://www.hta.gov.uk/launch-draft-hta-codes-practice-and-standards accessed 7/7/2016.
[353] The HTA may not issue a Code unless a draft has been sent to the Secretary of State who must bring it before both houses of Parliament, the National Assembly for Wales as well as the Northern Ireland Assembly. See section 29 of the 2004 Act for the details of the approval process.
[354] These include the carrying out of anatomical examinations; storage of anatomical specimens; the storage and disposal of former anatomical specimens; the definition of death for the purposes of the 2004 Act; communication with the family of the deceased regarding the post-mortem examination; the carrying out of post-mortem examinations; communication with the family of the deceased regarding the removal from the body of the deceased any relevant material; the removal of a human body; storage of a body or relevant material; the import and export of a body or relevant material; the disposal of relevant material which has been removed from a human body.
[355] Section 26(3) of the 2004 Act states that "…the Authority shall, in particular, deal with consent."
[356] See paragraph 2.5.4 *supra* for this ranking of qualified persons.
[357] Section 27(6)-(8) of the 2004 Act.
[358] Human Tissue Authority (2014) *Code of practice 1: Consent*: 4.

these matters. The Code addresses the need for consent and the closely related matters of communication and consultation with patients or other individuals.[359]

According to the Code the following six issues are central to the provisions of consent contained in the 2004 Act:[360]

1. Whether or not consent is required;
2. What would constitute the appropriate consent in the particular circumstances;
3. What would constitute valid consent:
4. The scope of consent;
5. The duration of consent; and
6. The withdrawal of consent.

In order to determine whether or not consent is required, it must be kept in mind that under the 2004 Act, consent relates to the purpose for which the relevant material might be removed, stored or used. These purposes are the so called "scheduled purposes" which have been discussed in the course of this chapter. Broadly speaking, consent is required where human bodies or relevant material is to be stored, used or where material is to be removed. Consent to research or treatment is largely governed by common law and, where appropriate, the Mental Capacity Act 2005.[361]

The 2004 Act is clear on what constitutes the appropriate consent and defines it in terms of the person who may consent to a proposed purpose. This is thus either the person concerned, a nominated representative of that person or consent from a person in a qualified relationship.[362]

Consent is understood as a positive act and so, in order for consent to be valid, it must be given voluntarily by the appropriate person who has the capacity to understand the proposed purpose and the risks involved. Here, the experience and sensitivity of the health care professional attempting to obtain consent becomes relevant, as this process must be treated with respect despite the scope and duration of the sought after consent and since the persons whose consent is sought must be given the necessary information. It must be clear that consent has been obtained prior to any removal, storage or use of materials in order for this activity to be lawful, and obtaining such consent presupposes that the consenting person had the

[359] *Idem* 5.
[360] *Idem* 7.
[361] See chapters 3 and 3 *supra* for the discussion on consent in South Africa as South African medical law is based on the common law referred to here.
[362] HTA (2014) *Code of practice* 8.

necessary information and time to make an informed decision.[363] The necessity of sufficient information and time to consider said information has been discussed previously in this thesis.[364]

The scope of consent will differ in each case and may be generic or specific according to the Code. The Code states that generic consent typically applies to research, as it avoids the need to obtain further consent as the research develops. It is still important for this consent to be valid. From this it may also be assumed that specific consent is preferred for medical treatments.[365] This is in line with the premise of this thesis that a new model of consent is required in instances where medical treatment is tantamount to research involving human subjects. This thesis argues that both the traditionally accepted models of informed or broad consent are insufficient in the context of stem cell therapy-research and a new format is necessary. This argument may be substantiated here as the Code itself distinguishes between specific or informed consent in context of medical treatments and generic or broad consent in context of research participation.

Consent may differ in duration and it may be enduring or time-limited. Enduring consent remains in force until it is revoked. A person may, however, specify a time limit for the period they wish for the consent to be in force. In either instance, their decision should be properly and clearly documented. The dynamic model introduced in the course of this thesis offers a mechanism whereby this may be easily achieved.

Lastly, consent may be withdrawn at any time whether it is generic or specific. Withdrawal of consent should be discussed at the onset of any proposed activity while consent is being sought. Withdrawal need not mean that whatever material must be destroyed, but any sample for which consent has been revoked may no longer be used or stored for the purpose for which consent was originally obtained.[366]

Some further issues which are dealt with in the Code relate to when consent must be sought, who must seek consent and in what format consent must be obtained. Consent is usually sought in a clinical setting for treatment or research and where possible it should be sought prior to the proposed treatment or research. Preferably, enough time should be allowed to discuss what the

[363] *Ibid*. It must be noted that where a person does not consent to a particular activity, this may not affect any investigation or treatment they receive.
[364] See chapter 4 *supra*.
[365] HTA (2014) *Code of practice* 9.
[366] *Idem* 10.

procedure entails as well as other pertinent matters such as the expected benefits or possible risks.[367]

The health care professional is usually tasked with obtaining consent from the concerned person. This is in line with the South African position. It is recommended that procedures be in place setting out the responsibility of the person who must obtain consent. It is important that the person obtaining consent be sensitive to the situation and must have a good understanding of the purpose for which consent is sought. They must be able to answer any questions the concerned person has and for this reason such person should have successfully completed training in the relevant fields.[368] The Mental Capacity Act 2005 also comes into play here and must be taken into account in circumstances where adults are unable to make decisions due to temporary or permanent incapacity.[369]

The Code also provides for aspects regarding religion, belief and culture as well as communication. In brief, the Code states that the religion, belief and culture of the person from whom consent is sough should be respected. Also, consideration must be given to the first language of such a person, and where possible, they should be provided with the relevant information in a language that they understand.[370]

As previously mentioned, the 2004 Act does not specify the format wherein consent should be obtained and the format will therefore depend on the particular circumstances.[371] It is, however, submitted that written consent should always be obtained for treatment or research using stem cells and then in a dynamic format, as will be discussed in the course of this thesis.[372] Written consent serves as evidence of consent but a mere signature on a form does not constitute proper valid consent and, for this reason, procedures need to be in place to ensure that consent is lawfully obtained. In circumstances where written consent is not required, the Code states that consent should be clearly recorded on any patient records. The record must reflect when consent was granted and for which purposes.[373]

In summary, the Code therefore states that, in the event of a proposed scheduled purpose activity, consent must be obtained from the person concerned, their nominated representative or a person in a qualified relationship. The obtained consent must be valid, meaning that it must have been given voluntarily and by a person who is able to understand the proposed purpose

[367] *Idem* 11.
[368] *Idem* 12.
[369] *Idem* 13.
[370] *Idem* 14.
[371] Written consent is only explicitly required in instances of anatomical examination and public display.
[372] See chapter 9 *infra*.
[373] HTA (2014) *Code of practice* 13.

and risks of the removal, storage or use of the material. The consent does not have to be obtained in a specific format but it should be documented. Consent may be either enduring or time-limited and it may be withdrawn at any time.

Consent must be obtained prior to the commencement of the proposed activity and by a trained health care professional who is sensitive to the process and has sufficient knowledge to answer any questions by the concerned person. Regard must be given to the concerned person's religion, belief, culture and language proficiency.[374]

7 CONCLUSION

The object of this chapter was a comparative and explanatory examination of the regulatory environment of human material intended for removal, storage and use with specific attention given to the consent provisions regarding these matters as found in the United Kingdom. Not only is South African medical law influenced by the laws and common law of the United Kingdom, but the South African Constitution also encourages comparative examinations of foreign law. With a history of biomedical regulation reaching back to the 1970's, the UK is therefore an ideal example to be studied and drawn from.

In the course of this chapter the Human Tissue Act 2004 as well as the Human Tissue (Scotland) Act 2006 were discussed in relation to the scope of the Acts, the activities permitted under the particular Acts, the consent or authorisation provisions and the existence of any exemptions to the requirement of consent or authorisation and the offences under the Acts. Other supplementary legislative documents were also identified and discussed as falling under the empowering provisions and issued instruments of the Human Tissue Authority. Regarding the HTA, activities regulated, the mechanisms of regulation, relevant legislation regarding the HTA and the Codes of Practices issued by the Authority were discussed.

The 2004 Human Tissue Act was assented to on the 15th of November 2004 and is a consolidation of previous legislation to regulate the removal, storage, use and disposal of human bodies, organs and tissues. This is an Act of the Parliament of the United Kingdom and does not extend to Scotland. The Scottish counterpart is the 2006 Human Tissue (Scotland) Act. The English Act includes various provisions which deal with a wide variety of matters and thus also

[374] This matter requires some delicacy, especially in a multicultural society such as South Africa as these aspects are also constitutionally protected in the South African Bill of Rights. See section 15 of the South African Constitution.

generally regulates biobanks. Biobank regulation is not specifically discussed in this thesis, however, as it falls outside the ambit of this study.[375]

The 2004 Act contains rules regarding the removal and storage of human organs and other tissue, the regulation of activities involving human tissue which includes licensing, codes of practice and even trafficking. Lastly, miscellaneous and general provisions are also provided for in the 2004 Act. The 2004 Act is divided into three parts which provide for removal, storage and use of human organs and other tissue for scheduled purposes; the regulation of activities involving human tissue and miscellaneous and general provisions.

Part 1 of the Act relates, *inter alia*, to consent and establishes requirements for obtaining the appropriate consent for the regulated activities under the Act. Appropriate consent is defined with reference to the person who may consent to an activity or for a nominated representative to make decisions on their behalf. It is important to note that consent is the cornerstone of the 2004 Act and acts as a foundational principle to numerous provisions found in Act.

The 2004 Act requires consent for research in three situations: firstly, where tissue from a living person is to be used and the sample is identifiable; secondly, where a sample from a living person has been anonymised but the research study is not approved by a NHS Research Ethics Committee; and thirdly, where the tissue is collected from a deceased person after 1 September 2006 and has been anonymised or is identifiable. Adults with capacity must consent to an activity themselves but in instances of incapacity, consent must be obtained in accordance with the Mental Capacity Act 2005. In certain instances, consent may also be deemed to exist. In the case of a deceased adult who had not given consent prior to their death, a nominated representative of that person may grant consent to an activity on their behalf. A nominated representative may be either a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half-sibling or longstanding friend.

Where children are involved, a distinction is made between living and deceased children. Where a child is alive and below the age of 16 years, a person with parental responsibility may consent on their behalf where the child is incompetent to or cannot make decisions. Where a child has died before reaching the age of 16 and such child did not decide to consent or was incompetent, a person with parental responsibility may also grant consent. Where no such person exists, a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half sibling or longstanding friend may do so. Existing holdings and material created outside of the human body are exempt from consent requirements under the 2004 Act.

[375] For more on the regulation of biobanks in the United Kingdom see Prinsen L (2015) "Meeting the standard: An overview of European Biobank regulation and a comparison to the current South African position" *African Journal of International and Comparative Law* 23(1): 54-73.

It is noteworthy that the position as set out in the 2004 Act is very similar to the South African and international legal position on the matter of consent where new medical treatment, whose efficacy has not been tested borders on research involving human subjects. It is also important to note that once again consent is given primary and pivotal status as regulatory instrument but the format is not specified. Although the 2004 Act applies, Northern Ireland has no specific legislation of its own dealing with these matters.

The 2006 Scottish Act is an Act of the Scottish Parliament which consolidates all previous legislation dealing with human tissue. The Scottish Act creates broad rules which deal with, *inter alia*, transplantation, post-mortem examinations and tissue samples or organs which are no longer necessary for Procurator Fiscal purposes. The Scottish Act regulates research using organs, tissues and samples from deceased persons but not research using tissue from living donors. It is, however, still of informative value regarding the person from whom consent may be obtained.

In terms of the 2006 Act, authorisation is required for the removal and use of post-mortem tissue samples intended for research. Adults are persons over the age of 16 in Scotland, and may authorise such removal, use and storage of organs, tissue or samples for research purposes themselves. Where an adult is incapacitated they may nominate a person or a nearest relative to grant authorisation on their behalf. Authorisation may be written or verbal.

A child who is over the age of 12 may authorise activities themselves on condition that they are competent to do so. A nominated person or person with parental responsibility may give authorisation on behalf of a child where they are not competent. Any authorisation, by the child or representative person, as well as the withdrawal thereof must be written and signed. Where a child is below the age of 12, only a person with parental responsibility may grant authorisation in relation to that child. Although existing holdings are exempt from authorisation requirements, principles of good practice dictate that authorisation and/or consent should be obtained for use of all tissue samples for research, where possible.

The 2004 and 2006 Acts, however, do not regulate matters related to human tissues and cells on their own and it was found that there are various legal instruments have a bearing on these issues in the United Kingdom. These subsidiary instruments include the Human Tissue (Quality and Safety for Human Application) Regulations of 2007, the *Guide to Quality and Safety Assurance of Human Tissue and Cells for Patient Treatment*, the European Union Tissue and Cells Directives as well as certain Codes of Practice.

The Q&S Regulations fully implemented the EUTCD and extended the remit of the HTA by bringing the regulation of procurement, testing, processing, storage, distribution as well as import and export of cells and tissues under the regulatory authority of the HTA. In practice this means that the HTA under the Q&S Regulations must license any establishments carrying out any of the aforementioned activities. Additionally, the standards set by the Q&S Guide will have to be met by these licensed establishments. The Q&S Regulations, although dealing with a multitude of matters, do not specifically provide for consent. This aspect is provided for in the Q&S Guide.

The Q&S Guide provides for compliance with the 2004 Act and the HTA Codes of Practice. It also establishes the requirement that all establishments licensed under the HTA ensure that consent information is provided to a donor prior to donation and in a manner as prescribed by the 2004 Act and the Code. The establishment must also ensure, firstly, that the donor is provided with information by a trained personnel member in an easily understood manner, and secondly, the donor must be informed of the necessity of obtaining their prior consent. Thirdly, the donor must be informed of at least the following:

1. The purpose and nature of the donation;
2. The consequence and risks thereof;
3. Any analytical tests that are to be performed;
4. The manner of recording and protection of donor data and medical confidentiality;
5. Any therapeutic purposes and potential benefits of the donation; and
6. All information on the applicable safeguards intended to protect the prospective donor.

And lastly, any prospective donor must be informed of their right to receive confirmed results of any analytical tests which may have been performed on their donations.

The EUTCD is comprised of three separate Directives, namely the Parent Directive and two Technical Directives. The Parent Directive sets framework legislation and makes some mention of consent related matters. Consent is addressed by reading together article 13 of and the Annexure to the Directive. When done in this fashion, the Directive provides that the procurement of human tissue or cells may only be authorised once all consent requirements have been met. This includes providing the donor or person consenting on their behalf with the appropriate information. The donor of tissue or cells must be informed, in an easily understandable manner by a trained person, of the necessity of consent in order to proceed with the procurement; the nature and purpose of the procurement; the consequences and risks involved; the possibility of analytical tests; all aspects related to recording and protecting donor data and medical confidentiality; the therapeutic purposes and potential benefits which may

arise from the donation; information on safeguards intended to protect the donor and that they have the right to receive the confirmed results of the mentioned analytical tests and also to have these tests clearly explained to them.

The HTA prepares Codes of Practice which serve as practical guides to persons who carry out the activities permitted under the 2004 Act and lays down standards expected in carrying out these activities. Since the Human Tissue Act 2004 provides for whose consent is necessary in all relevant circumstances, the Code clarifies the details pertaining to when and how consent should be sought and what information should be provided. According to the Consent Code, six central issues related to consent exist.

The first issue is whether or not consent is required. In general, consent is required where human bodies or relevant material is intended to be stored, used or removed. The second issue is what constitutes the appropriate consent in the particular circumstances. The 2004 Act, however, clearly states what constitutes appropriate consent and as such it is defined in terms of the person who consents to a purpose. In other words, this is the person concerned, their nominated representative or a person in a qualified relationship.

The third issue is what constitute valid consent and in terms of the 2004 Act and the Code, consent is a positive act and in order for it to be valid, it must be voluntarily given by the appropriate person with the capacity to understand the purpose and the risks involved. For an activity to be lawful, consent must have been obtained prior to the removal, storage or use of materials. Obtaining prior consent presupposes that the consenting person was given the necessary information and time to make a decision.

The fourth issue pertaining to consent according to the Code is the scope thereof. The scope of consent will vary according to the circumstances and may be generic, in instances of research, or specific, in instances of medical treatment. Fifthly, the duration of consent is an issue to be addressed and the Code states that it may be enduring or time-limited. Enduring consent will remain in force until it is revoked. A person may also specify a time limit for the period wherein the consent will remain in force. Lastly, the issue of withdrawal is noted and the Code provides that consent may be withdrawn at any time.

The Code further provides that, where possible, consent ought to be sought prior to a proposed treatment or research activity; that enough time should be available to discuss the details of the procedure and other pertinent matters which include the expected benefits or possible risks involved. According to the Code, the health care professional is normally the person responsible for obtaining consent from the concerned person.

All these legal instruments would, however, be of no effect if it were not for the Human Tissue Authority which operates as watchdog. In order to regulate activities as envisioned by the relevant legislation and other legal documents, the HTA was therefore created with the objective of regulating activities and establishments and providing information to the public as well as providing practical guidance and standards. In order to fulfil these objectives, the Authority therefore issue licences and Directives. These Directives include the Parent Directive as well as the First and Second Technical Directives and together these Directives attempt to harmonise the approach whereby tissues and cells are regulated across the United Kingdom and European continent. The Directives also brought into force the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The Authority is concerned with the task of ensuring that valid consent is obtained, that the donors understand the risks involved in donating material, donors donate of their own free will and not due to coercion or duress, and that no reward is offered or sought for any donations. It is submitted that a South African counterpart to the Authority should be established in order to exercise the same functions. Other lessons may also be learnt from the UK position and thus, in closing, it is convenient to summarise some pertinent points into which insight has been gained.

This chapter paid specific attention to the provisions found in all the above legal documents regarding consent. Read together, it became possible firstly to form a description of the principle of consent and secondly, to identify certain "rules" for the obtaining of consent. Consent, or authorisation, may therefore be described as permission, and the giving of consent or authorisation is a positive act which means that it must be given voluntarily by a person who is capable of making an informed decision. It is also essential that the person making the decision be given all the relevant information in order to enable them to make the best decision. The recognition of the importance of sufficient information and influence of time on decision making are relevant to this thesis, which introduces a dynamic model of consent which provides a patient-participant with more than sufficient information and which adapts over time, taking into account the changing preferences of the concerned person. It is flexible and as such is better able to accommodate the ever-evolving nature of a high-tech field of science such as stem cell therapy and research. With reference to the "rules" for obtaining voluntary and valid consent, the following were identified:

1. Consent must be obtained prior to the proposed removal, storage or use of the donation. This applies in both treatment and research settings. In context of this thesis, this means that consent must be obtained prior to carrying out stem cell therapy-research involving a patient-participant;

2. A trained health care professional is responsible for obtaining consent in clinical treatment-focused settings. It is therefore submitted that in research situations, the relevant researcher must obtain consent from the participant. According to the Q&S Regulations as well as the EUTCD, this person must inform the concerned person of the necessity of consent, the purpose of their donation, the consequences or risks or benefits thereof, whether or not any tests will be performed on the donated material and the manner wherein donor data will be recorded and protected. For stem cell therapy-research, it is therefore the duty of the physician-researcher to obtain consent and to inform the proposed patient-participant of the risks, benefits, consequences and other mentioned aspects;
3. Depending on the circumstances, the person from whom consent should be sought will differ. An adult with capacity, meaning that such a person understands the proposed procedure as well as the risks and benefits thereof, may give their consent or authorisation. An adult who is incapable of doing so may nominate a representative in a qualifying relationship such as a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half-sibling or longstanding friend. A person who has parental responsibility for a minor may provide the necessary consent in such circumstances. Proxy consent is thus permissible and consent should not be a rigid, inflexible concept which may be used to exclude the participation of certain persons. In other words, in context of this thesis especially, consent must be adaptable in accordance with the circumstances at hand; and
4. Consent may be granted for an enduring period of time or may be time-limited and may be withdrawn or revoked at any point. In context of this thesis, this once again supports the notion of a dynamic model of consent which may be amended or ended, depending on the preferences of the patient-participant from whom it was obtained; however,
5. No specific format for consent is prescribed. It is therefore suggested that a format of dynamic consent which will be discussed in the following chapter be followed. This is due to the openness to interpretation left by the omission of a specified consent format and it is suggested that this leaves the door open to, or at least does not bar the application of, dynamic consent.

Part D of this thesis started by providing a broad and general overview and explanation of the various legal systems at play in the United Kingdom and how these systems coexist and are applied. The focus was then narrowed and attention was zoomed in on the specific legislation, legislative policy documents and practical guides which prescribe and form the regulatory framework of human tissue and cell related matters in the United Kingdom. The Authority who

and the mechanisms whereby control of this field of medical science is maintained were also discussed and examined. At the conclusion of this specific discussion the focus is, however, narrowed once again and in the following chapter a special investigation and explanation of Dynamic Consent and EnCoRe will be undertaken. Dynamic Consent and EnCoRE are models of decision making and obtaining consent and may be described as modern, cutting edge ideas, techniques and procedures. They are an essential component of this thesis and it becomes pertinent to examine them at this juncture. It is also in the introduction of a dynamic consent format that this thesis makes a novel contribution to the South African legal environment.

CHAPTER 9
DYNAMIC CONSENT

1 INTRODUCTION

Throughout this thesis, it has been shown that consent is an indelible requirement in any medical or scientific venture, be it treatment or research, involving humans. Various legal documents have therefore been examined and the manner wherein the consent requirement manifests therein has been discussed.

It was shown that informed consent is normally required but that the exact format of consent may differ from case to case, depending on the type of intervention being proposed. It was also argued that the scope of informed consent, which has an influence on the validity and meaningfulness of consent, is greatly problematic in terms of stem cell treatment and research. In an attempt to address these problems, broad consent has been advocated in instances of medical research but it is also controversial as consent cannot be made "future-proof" and the autonomy involved in broad consent may not be worthy of respect. The issue of consent is further complicated by issues relating to the control of personal information and biological samples by the rise of new technologies as well as a lack of uniform consent standards even though consent is regarded as fundamental. "User-centric" approaches referred to as "participant-centred initiatives" have therefore become more prominent.

A part of such participant-centred initiatives is the use of Information Technology (IT) mechanisms which have not been commonplace in obtaining consent. Considering the presence of technology in everyday human life, this seems strange and out of step with modern thought. Attention must be given to the application of electronic resources in health and research and therefore it is clear that new research trends demand new, perhaps digital, models of consent.

It was argued previously in this thesis that in context of stem cell technology, treatment borders on research to such an extent that it may be seen as a consolidation of treatment and research due to the vastly uncertain nature of the scope of such research and the immense potential of any intervention. Two conclusions may thus be drawn from this consolidation. Firstly, that a patient is also a research subject and as such the regulatory and ethical provisions pertaining to both patients and research participants need to be considered in obtaining consent in the context of stem cell technologies. Secondly, since the concerned person is a consolidated

"patient-participant," a separate consent format of either informed or broad consent is not sufficient and does not allow for truly valid, meaningful and appropriate consent.[1] This issue forms the focus of this thesis as an attempt is made in understanding consent and proposing a solution to the consent dilemma.

The purpose of this chapter is thus to make a contribution to the field of law by introducing a new form of consent. This is achieved by suggesting that different types of consent must be consolidated in the same manner as the roles of the concerned person are merged to develop a new format of consent. By combining the informed requirement of informed consent and the open-endedness of broad consent, an appropriate model of consent may therefore be found. This chapter introduces dynamic consent as a new, appropriate consent model which may potentially find real application in the context of stem cell treatment and research.

In the course of this chapter, dynamic consent will be introduced and explained. This will be done by discussing the reason for dynamic consent, the meaning thereof as well as the workings of dynamic consent. Reference will be made to the benefits and claims of superiority of a model of dynamic consent and new terminology such as participant-centred initiatives will be discussed as well as the challenges which accompany this consent format. True consent means having access to extendible information, the ability to revoke or rescind consent as well as to *veto* certain activities. Currently, existing consent models fall short in fulfilling these requirements, and new formats of consent have therefore been developed, such as dynamic consent.

This chapter will show that consent is an ongoing process and dynamic consent is a new approach to consent which engages persons in the use of their information and biological material. It is dynamic in that consent is seen as a changeable and adaptable concept. As a participant-centred initiative, it places researchers and research participants in the centre of decision making in an interactive and bidirectional relationship. This model of consent will be shown to allow for the use and re-use of material or information, revocation and record keeping, while enabling amendments to a person's preferences in real time. The characteristics of dynamic consent are discussed to better explain the capability of the model of consent as well as the benefits and claims of superiority of this model which includes fine-grained consent and revocation. As a participant-centred initiative, this concept is also discussed as well as the functions and benefits of such initiatives.

[1] See in general, Caulfield T & Kaye J (2009) "Broad consent in biobanking: Reflections on seemingly insurmountable dilemmas" *Medical Law International* 10(2): 85-100.

Dynamic consent has great potential but it also faces certain implementation challenges due to its high-tech nature. These challenges are discussed and addressed in the course of this chapter. The two-way, circular working of dynamic consent is then explained which leads into a discussion of various different projects and initiatives applying the concept of dynamic consent. Reference is made to First Genetic Trust, Private Access, 23andMe, PatientsLikeMe and especially the Ensuring Consent and Revocation project. It will be shown that dynamic consent and the Ensuring Consent and Revocation project have an intertwined and collaborative relationship.

Attention is then given to the Ensuring Consent and Revocation project, or EnCoRe project, which is a recent research project in the field of information and communications technology. It is also patient-centric and attempts to enable persons to exercise their choice of granting or revoking consent in an easy, intuitive and reliable manner. In discussing the EnCoRe project, attention is given to the aims of the project, the features thereof, how the EnCoRe system works, as well as the challenges to this system, and lastly attention is given to why this system is proposed as a good practical manifestation of the dynamic consent idea.

It must be noted that while the principles underlying dynamic consent are introduced and propagated in this thesis as it may, in theory be a solution to the consent issue even in South Africa, EnCoRe is used as an example of the application thereof. At the conclusion of this chapter, dynamic consent in context of this thesis is discussed and the motivation behind its proposal as a contribution to South African law is established.

2 DYNAMIC CONSENT

New ways of conducting research have brought about new ethical norms, practices and standards, especially regarding consent. The standing of participants and their level of involvement has been a particularly prominent question as well as concerns regarding the appropriate format of consent. A marked shift has also taken place towards more participant-centred initiatives (PCI), which places the participant in a partnership with the researcher in both the decision making process as well as the research study.[2] Dynamic consent is an example of how IT may be applied in satisfying the legal requirement of consent while also providing a personalised communication interface with patients and research participants.

[2] Steinbekk KS, Myskja BK & Stolberg B (2013) "Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?" *European Journal of Human Genetics* 21(9): 897.

The dynamic consent framework is based on the work of an expert group who study social, legal, technical and compliance aspects of consent.[3] It was first examined as part of the Ensuring Consent and Revocation (EnCoRe) project which was undertaken from 2008 to 2012 in the context of the Oxford Radcliff Biobank, the Oxford Musculoskeletal Biobank and the Oxford Biobank, and is discussed in more detail in the course of this chapter.[4] Although originally developed for biobanking, this model of consent may find broader application in research where other forms of consent have been used. For example, dynamic consent may be applied for research purposes using surplus tissue, *de novo* research projects, organ donation and clinical trials. Dynamic consent may therefore be understood as a specific project as well as a general concept which has the potential to radically alter the nature of consent in research[5] as it supports the flow of new knowledge between a laboratory, clinic, researcher and participant.[6]

Normally, when an individual decides to participate in medical research, consent is obtained in paper format which is then filed away. Dynamic consent makes use of an electronic system.[7] This new system would enable persons to keep track of their data which includes records of donated material and what this material has been used for. Furthermore, it would allow an individual to monitor and update consent choices over time. For example, a person may wish to permit the use of their sample in a new research project or may wish to limit the research which may be done making use of a sample or information pertaining to the person.[8] It may therefore be noted that this model of consent allows for control over past and presently donated materials as well as any future material to be donated.

In order to better understand the concept of dynamic consent, it will be discussed in the following section of this chapter with reference to why dynamic consent has become necessary and has been developed, what dynamic consent means and how it works.

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[3] Dynamic Consent Open Framework (2010) "Dynamic consent open framework home page" available online at http://www.dynamic-consent.info accessed 25/9/2013.
[4] Kaye J, Whitley EA, Lund D, Morrison M, Teare H & Melham K (2015) "Dynamic consent: A patient interface for the twenty-first century research networks" *European Journal of Human Genetics* 23(2): 145.
[5] Kaye, Whitley *et al*. (2015) 141.
[6] Mason NC & O'Neil O (2007) *Rethinking informed consent in bioethics*: viii-ix.
[7] Such as a desktop computer, laptop or iPad. It must be mentioned that relying only on electronic communication strategies may exclude certain individuals or groups since not all people have equal access to technology in accordance to the phenomenon known as the "digital divide." See in general, Brandtzæg PB, Heim J & Karahasanovic´ A (2011) "Understanding the new digital divide-A typology of Internet users in Europe" *International Journal of Human-Computer Studies* 69: 123-138.
[8] HeLEX (2014) "Patient information leaflet: Making consent dynamic" available online at http://ndph.medsci.ox.ac.uk/research/centre-for-health-law-and-emerging-technologies-helex/projects/dynamic-consent/helex_direct_patient-info-leaflet.pdf accessed 11/11/2013. Suggested further reading, Wright Clayton E, Steinberg KK, Khoury MJ, Thomson E, Andrews L, Ellis Kahn MJ, Kopelman LM & Weiss JO (1995) "Informed consent for genetic research on stored tissue samples" *Journal of the American Medical Association* 274(22): 1786-1792.

2.1 THE REASON FOR DYNAMIC CONSENT

As has been clearly shown throughout the course of this thesis, the requirement that consent be obtained by researchers or physicians prior to initiating the proposed study or procedure is a fundamental principle of medical ethics as well as the law.[9] The requirement of consent has also been repeatedly shown to underpin respect for persons and their autonomy.[10] The consent form has thus become a method of recording individual involvement and for determining the scope of what is included under consent. As such, it may be seen as the formalising of the implicit social contract between the public and researchers.[11] However, new forms of biomedical research challenge the meaning of informed consent and question the existing process of engaging participants.[12] The uncertain scope of consent is an especially vexing issue. As such, broad consent has been suggested as an understandably practical solution but various reasons exist why a broad consent approach is inadequate in meeting the requirements of meaningful informed consent.[13]

Unlike traditional research, stem cell and biomedical research does not follow a single experimental procedure to which participants are being asked to participate. Rather it is a request to participate in an ongoing inquiry with multiple questions and methods which entail unknown risks and it is suggested that new research trends demand new models of consent.[14] In other words, the consent procedure must also be an ongoing one.

Ethically speaking, it is necessary to enable a research participant who has granted consent under a set of circumstances to review this consent as new research possibilities using the same data or samples emerge. Also, the possibility exists that research participants may benefit clinically from updated information regarding their data and samples.[15] For example, at the time of donating a sample and giving the relevant consent, no method has been discovered to interpret a certain genetic code which may indicate a recessive gene which may cause a terrible, yet treatable if found early enough, disease or illness. In future however, this becomes possible using the same sample. It would then be of clinical benefit to inform the research participant and donor of the sample of the existence of this gene after which they will then be able to go for

[9] See chapter 4 paragraph 5.1.1 and chapter 8 paragraph 7 *supra*.
[10] See chapter 3 paragraph 6 and chapter 6 paragraph 3 *supra*.
[11] Kaye, Whitley *et al.* (2015) 141. The social contract is a model of thought which originated in the Age of Enlightenment whereby individuals expressly or tacitly consent to surrender some of their freedoms and submit to an authority above themselves in exchange for the protection of their other remaining rights. Suggested further reading, Rousseau JJ (1762) *Du contrat social ou Principes du droit politique (The social contract).*
[12] For example, the uncertain scope of future research means that informed consent as formulated in the Declaration of Helsinki is not sufficient. See chapter 6 paragraph 3.3.2 *supra* for a discussion of the Declaration of Helsinki.
[13] See chapter 4 paragraph 5.4 *supra*.
[14] Kaye J, Curren L, Anderson N, Edwards K, Fullerton SM, Kanellopoulou NK, Lund D, MacArthur DG, Mascalzoni D, Shepherd J, Taylor PL, Terry SF & Winter SF (2012) "From patients to partners: Participant-centric initiatives in biomedical research" *Nature Reviews Genetics* 13(5): 372.
[15] *Ibid*.

preventative tests and/or check-ups.[16] Practically speaking, by providing a more comprehensive form of consent, one is "covering more bases" and so, the legal liabilities which could arise due to the absence of consent are reduced as clearer lines are drawn regarding the scope of the consent. As the nature of biomedical research changes, so too the social contract mentioned earlier must change and evolve.[17] Individual autonomy is also not a static entity and involves changing choices, opinions and preferences. Patients or research participants need no longer be passive human subjects, but should be recognised as active and interested participants and in fact, consent is now regarded as a process of ongoing interaction between a physician or researcher and a patient or participant.

As was mentioned previously in this thesis, O'Neil stated that genuine consent is reliant on access to extendable information, the concept of rescindable consent and the right to *veto* certain activities.[18] Respect for an individual and his autonomy therefore means that a person must be provided with as much choice and control over information as well as their material and data as possible.[19]

Theoretically speaking, dynamic consent is of benefit to the researcher as well as the subject. The research subject is provided with information related to their material, transparency regarding their information usage and sharing, and the option of revoking their consent. This promotes the relationship between research subject and researcher. The researcher then benefits from a system of dynamic consent as they then have an edge in business for setting best practice, and the relationship with the subject is flexible, meaning that newer and more refined usage may be allowed.[20] Clearly, dynamic consent addresses the changing nature of biomedical research and may therefore overcome the limitations set by static consent as well as fluctuating legal and regulatory requirements.

The necessity of a new consent model has now been established and at this juncture it therefore becomes pertinent to clarify what is meant by the concept of dynamic consent.

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[16] See in general, Mascalzoni D, Paradiso A & Hansson M (2014) "Rare disease research: Breaking the privacy barrier" *Applied & Translational Genomics* 3: 23-29.
[17] Kaye, Whitley *et al*. (2015) 142. See in general, Meslin EM & Cho MK (2010) "Research ethics in the era of personalised medicine: Updating science's contract with society" *Public Health Genomics* 13(6): 378-384.
[18] Campbell AV (2013) "The ethical challenges of biobanks: Safeguarding altruism and trust" in McLean SAM (ed) *First do no harm: Law, ethics and healthcare*: 206. See also chapter 4 paragraph 6 *supra*.
[19] Kaye, Whitley *et al*. (2015) 142.
[20] Dynamic Consent Open Framework (2010) "Dynamic consent open framework home page: What, how, why" available online at http://www.dynamic-consent.info/WhatWhyHow#1 accessed 25/9/2013.

2.2 THE MEANING OF DYNAMIC CONSENT

Dynamic consent, as the name suggests, is dynamic in that the consent granted is changeable and adaptable. This concept, however, has two meanings, one is broader while the other is more specialised. In the narrow, specialised sense, it is a personalised communication interface which enables greater participant engagement in research activities by enabling an interactive relationship between researchers and participants.[21] Researchers should foster a relationship of confidence, understanding and trust in order to establish true insight into what is at stake in the course of research.[22] Dynamic consent may therefore be defined as a new approach for engaging individuals in the use of their information and material. It is furthermore, in a broader sense, also an interactive and personalised interface which allows participants to engage as much or as little as they prefer and to change their consent decisions in real time.[23] At its core, dynamic consent is a mechanism which enables communication between participant and researcher, and which offers participants the opportunity to be informed and in control of their information and material on a continuous basis.[24]

Dynamic consent is a PCI which places patients as well as research participants at the centre of the decision making process by providing them with an interactive IT interface. It is a dynamic approach since it allows interaction over time, enables participants to consent to new projects or studies, or to amend their consent in real time as their circumstances change, and to have confidence that their amendments will have an actual effect.[25] When an individual initially agrees to any processing of their personal information or material, they may do so without fully understanding the implications of what they are agreeing to. After some time, a person may then wish to review or revoke the initial agreement in order to create one which is more suitable to their preferences. With dynamic consent, the individual is able to monitor the uses and flow of their information and material and change their consent regarding what is permitted and what is prohibited.[26]

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[21] Steinbekk, Myskja *et al*. (2013) 898.
[22] Dynamic consent improves an individual's trust in online enterprises by offering the user the opportunity to remain informed and in control of their information. See HW Communications (2012) "Dynamic consent" available online at cyber.hwcomms.com/cyber/DynamicConsent accessed 25/9/2013. See also Erlich Y, Williams JB, Glazer D, Yocum K, Farahany N, Olson M, Narayanan A, Stein LD, Witkowski JA & Kain RC (2014) "Redefining genomic privacy: Trust and empowerment" *PLoS Biology* 12(11): 1-5.
[23] Kaye, Whitley *et al*. (2015) 142.
[24] Wee R, Henaghan M & Winship I (2013) "Dynamic consent in the digital age of biology: Online initiatives and regulatory considerations" *Journal of Primary Health Care* 5(4): 341 at 344.
[25] Kaye, Whitley *et al*. (2015) 142.
[26] For example, when a person subscribes to a forum and they allow for newsletters related to the forum to be sent to them via email, they offer an initial consent. Over time, however, they are bombarded with unwanted advertisements and spam emails. This prompts the person to fine tune their security filters so that they no longer receive such emails and receive only those that they are interested in and allow.

Dynamic consent thus allows a material sample to be used or re-used with the knowledge and consent of the concerned person; enables individuals to provide or revoke consent as their preferences change; provides a record of all transactions and interactions; allows for approaching persons for various different types of projects and enables the modification of consent preferences over time. Consent preferences therefore accompany samples or data in order to inform any third parties or further studies of the scope of the consent. A person will, in the course of monitoring and changing consent preferences, gain awareness regarding the use, sharing and flow as well as the privacy and the implications of their information and samples.[27]

Dynamic consent therefore entails certain characteristic features. In short, the participant may consent to new research developments with ease and change their consent preferences in real time; amend their contact information and also receive information as to how their samples have been used and select the type of information they wish to receive in this regard in in future.[28] The researcher may customise the consent interface to facilitate the needs, resources and capabilities of a project and may also integrate the system of information with other such sources.[29] These features are discussed in more detail at this juncture.

The first feature of dynamic consent is that it contains different consents. Dynamic consent is not locked in time at the onset of a research project and, depending on the nature of the project, participants are able to consent to a broad range of uses of their samples and data or may choose to be approached on a case-by-case basis or create numerous preferences for varying research types. These preferences may be opt-in or opt-out in nature and in so doing the research participant tailors his profile to receive certain information at certain times.[30] It must be mentioned here that dynamic consent does not propose to replace other forms of consent such as broad consent but rather to facilitate an improvement tool for the obtaining of consent. Due to the opt-in or opt-out nature of dynamic consent, a participant may still choose to give broad consent to a research study and to not receive further information.[31] However, where such a participant later decides that they do wish to be kept informed, dynamic consent offers

[27] Dynamic Consent Open Framework (2010) "What, how, why" online.
[28] These characteristics are thus concerned with the participant.
[29] These characteristics are thus concerned with the researcher.
[30] Some have argued that dynamic consent requires participants to provide consent over and over again and thus violates their decision to participate passively and may lead to "consent fatigue." Kaye, Whitley *et al*. (2015) 142-143. See in general, Genetic Alliance UK (2015) "Information for patients and the public about informed consent" available online at http://www.geneticalliance.org.uk/docs/eurogenguide/03_information_for_patients_informed_consent.pdf accessed 27/5/2015 and Plough T & Holm S (2013) "Informed consent and routinisation" *Journal of Medical Ethics* 39: 214-218.
[31] See in general, Williams H, Spencer K, Sanders C, Lund D, Whitley EA, Kaye J & Dixon WG (2015) "Dynamic consent: A possible solution to improve patient confidence and trust in how electronic patient records are used in medical research" *JMIR Medical Informatics* 3(1): e3.

them the opportunity to do so.[32] In other words, dynamic consent is both broad and informed. It must be kept in mind that this thesis is more concerned with this first feature of dynamic consent, being dynamic consent as a concept, than the technical communication interface aspect thereof.

The second feature of dynamic consent relates to the tailored consent aspect thereof. Since the dynamic consent interface acts as a personalised communication forum, an informational source and a platform whereby consent may be modified, all aspects of the dynamic consent interface may be tailored to the preferences of the person concerned. Persons may choose how and when they are to be contacted and what information they wish to receive.[33] This feature of dynamic consent, however, raises the question of access and the "digital divide" since internet access is not equally available and also depends on race, age, culture and health.[34] This issue may, however, be addressed by making the dynamic consent model both paper based as well as electronic and then adaptable to different formats such as desktop, tablet and mobile friendly.[35]

The third feature of dynamic consent entails the customisation of research needs. The dynamic consent model explicitly incorporates a flexible design which accommodates the researchers as well as the participant. All aspects of the interface may therefore be tailored to the proposed project and so extends the interaction between the mentioned persons.[36] This would naturally be a costly enterprise but such costs may be offset by the long term benefits of dynamic consent. At this juncture it thus becomes pertinent to discuss the benefits of dynamic consent.

2.2.1 Benefits and Claims of Superiority

In understanding, recognising and supporting biomedical research as a partnership between researchers and participants, dynamic consent enables research as well as an improved research experience. Dynamic consent therefore offers participants involvement in the process, better respect of their autonomy and meaningful consent. Researchers are benefitted by engaged participants, streamlined participant recruitment and improved public trust. Legally,

[32] Suggested further reading, Flory J & Emanuel E (2004) "Interventions to improve research participant's understanding in informed consent for research" *Journal of the American Medical Association* 292(13): 1593-1601.
[33] This may be by way of letters or newsletters, email, sms, telephonically or even social media notifications. The dynamic consent model may also make use of various medias whereby information may be provided such as videos, animations and lay summaries. See Williams, Spencer *et al.* (2015) e3.
[34] Kaye, Whitley *et al.* (2015) 143. See also Wee, Henaghan *et al.* (2013) 345. See in general, Brodie M, Flournoy RE, Altman DE, Blendon RJ, Benson JM & Rosenbaum MD (2000) "Health information, the internet and the digital divide" *Health Affairs* 19(6): 255-265.
[35] It has been argued that mobile or "m-health" options have the potential of reaching vulnerable groups such as the elderly, the socio-economically underprivileged and persons in developing countries. See in general, Bodie GD & Dutta MJ (2008) "Understanding health literacy for strategic health marketing: eHealth literacy, health disparities and the digital divide" *Health Marketing Quarterly* 25(1-2): 175-203.
[36] Kaye, Whitley *et al.* (2015) 143.

dynamic consent is beneficial as it offers greater protection by eliminating any ambiguity. Ethically, dynamic consent may also be beneficial as it allows for the true expression of autonomy. The further benefits of dynamic consent are discussed below in more detail and include the facilitation of efficient re-contact; conformity to the highest legal standards; fine grained withdrawal; enabling of better communication; improved scientific literacy; as well as transparency and risk management.

2.2.1.1 Facilitation of efficient re-contact

Currently, re-contact is often impractical. Dynamic consent provides a method of easy re-contact with participants which provides them with accessible information and allows them to make an informed decision.[37] Maintained contact with research participants assists researchers in addressing various ethical and legal issues which may emerge in unforeseen circumstances. The following benefit of dynamic consent then looks slightly more towards the legal benefit it has to offer.

2.2.1.2 Conformity to the highest legal standards

Freely-given informed consent is deemed unanimously as a requirement of biomedical research as seen in legal and regulatory documents across the globe.[38] Dynamic consent provides for a flexible and responsive method of addressing changing legal and ethical requirements. It may even provide further protection to autonomy than most current international standards.[39] It is then in this flexibility that dynamic consent is capable of accommodating the slightest change in circumstances surrounding the consent and since the devil is most often in the detail, the fine grained functioning of dynamic consent is deemed a further benefit thereof.

2.2.1.3 Fine grained withdrawal

Research participants have the right to withdraw their consent and material or data by requesting that such samples or data not be made available for certain further research or even destroyed. Dynamic consent allows for a more nuanced choice by providing more information

[37] Dynamic consent interfaces must however not replace the human element and exclude face-to-face discussions between researchers and participants. See Kaye, Whitley *et al*. (2015) 144.
[38] See in general chapter 3 and chapter 6 *supra*.
[39] Kaye, Whitley *et al*. (2015) 144.

and preference related options and in so doing excludes the "all or nothing" mode of withdrawal which is often found in withdrawal circumstances.[40] This serves research in the collection of information and knowledge whereby the patient-participant and physician-researcher stand on more equal footing and are able to enter into a conversation with similar information.

2.2.1.4 Enablement of better communication

Traditionally, consent procedures entail an initial engagement session with the patient or participant at the onset of the treatment or research project but rarely provide for mechanisms of continued communication with such patients or participants.[41] Also, research findings are rarely conveyed to the participants. The dynamic consent interface allows for the return of general research findings according to the participant's selected preferences. This model of consent also establishes a means whereby broader engagement may be fostered which extends far beyond an information sheet. This adds value to the research study.[42] It also enriches the patients or participants as they increase their knowledge on a certain matter and scientific literacy.

2.2.1.5 Improved scientific literacy

Dynamic consent, by implementing an interface which is accessible to participants in their own time, allows for additional opportunities to gain knowledge and understanding of the information provided. Participants are allowed time for reflection and consideration. An individual is hereby empowered to control the type and amount of information they receive and when they wish to receive it. This may lead to a more realistic understanding of research as an interactive and long term process, it may enhance participant confidence by transparency and accountability, and it may aid in developing appropriate expectations of what research may achieve.[43] Enhanced transparency promotes responsibility and this in turn leads to the next benefit of dynamic consent, namely improved risk management.

[40] *Ibid*.
[41] Mascalzoni D, Hicks A & Pramstaller PP (2009) "Consenting in population genomics as an open communication process" *Studies in Ethics, Law and Technology* 3(1): 2.
[42] Kaye, Whitley *et al*. (2015) 144.
[43] *Ibid*.

2.2.1.6 Improved transparency and risk management

Transparency and accountability, as were mentioned, may be improved by dynamic consent as the research process, the use of material or data and consent may be tracked throughout all studies. Operational control over risk is thus provided for. Participants may also be contacted in relation to controversial issues and so trust is safeguarded.[44] In effect, each patient or participant becomes their own personalised ethics committee.[45]

In summary, dynamic consent is beneficial because it enables research as well as an improved experience thereof; it offers participants the opportunity to be involved in the process; it better respects their autonomy, and, perhaps most importantly in context of this thesis, it allows for meaningful consent. Researchers are also benefitted by engagement of participants; a streamlined recruitment mechanism, and improved public trust. Dynamic consent meets the highest ethical and legal standards; it creates a record of consent; participants are allowed to amend their preferences regarding the type, amount and time of receiving information as well as the type of research they are willing to participate in; scientific literacy is improved and withdrawal is fine tuned.

As was mentioned previously in this thesis,[46] in addition to the already discussed benefits of dynamic consent, writers have identified six claims of the superior nature of dynamic consent. These claims are more fully discussed here, as well as some counter arguments thereto:[47]

1. Dynamic consent offers greater respect for patient autonomy than other types of consent according to proponents of dynamic consent, who argue that it is better able to meet the specifications of autonomy embedded in informed consent requirements. Dynamic consent enables persons to exercise their autonomy by providing informed consent to new types of research in real time as opposed to once-off broad consent.[48] This means that participants are permitted the opportunity to consent to primary and secondary uses of their material and data, by making their preference the point of departure when determining possible uses of the material or data;
2. Participants are kept better informed by dynamic consent. The ability to keep participants informed regarding the research they are involved in is seen as essential in all research consent processes, and dynamic consent is better suited to fulfil the ideals of

[44] Kaye, Whitley *et al*. (2015) 145. See also Williams, Spencer *et al*. (2015) e3.
[45] As was mentioned previously in this thesis, the Minister is granted excessive powers. This may also be true of some ethics committees. By applying a dynamic consent model, this may be rectified.
[46] See chapter 4 paragraph 6 *supra*.
[47] Steinbekk, Myskja *et al*. (2013) 898-901.
[48] Kanellopoulou NK, Kaye J, Whitely EA, Creese S, Lund D, Hughes K (2011) "Dynamic consent: A solution to a perennial problem?" *BMJ Recent Rapid Responses* available online at http://www.bmj.com/content/343/bmj.d6900?tab=responses accessed 25/11/2015.

distributing detailed information.[49] Extra or more information may appeal to persons who wish to be in control or who are not certain of the specifics of what they are participating in. More or extra information does not, however, mean that consent is informed. Rather, the information should be relevant to render consent informed.[50] This, however, makes it difficult to distinguish between relevant and irrelevant information when having to provide possible participants with information as required by the dynamic consent model to achieve informed consent;[51]

3. The dynamic consent model will encourage more participation in biomedical research. Since trust is garnered by the transparent and accountable nature of dynamic consent, proponents thereof hope that it will have positive implications not only on participant recruitment but also on retention. This ultimately leads to sustainable biomedical research.[52] Dynamic consent then also addresses any criticism that human subjects are regarded as mere raw material providers as the participant becomes an active partner.[53] Also, public insight and knowledge are increased by the dynamic consent model. It may, however, be argued that possible participants may be deterred by being confronted with, and perhaps even intimidated by, all the details and complexities of biomedical research and then being asked over and over again for their consent.[54] Due to this, dynamic consent may better be described as a two-edged sword in the context of participant recruitment. Obviously, it could increase trust because individuals are given different choices and trust is fostered by transparency, and the participant's sense of control is increased. Also, it seems that reciprocity is increased since dynamic consent accommodates the return of individualised information which in turn promotes personalised medicine.[55] On the other hand, people might then have overblown hopes and expectations of what the research might yield. When this is not achieved, trust may be breached and recruitment may decrease. Harm, real and potential, is therefore an important aspect which needs to be discussed with a potential patient-participant as it may even include psychological harm. This means that in the context of the potential of

[49] Whitley EA, Kanellopoulou NK & Kaye J (2012) "Consent and research governance in biobanks: Evidence from focus groups with medical researchers" *Public Health Genomics* 15(6): 236. See also Kuehn BM (2013) "Groups experiment with digital tools for patient consent" *Journal of the American Medical Association* 310(7): 678-680.
[50] This is similar to the issue of informing a patient of the risks involved in a proposed treatment. See chapter 3 paragraph 5 *supra*.
[51] Steinbekk, Myskja *et al*. (2013) 899. See also chapter 4 paragrapgh 5.3 *supra*.
[52] Kaye, Curren *et al*. (2012) 373. See also O'Neill O (2006) "Transparency and the ethics of communication" in Hood C & Heald D (eds) *Transparency: The key to better governance*: 74-91.
[53] Saha K, Hurlbut JB (2011) "Research ethics: Treat donors as partners in biobank research" *Nature* 478(7369): 312.
[54] This is reminiscent of therapeutic privilege. See chapter 4 paragraph 2.3 *supra*.
[55] Contemporary medicine is moving away from being reactionary to being personal, predictive, preventative and participatory. This is referred to as "P4 medicine." See in general, Hood L, Rowen L, Galas D & Aitchison J (2008) "Systems biology at the Institute for Systems Biology" *Briefings in Functional Genomics and Proteomics*: 239-248 and Loscalo J & Barabasi A (2011) "Systems biology and the future of medicine" *Wiley Interdisciplinary Review of Systems Biology Medicine* 3(6): 619-627.

harm based on unfulfilled expectations, broad consent may have the upper hand over dynamic consent;[56]

4. Dynamic consent transfers control to the participant. Concerns regarding the lack of control a participant has in both the research and the results are addressed by dynamic consent.[57] This is perhaps the strongest argument in favour of dynamic consent and may even create new participant rights.[58] Seeing participants as something other than passive contributors of material is as important an aspect of consent as governance itself according to the dynamic consent model. The actual importance may, however, be debated since dynamic consent assumes that persons should be engaged in the process and decisions related to biomedical research. Biomedical research, however, deals with potential health benefits of future generations and not only those which the participant themselves may acquire. This supports the argument that the distinction between therapeutic and non-therapeutic research should be done away with in the context of stem cells.[59] For this reason, it may be said that an important motivation for active engagement in biomedical research is lacking.[60] Some scholars then argue in favour of broader involved deliberation and decision-making since scientific knowledge is also changing and becoming broader. This is especially true in areas where the outcome and consequences of the scientific activity are uncertain;[61]
5. Ethical responsibility is transferred from research ethics committees to participants. This would constitute a moral difference and a move towards an open and democratic scientific process which ensures socially robust knowledge.[62] Since new consent must be provided for new projects, the need for ethics review boards is eliminated.[63] This might mean that where there is a lack of support for a project, it will not be realised. However, lack of support may perhaps not imply that research is unethical or controversial and it may simply be due to the fact that the proposed project was uninteresting to the approached participants. A second concern regarding this transference of ethical review is that since participants are not well informed and educated ethicists, it may lead to a weakened ethical assessment. Not all participants will educate themselves on a specific

[56] Steinbekk, Myskja *et al*. (2013) 899.
[57] Wagstaff A (2011) "International biobanking regulations: The Promise and the pitfalls" *Cancer World* 42: 24. See also Angrist M (2011) "You never call, you never write: Why return of 'omic' results to research participants is both a good idea and a moral imperative" *Future Medicine* 8(6): 653.
[58] Whitley EA (2009) "Informational privacy, consent and the 'control' of personal data" *Information Security Technical Report* 14(3): 154-159. See in general, Saha & Hurlbut (2011) 312, Wagstaff (2011) 23-29 and Angrist (2011) 651-657. See also chapter 5 paragraph 4.1 *supra*.
[59] See chapter 4 paragraph 4 *supra*.
[60] Steinbekk, Myskja *et al*. (2013) 899.
[61] *Idem* 900. See also Funtowicz SO & Ravetz JR (1993) "Science for the post-normal age" *Futures* 25(7): 739-755.
[62] See in general, Nowotny H (1999) "The need for socially robust knowledge" *TA-Datenbank-Nachrichten* 3(4): 12-16.
[63] Kaye J (2012) "Embedding biobanks as tools for personalised medicine" *Norsk Epidemiologi/The Norwegian Journal of Epidemiology* 21(2): 172.

issue or idea and may find biomedical research complicated, complex or even uninteresting and boring.[64] If the participants do not engage, autonomy is weakened rather than strengthened and this may then nullify the arguments in favour of dynamic consent based on autonomy;[65] and

6. Dynamic consent enables the return of results and incidental findings in an easy and tailored manner. Proponents of dynamic consent argue that the return of results and findings is a necessity as it respects the values of autonomy as well as reciprocity and beneficence.[66] This is based on the idea that it is of importance to a person to have full access to information related to their health and to exercise decisions related to this information. It may be argued, however, that the return of such results and findings is not always good and there are still arguments in favour of restricting information and non-disclosure.[67] Dynamic consent may conflate research and health care and this may have numerous effects on research.[68] Firstly, resources could then be diverted from the core activity of the research project. Secondly, it could lead to restrictions being placed on the analysis of the findings and this would then hamper freedom of research and reduce future outcomes.[69] Also, this may lead to premature translation of group-based research which may lead to over-diagnosis and medicalisation.[70] Biomedical research is a balancing act between creating better understandings of disease and disease prevention and not being overzealous in translating research findings into practical medicine and creating health issues at the same time.[71]

In the previous section of this chapter, the benefits and some possible disadvantages of dynamic consent were discussed. This was done because, although technological advances,

[64] Steinbekk, Myskja *et al.* (2013) 900.
[65] *Idem* 901.
[66] Tabor HK, Berkman BE, Hull SC & Bamshad MJ (2011) "Genomics really gets personal: How exome and whole genome sequencing challenge the ethical framework of human genetics research" *American Journal of Medical Genetics* 155A(12): 2918. See in general, Wolf SM, Crock BN, Van Ness B, Lawrenz F, Kahn JP, Beskow LM, Cho MK, Christman MF, Green RC, Hall R, Illes J, Keane M, Knoppers BM, Koenig BA, Kohane IS, Leroy B, Maschke KJ, McGeveran W, Ossorio P, Parker LS, Petersen GM, Richardson HS, Scott JA, Terry SF, Wilfond BS & Wolf WA (2012) "Managing incidental findings and research results in genomic research involving biobanks and archived data sets" *Genetics in Medicine* 14(4): 361-384.
[67] For more on these arguments see in general, Christenhusz GM, Devriendt K & Dierickx K (2012) "To tell or not to tell? A systematic review of ethical reflections on incidental findings arising in genetics contexts" *European Journal of Human Genetics* 21: 248-255 and Solberg B & Steinsbekk KS (2012) "Managing incidental findings in population based biobank research" The *Norwegian Journal of Epidemiology* 21(2): 195-202. This is once again reminiscent of therapeutic privilege.
[68] See Appelbaum regarding "therapeutic misconception." Appelbaum PS, Roth LH, Lidz CW, Benson P & Winslade W (1987) "False hopes and best data: Consent to research and the therapeutic misconception" *Hastings Centre Report* 17(2): 20-24.
[69] Keep in mind that freedom of research is constitutionally protected in South Africa. See section 16 of the Constitution of the Republic of South Africa, 1996. See also chapter 3 paragraph 6 *supra*.
[70] Moynihan points out that society strongly emphasises population health and that medicine may harm healthy people in its quest to diagnose illnesses early and by its wider definition of diseases. See Moynihan R, Doust J & Henry D (2012) "Preventing overdiagnosis: How to stop harming the healthy" *BMJ* 344: e3502.
[71] Steinbekk, Myskja *et al*. (2013) 901.

developments and innovations create novel methods of doing things in different manners, certain implications and limitations exist which must be identified and recognised.[72] Attention is given to the challenges facing the implementation of such a system of dynamic consent making use of technology. Firstly, however, it is pertinent to clarify a term which is referenced throughout this chapter, namely a "participant-centred initiative."

2.2.2 Participant-Centred Initiatives

Throughout the course of this chapter, reference is made to participant-centred initiatives or PCIs. A PCI may be defined as "a tool, program and project that empowers a participant to engage in research processes using IT."[73] Making use of an IT interface provides an ongoing, interactive means of obtaining consent and maintaining communication between the participant, the clinician, the researcher and any other relevant parties.[74] The key characteristics of a PCI are that it is founded on respect, promotes the empowerment of individuals and is orientated towards participation. The researcher and the participant are the central focus of decision making and are equal partners in the research process.[75] PCIs therefore greatly emphasise autonomy.

PCI approaches, currently at least, exhibit four functions. Firstly, PCIs serve a matchmaking function which enables the recruitment of research participants. Secondly, it provides a "direct-to-consumer" service in that it provides participants with genetic testing and analysis as well as the chance to partake in research projects.[76] A third function is that of dynamic control which enables an ongoing interaction between the researcher, the clinician and the participant and lastly, it has a so-called citizen science function which involves participants in facilitating, designing and executing research projects.[77]

Although PCIs are currently still an emerging area, there are a number of designs for PCIs to be utilised in research contexts and a diversity of formats and objectives exist. However, there are some common features whereby it is possible to characterise an interface as being a PCI

[72] Wee, Henaghan *et al*. (2013) 344.
[73] This is according to Bragg K & Hartzler A in an unpublished presentation at the European Academy of Bozen/Bolzano International Conference in Rome, Italy on 28 October 2011. Suggested further reading, Minari J, Teare H, Mitchell C, Kaye J & Kato K (2014) "The emerging need for family-centric initiatives for obtaining consent in personal genome research" *Genome Medicine* 16: 118-120 and Kaye J & Hawkins N (2014) "Data sharing policy design for consortia: Challenges for sustainability" *Genome Medicine* 6: 4-11.
[74] Kaye, Curren *et al*. (2012) 372.
[75] *Ibid*. See in general, Irwin A (2001) "Constructing the scientific citizen: Science and democracy in the biosciences" *Public Understanding of Science* 10(1): 1-18.
[76] See in general, Tamir S (2010) "Direct-to-consumer genetic testing: Ethical-legal perspectives and practical considerations" *Medical Law Review* 18(2): 213-238.
[77] Kaye, Curren *et al*. (2012) 685-687.

interface. These include: placing participants in control; using social media technology; promoting active participation; facilitating communication and appealing to public good.[78] From this it should be clear that dynamic consent and EnCoRe qualify as PCIs.

Making use of a PCI approach may greatly benefit research governance by ensuring conformity with basic ethical and legal principles, improve recruitment methods, and maximise retention of participants. It may also minimise costs, enhance the knowledge and understanding of the research process, and encourage as well as sustain public confidence through greater involvement and transparency. PCIs are able to achieve these benefits by:[79]

1. Streamlining the consent process. Making use of a PCI simplifies obtaining consent and ensures compliance with data privacy protection legislation;
2. Decreasing the need for anonymised data. The need to anonymise data is mitigated since participants may be approached directly to obtain the consent necessary to use their information or sample for new research purposes;[80]
3. Facilitating participant recruitment. PCIs have positive implications for participant recruitment as it opens the possibility of ongoing and easy communication with participants regarding their involvement in further and/or future projects;
4. Facilitating participant retention. Where participants wish to be informed on an ongoing basis, or at least have the option to be kept informed, meaningful communication may be possible. This may in turn improve clinical practice;[81]
5. Promoting the delivery of better quality health care. Opening access to health data in order to include patients may lead to positive changes such as more active patients who take responsibility for and manage their health care;[82]
6. Sustaining public confidence in research. Greater involvement in research has a dual effect. Firstly, it improves knowledge of the research process and secondly, it ensures transparency and accountability on the part of the researcher. Research will be conducted on a higher standard and will be in tune with societal expectations and concerns which will lead to enhanced public confidence; and

[78] *Idem* 373.
[79] *Idem* 373-375.
[80] Traditionally, anonymising data has been used to protect individual privacy. It has also however removed information from external oversight and from the requirements of data protection and privacy laws. A PCI approach allows for consent to be obtained while the research is in its planning phases which removes the need to anonymised data fully. See Brown I, Brown L & Korff D (2010) "Using patient data for research without consent" *Law Innovation and Technology* 2: 219-258. This will also have an influence on the relevance of ethics review committees and boards.
[81] See in general, Trinidad SB, Fullerton SM, Bares JM, Jarvik GP, Larson EB & Burke W (2010) "Genomic research and wide data sharing: Views of prospective participants" *Genetics in Medicine* 12: 486-495. See also Shelton RH (2011) "Electronic consent channels: Preserving patient privacy without handcuffing researchers" *Science Translational Medicine* 3, 69cm4 and Terry SF & Terry PF (2011) "Power to the people: Participant ownership of clinical trial data" *Science Translational Medicine* 3(69): 69cm3.
[82] See in general, Teich JM (1998) "The benefits of sharing clinical information" *Annals of Emergency Medicine* 31: 274-276.

7. Improving the quality of research. A PCI will allow research to be conducted in a manner which is more efficient and utilises new methods.[83]

Implementation of PCI approaches vary as there still exist numerous challenges to wide scale adoption of PCIs in the context of research.[84] Due to the digital nature thereof it will also be a herculean task to fully implement PCIs in developing countries. Although the potential of such initiatives should not be ignored, it is, however important to discuss some of the implementation challenges facing dynamic consent and, by implication, PCIs.

2.2.3 Implementation Challenges

Implementing a system of dynamic consent will require cultural changes both by individuals as well as by health care providers and will necessitate healthcare relationships which are open, transparent and engaging, and is appreciative of the role that participants play in research as the sources of material and information. Dynamic consent will also require the development of new policies and standards of practice.

This model of consent requires technical capacities allowing biobanks, research facilities and participants to interface and exchange information. It will therefore demand various resources including time, expertise, money and commitment from researchers, doctors, institutions and governments.[85] Unfortunately, heavy reliance on electronic communication strategies excludes some individuals from partaking in activities such as biomedical research, for example.[86]

The practical implementation of dynamic consent introduces issues which are not only technically or technologically related, but concern the deeper ethics pertaining to the digital divide.[87] In a developing country such as South Africa, this is perhaps the greatest impediment to implementation of a system of electronic dynamic consent. Access to technology is still largely exclusive and not equally distributed. Although various new methods of online engagement are becoming more commonplace, such as by way of mobile phone or tablet, access to all is still a long way off.

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[83] See in general, Do CB, Tung JY, Dorfman E, Kiefer AK, Drabant EM, Francke U, Mountain JL, Goldman SM, Tanner CM, Langston JW, Wojcicki A & Eriksson N (2011) "Web-based genome-wide association study identifies two novel loci and a substantial genetic component for Parkinson's disease" *PLoS Genetics* 7: e1002141.
[84] Kaye, Curren *et al.* (2012) 375.
[85] Kaye, Whitley *et al.* (2015) 145.
[86] Steinbekk, Myskja *et al.* (2013) 899. See also Stein DT & Terry SF (2013) "Reforming biobank consent policy: A necessary move away from broad consent toward dynamic consent" *Genetic Testing and Molecular Biomarkers* 17(12): 856.
[87] Wee, Henaghan *et al.* (2013) 345. See also Williams, Spencer *et al.* (2015) e6.

As was suggested above, this issue may perhaps be addressed by making dynamic consent both a paper-based as well as electronic format and adapting the electronic version thereof to different devices. However, regardless of the challenges to implementing a system of dynamic consent, it holds great potential to at least build on the elements of informed consent and to aid in fostering and encouraging the rights and interests of patients and research participants.[88] This circular fostering of the rights of both parties involved in the process will be clarified in the following section of this chapter as the working of dynamic consent is explained.

2.3 HOW DYNAMIC CONSENT WORKS

As mentioned previously, dynamic consent may be seen as an idea or theory which may be achieved in practice by making use of technical solutions, compliance services and legal accountability.[89] EnCoRe which is discussed below, is an example of the practical mechanisms whereby dynamic consent may be exercised. Dynamic consent thus entails a new digital system which allows patients and donors to grant consent electronically and to monitor the possible uses of their tissue samples and personal information and to make decisions about how these may be used in future.[90] By offering dynamic consent along with online services the participant is permitted to be in control of their personal data and material and to monitor the use thereof.[91]

Dynamic consent works in a circular manner as illustrated by *Figure J* below. The research participant or "data subject" change their consent preferences. The researcher, or "data controller" then uses and shares the data or sample in accordance with the restrictions set by the "data subject's" consent and the "data subject" is then notified and kept informed of where and when their data was used.[92]

[88] *Idem* 341.
[89] Dynamic Consent Open Framework (2010) "What, how, why" online.
[90] HeLEX (2011) "Dynamic consent project" available online at http://www.publichealth.ox.ac.uk/helex/about/research-projects-1/dynamic-consent-project accessed 25/9/2013.
[91] Dynamic consent indirectly improves an individual's trust in online enterprises by offering the user the opportunity to remain informed and in control of their information. See HW Communications (2012) online. See also Dynamic Consent Open Framework (2010) "Home page" online.
[92] Dynamic Consent Open Framework (2010) "Home page" online.

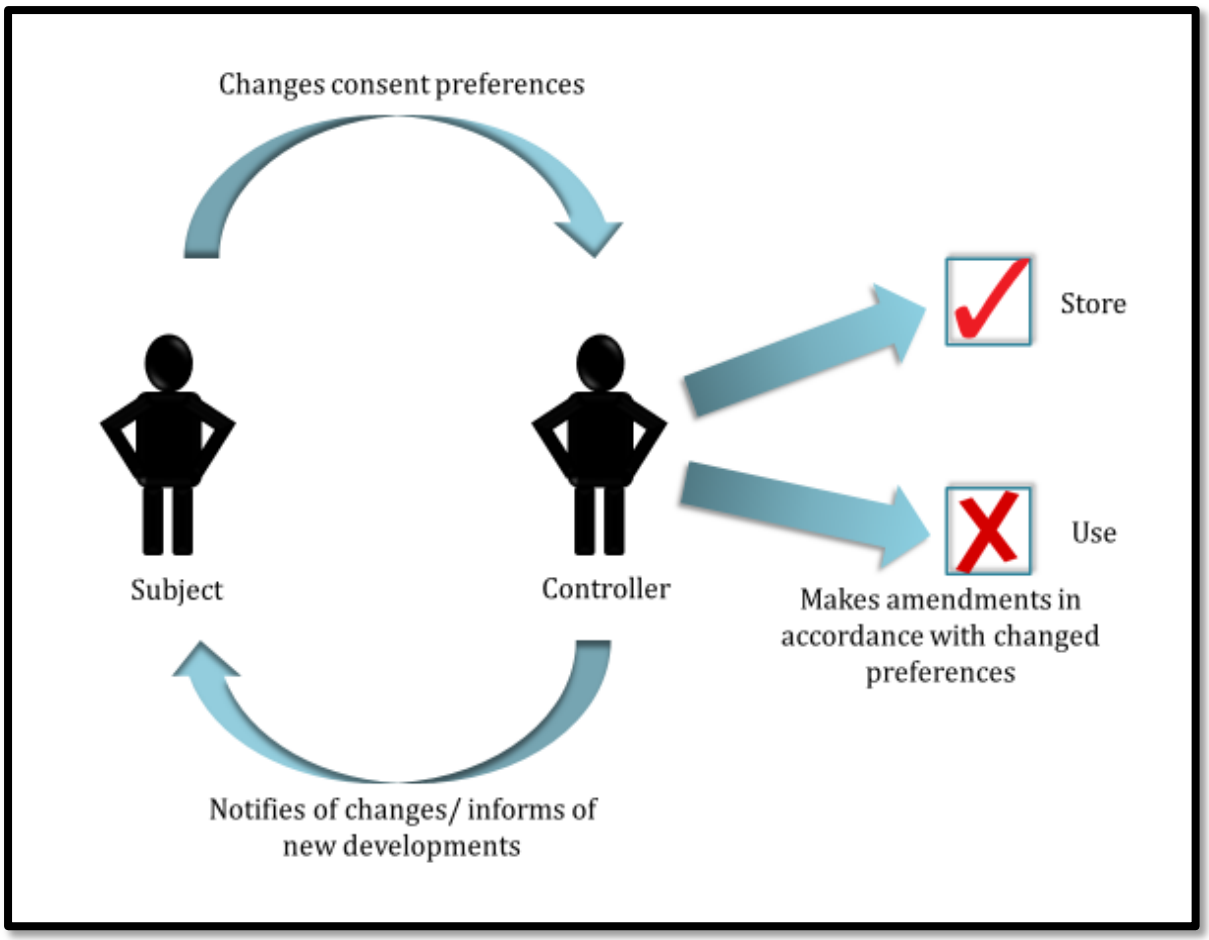

Figure J: The circular nature of dynamic consent

Dynamic consent, while being perhaps the most informed manifestation of informed consent, utilises web-based technology features to solve the problem, as observed in using broad consent, namely the lack of specific "real-time" information about individual research projects.[93] The interface must, however, be capable of providing a flexible method which provides different degrees of control to participants, based on their personal preferences.[94] The EnCoRe dynamic consent model is a web-based platform which allows research participants to have an "interactive relationship with the custodians of biobanks and the research community."[95] Dynamic consent promotes a process which emphasises continuous re-contact with donors of material or participants by providing real-time information on research projects and allows for easy revocation of any previously given consent.[96] EnCoRe as discussed below is suggested to be a prime example of the practical application of the principles of dynamic consent. Other

[93] Whitley, Kanellopoulou *et al*. (2012) 232-242.
[94] Kaye, Curren *et al*. (2012) 372.
[95] Kaye (2012) 177.
[96] Steinbekk, Myskja *et al*. (2013) 898. See also Whitley, Kanellopoulou *et al*. (2012) 232-242.

examples also exist and illustrate that the concept of dynamic consent is in fact practically applicable.

2.3.1 Projects and Online Initiatives Making Use of the Dynamic Consent Approach

This section briefly discusses projects and collaborations such as First Genetic Trust and Private Access as well as online initiatives such as 23andMe and PatientsLikeMe other than EnCoRe making use of a dynamic consent approach. A distinction may be drawn, for interest's sake, as First Genetic Trust and Private Access are projects and collaborations, while 23andMe and PatientsLikeMe are initiatives.

2.3.1.1 First Genetic Trust

Some of the earliest references to dynamic consent originated in 2001 when an online proprietary genetic banking system was proposed by First Genetic Trust (FGT). This proposal held that FGT identified the individual's concern regarding the security of their genetic data as a potential restriction to pharmacogenetics[97] and personalised medicine. In order to address this concern, FGT proposed dynamic informed consent mechanisms to protect the individual's medical and genetic confidentiality and which allows access to information, use and application of such data and material only where an individual has given consent thereto.[98] FGT would therefore play the role of a broker between patients or research subjects on the one hand and researchers, health care providers and pharmaceutical companies on the other.[99]

As a broker, FGT would create a confidential database. Individuals would then grant consent to the storage of their genetic information in this database intended for clinical research and they would control access to this data. This would protect their privacy and maintain confidentiality of medical and genetic information while allowing the individual to be party to genetic research.[100] FGT would make use of the internet to maintain ongoing communication with individuals by providing them with updates on research findings, seek further consent for any new studies, supply information on the risks and benefits of research projects, and make re-contact with individuals where necessary. The FGT system would assist researchers in efficient

[97] Pharmacogenetics is a branch of pharmacology which concerns itself with the interaction between and effect a person's genes may have on their reaction to drugs.
[98] Marshall E (2001) "Company plans to bank human DNA profiles" *Science* 291(15504): 575.
[99] Wee R (2013) "Dynamic consent in the digital age of biology" *Journal of Primary Health Care* 5(3): 259.
[100] Cambridge Healthtech Institute (2004) "The art of translating genomic data into clinical practice: An interview with David Wang of First Genetic Trust" *Molecular Med Monthly* 41(1): 47.

collection, storage, management and analysis data. Drug companies would also be aided by FGT as a network would be established between them and physicians to enable direct access to patients or samples.[101]

Today FGT provides IT infrastructures that support the development and management of *inter alia* genetic data in drug discovery, development and commercialisation. It offers genetic data handling as well as bioinformatics services to medical researchers, pharmaceutical companies and health care providers involved in genetic research. Additionally, FGT operates an online portal for genetic information, education and counselling to facilitate decision-making pertaining to the use of private genetic information.[102]

2.3.1.2 Private Access

Private Access Incorporated was founded in 2006 and is widely seen as an example of the use of technology in connecting numerous stakeholders in an attempt to generate awareness of and participation in clinical trials. It also attempts to increase recruitment and enrolment and the obtaining of consent in an ongoing and interactive manner.

Private Access hopes to achieve the above-mentioned objectives by developing an online clinical trial community which engages patients, physicians, researchers and industry partners.[103] Private Access further provides social networking opportunities on the clinical trial experience and authentication of persons to search for highly confidential or sensitive information.

The technology as patented by Private Access allows individuals to exercise dynamic control over their information, in that a person may make alterations to their preferences at any time. This control is also granular in nature as it grants individuals the ability to be granularly exact down to a desired element of data.[104]

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[101] Lewis G (2004) "Tissue collection and the pharmaceutical industry" in Tutton R & Corrigan O (eds) *Genetic databases: Socio-ethical issues in the collection and use of DNA*: 189.
[102] Bloomberg (2016) "Company overview of First Genetic Trust" available online at http://www.bloomberg.com/research/stocks/private/snapshot.asp?privcapId=471982 accessed 11/7/2016.
[103] Business Wire (2009) "Pfhizer and Private Access announces plans to develop online community to accelerate clinical research" available online at http://www.businesswire.com/news/home/20090819005806/em/Pfizer-Private-Access-Announce-Plans-Develop-Online accessed 26/11/2015.
[104] Wee (2013) 260.

2.3.1.3 23andMe

23andMe is a private web-based company which sells direct-to-consumer DNA testing services online.[105] Research is conducted through 23andMe's research arm and is described as a customer-driven, web-based collaborative research study in that while individuals pay for genotyping, they are asked to participate in research which entails the completion of surveys.[106] Enrolment, participation as well as ongoing engagement in 23andMe's research is undertaken via an interactive web-based environment. Once an individual has accepted the 23andMe Terms of Service they are required to consent to the 23andMe research activities. A biobanking option is also offered to the individual.[107]

While 23andMe analyse the sample, the individual is presented with an invitation to participate in research surveys. Once the individual's data is available, they receive an email notifying them to log on to the website. They furthermore receive continual genetic reports and new surveys. This means that a continuous two-way interaction is maintained online between the company and the individual, with the individual choosing whether or not to participate further and if so, what surveys they are willing to complete. This model of interactive consent is beneficial in that it reduces the burden of re-contact and re-consent while also enabling the exercise of autonomy by providing informed consent to new research.[108]

An individual may withdraw from 23andMe's research at any time and such withdrawal does not affect their access to their genetic information or to ongoing services provided by the company. The company thus continues to generate and make available reports on their newest discoveries.

A somewhat concerning aspect of the 23andMe system must, however, be noted. Where an individual does not consent to their information being used in 23andWe[109] research or on the 23andMe Research Portal, their genetic and/or self-reported information may still be used for

[105] 23andMe (2013) "Genetic testing for health, disease and ancestry" available online at http:www.23andme.com accessed 26/11/2015.
[106] 23andMe waive their genotyping fee in exchange for participation in research, unethically it is submitted, involving Parkinson's Disease, sarcoma, myeloproliferative neoplasm and "Roots into the Future."
[107] The 23andMe process heeds the following steps: an individual signs up to 23andMe online and is then sent a collection kit whereby they provide a sample. The collection kit has a unique barcode number which the individual must then register on their personal account as part of the finalisation of the account. This includes accepting the Terms of Service (ToS) which set out the legal grounds for the genotyping services offered which includes extracting and processing DNA and uploading information to the website.
[108] Wee, Henaghan *et al*. (2013) 342.
[109] 23andWE is the research arm of 23andMe. See in general, Vorhaus D (2009) "Genomic research goes DTC" *Genomics Law Report* available online at http://www.genomicslawreport.com/index.php/tag/23andwe/ accessed 26/11/2015.

"R&D purposes."[110] These purposes include "other commitments" of 23andMe and may include *inter alia* improvement of services, quality control and data analysis or commercialisation.

2.3.1.4 PatientsLikeMe

PatientsLikeMe (PLM) was launched in 2006 and is a health data-sharing platform which incorporates social networking functions. It allows for an online peer support community consisting of patients to connect with one another and to share information regarding their health, medical condition and general well-being.[111] As such, PLM has been described as extending the functionality of a traditional qualitative online patient community to include quantitative patient-reported data.

Since being launched, PLM has amassed an enormous database of information and has developed a pioneering model whereby online health research may be conducted. It is, however, not strictly speaking a research biobank and does not store samples. Individuals who have had their DNA analysed may therefore decide to have their genetic information uploaded, entered onto their profile and made "findable" by other persons who share the same genetic characteristics.[112]

Although there are similar websites which offer patients the online ability to communicate and support one another, PLM prompts its members to enter data and makes use of a range of web-enabled tools in order to display that data to provide actionable information.[113] The objective of PLM is therefore to improve the quality of life of its members by the facilitation of shared information which might help patients to answer their questions. PLM is a significant, key international social-networking website which also serves as a real-time research platform and it conducts non-traditional research by collecting and analysing data on site.

In context of this chapter, it is important to note the dynamic manner whereby individuals participate and elect to supply their information to PLM. New information is provided to members as PLM incorporates real-tile ClinicalTrials.gov[114] listings where its members may be

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[110] 23andMe define R&D purposes as "research and development activities performed by 23andMe on user data." See 23andMe (2015) "Privacy highlights" available online at https://www.23andme.com/en-int/about/privacy/ accessed 26/11/2015.
[111] Allison M (2009) "Can web 2.0 reboot clinical trials?" *Nature Biotechnology* 27: 896.
[112] PatientsLikeMe (2009) "New Parkinson's genetics engine to enhance research through shared data" *The Value of Openness* available online at http://blog.patientslikeme.com/2009/08/ accessed 26/11/2015.
[113] Rollyson C (2008) "PatientsLikeMe: Healtcare web 2.0 innovator case study" available online at http://rollyson.net/patientslikeme-healthcare-web-20-innovator-case-study/ accessed 26/11/2015.
[114] ClinicalTrials.gov is a free, open access database, the largest in the world actually, for publicly and privately supported clinical trials and currently has 203 492 registered studies being conducted across 191 countries. See in general, ClinicalTrials.gov website available online at https://clinicaltrials.gov/ accessed 26/11/2015.

provided with information regarding research findings and new trails for which they may be eligible. PLM members may, at any time cancel or permanently deactivate their account.

A further online, web-based initiative which applies the concept of dynamic consent is the Ensuring Consent and Revocation, or EnCoRe, project which is discussed in greater detail below. At this juncture it is, however, pertinent to firstly explain the relationship between dynamic consent and EnCoRe.

2.4 RELATIONSHIP BETWEEN DYNAMIC CONSENT AND EnCoRe

Dynamic consent is both a specific project and, of more importance to this thesis, a broader idea or concept. EnCoRe is an implementable IT system. These concepts may be combined to become a powerful tool in exercising autonomy and granting, altering and revoking consent. In other words, dynamic consent is the model or theory and EnCoRe is the practical application thereof. It is submitted that although the EnCoRe project is currently mostly focussed on an individual's data and information, the functionality thereof may be broadened to include human biological material as well.

Dynamic consent and EnCoRe fall under the greater reach of the digital age of biology, and according to Craig Venter the digital and biological worlds are interchangeable and at some point in the future, personal biology will be transmittable across the internet.[115] Also, the concept of dynamic consent increasingly makes use of numerous health information and communication technology initiatives and as such the interest of various innovators and commentators has been piqued. It must therefore be possible to develop an infrastructure of control which may be used on different aspects of stem cell technology, be it information, material or associated data.

By making use of a combined approach of dynamic consent and EnCoRe, consent is therefore not a mere communication exercise but a bidirectional, ongoing and interactive process taking place between researchers and participants.

[115] J Craig Venter is the head of Celera Genomics. See Wee (2013) 259. See in general, Highfield R (2013) "J Craig Venter sequenced the human genome. Now he wants to convert DNA into a digital signal" available online at http://www.wired.co.uk/article/j-craig-venter-interview accessed 27/11/2015.

2.5 SUMMARY OF DYNAMIC CONSENT

The status of research participants in regard to their involvement in research decisions and the appropriate consent which results from this has become a prominent issue in biomedical scenarios. As such, a shift has become visible towards participant-centred initiatives which places the participant and researcher in a decision making partnership. A PCI is defined as "a tool, program and project that empowers a participant to engage in research processes using IT."

Dynamic consent finds it origins in this school of thought and may be understood as not only a specific project, but also as a general concept which may radically alter the nature of consent in research. This is due to the fact that dynamic consent makes provision for an electronic system of consent rather than the customary paper format currently used.

Consent has been shown to be an unequivocal requirement in lawful treatment and research and is a fundamental ethical and legal principle. However, the uncertain scope of biomedical procedures and research is problematic and broad consent has been suggested as a practical solution to the shortcomings of informed consent. It is, however, insufficient. This is due to the reason that stem cell and biomedical research does not follow a single experimental path and is better understood as a request to participate in an ongoing inquiry with multiple techniques and methods. Research participants must be enabled to review their consent as new research possibilities emerge in terms of ethical principles. It may also be of clinical benefit to such participants. Legally, a more comprehensive consent format might also be preferable as it excludes liability to a greater extent. Also, since autonomy is not static, research participants must be regarded as active partners in exercising their autonomy.

Consent should be based on extendable information, as much choice and control as possible and it should be rescindable and allow for the *vetoing* of activities. Dynamic consent addresses the changing nature of autonomy and research and evolves with it.

Dynamic consent may be defined as a new approach for engaging individuals in the use of their information and material, and it is dynamic in that it allows interaction over time, enables participants to consent to new studies or amend their consent in real time as their circumstances change, and to have confidence that their changed preferences will be adhered to. Consent is flexible and adaptable by providing a personalised, interactive communication interface which promotes participant engagement by enabling an interactive relationship between researchers and participants. At the heart of the matter, it is a mechanism which facilitates communication between participant and researcher and thus offers participants the

opportunity not only to be informed, but also to have control over their information and material on a continuous basis.

Dynamic consent facilitates the use and re-use of material or information with the knowledge and consent of the participant; it enables individuals to grant or revoke consent in accordance with their changing preferences; to establish a record of all transactions and interactions; it enables approaching individuals for different types of projects; and facilitates the modification of consent over time. As such, certain characteristics of dynamic consent approaches may be identified which include that the participant is able to consent to new research developments with ease and in real time; contact information may be amended; individuals may choose how to receive information pertaining to how their material has been used; as well as the type of information to be provided. Dynamic consent is a beneficial and superior consent model as it facilitates efficient re-contact, it conforms to the highest legal standards, it offers fine-grained revocation, it enables better communication, and it improves scientific literacy, transparency and risk management. It facilitates improved research, involves participants in the process, better respects their autonomy and permits meaningful consent. Participants are better informed by dynamic consent, it encourages participation in biomedical research, it transfers control and ethical responsibility to the participant and it enables the return of results and incidental findings.

Where dynamic consent is the idea or theory, technical solutions, compliance services and legal accountability are the practice. It therefore functions as a digital system whereby participants electronically grant and monitor their consent, samples and information. In other words, participants are given control by making use of online services such as EnCoRe and it then takes on a circular nature. It may thus be described as the epitome of informed consent while also solving the issues surrounding the scope of informed consent. It is therefore the best combination of informed and broad consent.

At this juncture it now becomes pertinent to discuss EnCoRe in detail as much mention has been made of this information technology research project throughout the course of this chapter.

3 ENSURING CONSENT AND REVOCATION (EnCoRe)

Ensuring Consent and Revocation (EnCoRe) is a relatively recent information and communications technology (ICT) research project which examines the development and design

of dynamic consent mechanisms.[116] The project was originally launched as an interdisciplinary research project into informational privacy undertaken by members of industry and academia in the United Kingdom.[117] It began in June 2008[118] and was initially set to run for a period of almost four years, ending in February 2012.[119] The creators of EnCoRe envisioned providing individuals with more control over their information.[120] The EnCoRe project therefore connects technology, process and regulatory research and development within the framework delineated by the requirements of the differing stakeholders in order to achieve an improved consent and revocation regulatory regime.[121] In order to understand the admiration which this thesis shows towards EnCoRe, it is necessary to discuss what it is, how it works and why it is recommended in this thesis and chapter.

3.1 DEFINING EnCoRe

EnCoRe may be described as a patient-centric IT system which makes use of the dynamic consent approach. It attempts to enable individuals to exercise the choice of granting or revoking consent over the use of their information in a manner which is easy, intuitive and as reliable as "turning a tap on and off."[122] It may be distinguished from other privacy projects as it emphasises consent and revocation as reverse processes.[123]

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[116] Wee (2013) 260.
[117] It is partially funded by the Technology Strategy Board, the Engineering and Physical Sciences Research Council and the Economic and Social Research Council. The project cost an estimated 3.6 million and consists of a multidisciplinary team of persons which include researchers from HP's Systems Security Lab in Bristol, WMG International Manufacturing Centre at the University of Warwick, QinetiQ, HW Communications, Oxford University's Ethox Centre legal department and business experts from the London School of Economics (LSE). See Kaye J (2010) "Ensuring consent and revocation (EnCoRe)" available online at www.publichealth.ox.ac.uk/ethox/research/research-archive/ensuring-consent-and-revocation-encore accessed 25/9/2013.
[118] HeLEX (2008) "EnCoRe project" available online at www.publichealth.ox.ac.uk/helex/about/research-projects-1/encore-project accessed 25/9/2013.
[119] EnCoRe (2008) "About the project" available online at www.encore-project.info/about.html accessed 25/9/2013.
[120] Wee (2013) 260.
[121] HeLEX (2008) online.
[122] Wee (2013) 260. This may be more eloquently stated as "the overall vision of the project is to make giving consent as reliable and easy as turning on a tap and revoking that consent as reliable and easy as turning it off again" by Agrafiotis I, Creese S & Goldsmith M (2012) "Developing a strategy for automated privacy testing suits" in Camensich J, Crispo B, Fischer-Hübner S, Leenes R & Russello G (eds) *Privacy and identity management for life: Selected papers* Springer: New York: 31 at 33. See also Mont MC, Sharma V & Pearson S (2012) "EnCoRe: Dynamic consent, policy enforcement and accountable information sharing within and across organisations" *HP Laboratories Technical Report 01/2010*: ii.
[123] Pearson S, Creese AS, Goldsmith M, Papanikolaou N & Mont M (2010) "Defining consent and revocation policies" *Proceedings of the IFIP PrimeLife Summer School* available online at http://www.dcs.warwick.ac.uk/~nikos/downloads/pdfprimelife2010definingcrpolslides.pdf accessed 25/9/2013: 4. Regarding revocation, it is interesting to note the PrimeLife research project. PrimeLife, which was a 36-month research project on bringing sustainable privacy and identity management to future networks and services which ended in October 2011, created a revocation model which distinguishes between core and derived revocation types. The core types of revocation are: no revocation, meaning that consent is irreversible; deletion of data; revocation of permission to process and revocation of permission to share the data. Delegated or derived revocation types are:

The intentions of the EnCoRe project are threefold. Firstly, it attempts to enable organisations to adopt scalable, cost effective and robust methods of consent and revocation whereby use, storage, location and dissemination of personal data and samples may be controlled. Secondly, to establish a meaningful, intuitive mechanism which will enable individuals to control the use of their personal data and any material held by other persons. Lastly, it hopes to restore confidence in participation in the digital economy.

Four categories pertaining to the key features of EnCoRe may be identified as follows:[124]

1. Individuals may, by making use of an IT interface, specify their preferences relating to the choices they are given regarding the use of their data and samples in research projects;
2. The EnCoRe system allows individuals to change their minds and accordingly, their preferences, over time and to make use of revocation options where appropriate;
3. Individuals may track and audit any amendments they make; and
4. Individuals are given the ability to decide when and how they are contacted.

Consent, in terms of the EnCoRe model, is no longer a mere exercise in communication, but a bidirectional, ongoing and interactive process which takes place between a researcher and a participant.[125] This dynamic, interactive relationship indicates a dynamic consent and it is made possible by the use of web 2.0 technologies.[126]

3.2 HOW EnCoRe WORKS

The EnCoRe project created a patient-centric IT system which utilises the dynamic consent approach to obtaining consent or consents from a patient or research participant.[127] As was mentioned previously, it establishes consent as a bidirectional, ongoing and interactive process between participant and researcher rather than an exercise in communication and is distinguishable from other projects as it emphasises consent and revocation as reverse

consentless revocation; cascading revocation; delegated revocation and revocation of identity known as anonymisation. In terms of the findings of the PrimeLife project, privacy policies must therefore contain: collection permissions; processing permissions; sharing permissions with regards to third parties; constraints, if any, on consent variables; and available revocation mechanisms. For more on this project see PrimeLife (2011) "PrimeLife-Bringing sustainable privacy and identity management to future networks and services" available online at http://primelife.ercim.eu/ accessed 2/11/2013 and Pearson, Creese *et al*. (2010) online 15-17.

[124] Wee (2013) 260-261.

[125] Wee (2013) 261.

[126] Kaye (2012) 172.

[127] For detailed information on the technical architecture of this system see Mont, Sharma *et al*. (2012). For more on the focus group process used to establish the workings of EnCoRe see, Whitley EA & Kanellopoulou NK (2011) "Privacy and informed consent in online interactions: Evidence from expert focus groups" available online at http://aisel.aisnet.org/icis2010_submissions/126/ accessed 25/9/2013.

processes.[128] The IT interface thus enables individuals to make and express preferences related to the use of their data and samples for research purposes.[129]

In order to characterise consent in a manner which is fine-grained, EnCoRe makes use of constraints in the form of so-called "consent variables."[130] This means that different options exist regarding the length of time consent is held, the volume of data to which the consent applies, the purposes for which data may be used, and the parties with whom the data may be shared.[131] Consent is seen as a combination of permissions and restraints granted to the data controller by the data subject in line with these variables.[132]

The EnCoRe dynamic consent model is a web-based platform which allows research participants to have an "interactive relationship with the custodians of biobanks and the research community."[133] Dynamic consent promotes a process which emphasises continuous re-contact with donors of material by providing real-time information on research projects and allows for easy revocation of any previously given consent.[134] In comparison to broad consent, dynamic consent entails a narrower, more specific consent with opt-in requirements for future research projects.[135]

During online interactions, each potential subject must be adequately informed of the aims and the methods of the research, the anticipated benefits and the potential risks of the interaction, and any other relevant aspects thereof.[136] Furthermore, the potential subject must be informed of their right to refuse to participate in the interaction or to withdraw their consent at any time. Attention must be paid to each subject's informational needs and also to the methods whereby information should be delivered.[137] After ensuring that the potential subject understands the information which they have been given, the researcher must attempt to obtain the subject's freely given consent.[138] It is therefore clear that a dynamic EnCoRe consent model is intrinsically informed and complies with other requirements to render consent lawful as well. In spite of the

[128] Pearson, Creese *et al*. (2010) online 4.
[129] Kaye J, Whitley EA, Kanellopoulou NK, Creese S, Hughes KJ & Lund D (2011) "Broad consent is informed consent: Dynamic consent-A solution to a perennial problem" *BMJ Online* available online at http://www.bmj.com/rapid-response/2011/11/08/re-broad-consent-informed-consent accessed 30/9/2013.
[130] The interface must provide a flexible method which provides different degrees of control to participants, based on their personal preferences. See Kaye, Curren *et al*. (2012) 372.
[131] Pearson, Creese *et al*. (2010) online 12.
[132] Consent is seen as a combination of permissions which the data controller is granted by the data subject and constraints on the consent variables. Pearson, Creese *et al*. (2010) online 13.
[133] Kaye (2012) 177.
[134] Steinbekk, Myskja *et al*. (2013) 898. See also Whitley, Kanellopoulou *et al*. (2012) 232-242.
[135] *Ibid*.
[136] Whitley & Kanellopoulou (2011) online 7.
[137] *Idem* 8.
[138] *Idem* 9.

great promise of this model of consent, there are, however, some challenges to the practical implementation thereof.

3.2.1 Implementation Challenges

In order to implement the EnCoRe model a clear strategy, resources and significant changes to existing practices, procedures and regulatory structures will be required. A reason for this is that treatment and research have been kept apart as being distinct activities. The *status quo* is currently kept by the law and regulatory practices, procedures and policies and a new system of consent which alters the relationship between a doctor and patient or researcher and participant will not be implemented without controversy, effort and upset.[139] It will be necessary to engage the community at large, to provide information regarding the system and to establish the wants and needs of patients and participants regarding sensitive issues such as privacy, commercialisation and ownership. In other words, issues of accountability and transparency will become key.

Since the flow of information is altered, new policies and protocols will have to be designed. This will necessitate collaboration between legislatures, patients, research participants, the research community, health care providers and facilities and industry members, to name but a few potential role players. In other words, various groups will have to pull together "like the teeth of a zipper."[140]

Probably the greatest implementation challenge will be the alignment of regulatory mechanisms to enable bidirectional information and sample flow. A shift in the current culture of research and treatment will also be required. The digital divide is also a concerning challenge to implementation and this mechanism of consent will have to be adapted to the South African environment. This may be justified when taking into account the compelling reasons to follow a dynamic consent EnCoRe approach to consent as will be discussed in the following section of this chapter.

3.3 WHY EnCoRe?

As a once-off process, consent is described in vague terms. In certain instances, it may even be granted implicitly. Either way, no real control exists over the divulged information or the

[139] Kaye (2012) 173.
[140] *Ibid.*

already removed material, no surety is given that the wishes of the relevant person will be adhered to and very importantly, no real option to revoke consent exists.[141] When an individual discloses personal data to an entity, he/she also grants consent, sometimes even implicitly, for the data to be used for other purposes. Any subsequent storage, use and sharing of this data is based on the notion of trust that the given consent will be respected.[142] However, at the time of granting consent a research subject may not be fully aware of the implications of such consent and may, as a result of this, decide to give the simplest form of consent. At a later stage, the subject may wish to revoke their consent or change what he/she had consented to. To do this, the relevant organisation is required to undertake a set of complicated interactions. EnCoRe attempts to provide the framework or system whereby this may be done in an easier and more streamlined, faster manner.[143]

EnCoRe will enable participants to achieve levels of control over how their information, data and material are used by researchers and clinicians. Two methods whereby this may be achieved are identifiable. Firstly, those whereby participants are informed, and secondly, those whereby meaningful decisions may be made which affect future uses of their information, data and material. In other words, EnCoRe will facilitate a two-way exchange of information which allows decisional functions to be exercised.[144]

It has been reported that most patients would prefer to have the opportunity to consent to the use of their information and samples.[145] There are, however, massive logistical challenges in obtaining such consents since ethical concerns prohibit researchers from making direct contact with patients.[146] Another difficulty which arises is providing all the relevant information about a complex issue. However, it is necessary to find ways of obtaining the required consent without stifling research and also to discover methods whereby public knowledge regarding a research process making use of data or human material may be improved.[147]

Currently, a person has no control over the distribution of their personal information after it has been divulged, and they also have no assurance that it is removed from a database after they have requested it be done. Information is often also handed over to third parties which

[141] EnCoRe (2008) "Welcome to the EnCoRe project website" available online at www.encore-project.info/index.html accessed 25/9/2013.
[142] Mont, Sharma *et al*. (2012) ii.
[143] *Idem* 1.
[144] Wee (2013) 260.
[145] See in general, Chen DT, Rosenstein DL, Muthappan P, Hilsenbeck SG, Miller FG, Emanuel EJ & Wendler D (2005) "Research with stored tissue samples: What do research participants want?" *JAMA Archives of Internal Medicine* 165(6): 625-655.
[146] Willison DJ, Keshavjee K, Nair K, Goldsmith C & Holbrook AM (2003) "Patients' consent preferences for research uses of information in electronic medical records: Interview and survey" *British Medical Journal* 326: 373. See also Rogers WA & Schwartz L (2002) "Supporting ethical practice in primary care research: Strategies for action" *British Journal of General Practice* 52: 1007-1011.
[147] Jepson RG & Robertson R (2003) "Difficulties in giving fully informed consent" *British Medical Journal* 326: 1039.

complicates any measure of control even further, justifying the need for a system where the flow of data and material is easy and intuitive to turn on and off.[148] Normally, organisations in control of data[149] do not feel compelled to allow an individual "fine-grained" control over their information. An individual's specific instructions relating to information as given to one organisation may also not be communicated to or respected by later organisations to which the information is sent. One reason for this is that computer and technology systems are not currently built to support such features.[150] This means that where individuals wishe to be more specific than the options offered in once-off, "opt-in/opt-out" consent formats, or where they would like to change or revoke their consent, they have to undertake a investigation of finding the relevant person to help them, finding that person's contact details, contacting that person and then making the desired changes or revoking the consent. The relevant data-controlling person then has to determine whether or not the desired wishes are feasible and then has to undertake numerous once-off actions to realise the wishes of the individual. Where the information has already been forwarded to a third party, this process becomes even more complicated. This means that the individual may be effectively prevented from exerting any meaningful control.[151]

Better control of material and data flow will then encourage and promote participation in research.[152] To achieve this "flow" goal, the processes whereby consent is obtained must be specific, reliable, rigorous, verifiable and compliant with legal regulations and of course, the preferences and wishes of the person concerned must be respected.[153] In order to enable control over information, consent management technologies must be developed; IT systems architectures which include these technologies must be developed; organisations' operational processes and systems must be designed or enhanced to be able to make use of these technologies; easy-to-use interfaces will have to be developed and implemented; and the regulatory regime wherein this all takes place will need to be enhanced and strengthened.[154]

EnCoRe attempts to transform consent into a powerful means of control by enabling persons to exercise more control over the information they disclose to an organisation. This control should be able to direct the purposes for which the information or material is used, which third parties

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148 Kaye (2010) online.
149 Referred to as "data controllers." See paragraph 2.3 *supra*.
150 EnCoRe (2008) "Welcome to the EnCoRe project website" online.
151 *Ibid*.
152 According to Professor Sadie Creese of WMG, "there are plenty of occasions when we want to be able to share our information but we need more control over the process. If we turn the tap on we need to know our data is only flowing where we want it to; if we turn the tap off, there must be no leaks." See Kaye (2010) online. It is suggested that it be considered separating the concepts of "control" and "ownership" of data and material. A further investigation into this, however, falls outside of the ambit of this thesis.
153 EnCoRe (2008) "About the project" online.
154 *Ibid*.

it may be shared with and for how long it may be stored.[155] This should also include the manner of destruction, if any, applicable in the case of revocation of consent.[156]

The system is of benefit both to the individual, who may be seen as a potential research participant, and to the eventual researcher and research project. EnCoRe and dynamic consent benefit the individual as they make it possible for such a person to change their mind and preferences over time, to revoke their choices, to track and audit any changes which they have made and even to choose if and how they may be contacted. In other words, this interface enables individuals to exercise their autonomy by enabling them to grant informed consent for new uses of their samples and data in real time rather than once-off broad consent in the beginning of a venture. The benefit to the research process is that recruitment of potential donors and participants is relaxed, it costs less and is more efficient; it is possible to meet the legal and the ethical requirements; the research process and its findings are more transparent and accountable; and the findings may be given to the participant as they are a part of personalised medicine.[157]

3.4 SUMMARY OF EnCoRe

EnCoRe, a recent information and communications technology project, examines the development and design of dynamic consent mechanisms. It may be described as a patient-centric IT system which utilises the dynamic consent approach and attempts to enable individuals to exercise their choice of granting or revoking consent in a manner which is as easy, intuitive and reliable as "turning a tap on and off."

The EnCoRe project has three objectives. Firstly, to enable organisations to adopt scalable, cost effective and robust consent and revocation methods which allow use, storage, location and dissemination of personal data and samples to be controlled. Secondly, to establish a mechanism which enables meaningful and intuitive exercise of control and lastly, it hopes to restore confidence in the digital economy. EnCoRe therefore has four key features which may be identified namely, the specification of preferences by making use of an IT interface; real-time preference amendments and revocation of consent; the ability to track and audit any changes made to preferences and the ability to decide when and how individuals may be contacted. This means that consent is a web-based, bidirectional, ongoing interactive process and not a mere exercise in communication.

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155 *Ibid*.
156 *Ibid*.
157 Kanellopoulou, Kaye *et al*. (2011) online.

EnCoRe achieves this by the development of a patient-centric IT system which applies dynamic consent principles and fine-grained consent is made possible by using consent variables. Consent, in terms of EnCoRe, is seen as a combination of permissions and restraints and therefore, consent variables are different options pertaining to the period of time for which consent is held, the amount of data or material to which it applies, the permitted purposes of use, options regarding the sharing of such data or material and the mode of destruction of material where appropriate. In other words, it facilitates a streamlined exchange or "flow" of information between a research participant and researcher. Ultimately, the exercise of autonomy is promoted.

This thesis endeavoured to examine consent in circumstances where the efficacy of a medical treatment is yet untested and this new therapy is therefore so uncertain that it is tantamount to research involving human subjects. It was found that neither informed nor broad consent constitute proper or sufficient consent in these instances and in an attempt to address this issue, dynamic consent was identified and introduced as a viable potential solution to the consent dilemma. At this juncture it therefore becomes pertinent to discuss dynamic consent in context of this thesis.

4 DYNAMIC CONSENT AS CONTRIBUTION OF THIS THESIS

Consent is an indelible requirement in any undertaking of a medical or scientific nature where a human being is involved. Numerous legal documents have built on this and as such, informed consent has become the most prominent requisite for lawful medical treatment or research participation and is entrenched and enforced by procedures, practices and policies.[158] This means that persons who decide and agree to partake in any form of medical or biomedical research are required to grant voluntary, informed consent to the use of their donated samples and the associated data before the research study may commence.[159] Informed consent is the norm but the exact form of appropriate consent, be that broad or simple or explicit or implicit or presumed, will depend on the type of research study to be conducted.[160] As has been argued in the course of this thesis, the scope of informed consent, which influences the validity and meaningfulness thereof, is greatly problematic in terms of stem cell treatment and research.[161]

[158] Kaye, Curren *et al*. (2012) 371.
[159] *Ibid*.
[160] See chapter 4 paragraphs 5.4 *supra* for a discussion of these forms of consent.
[161] See in general, Mascalzoni D (2013) *Upside down: How the health 2.0-era significantly changes our view of informed consent* presented at the eHealth Workshop, Middlesex University, London, 25-28 April.

Currently, due to the confusion and complexities surrounding informed consent, broad consent is used in order to lend legitimacy to research endeavours and to provide a blanket to cover future uses of samples and data. It is deemed a pragmatic and practical solution. Broad consent is however problematic in various areas since researchers cannot "future-proof" consent forms and participants are left unable to express their preferences or protect their interests over time as circumstances change.[162] The "one size fits all" format of consent may also exclude certain groups of persons such as persons who have a historically justified reason for mistrusting the research community.[163]

Typically, a research participant is taken through a process of consent which involves a one-on-one discussion and explanation which culminates in the signing of a paper-based informed consent form.[164] This encounter focuses on obtaining once-off consent rather than understanding the broader implications involved in participation or the interests of the participant which might evolve and change over time.[165] An example of such a changing interest might be that of a participant wanting to be kept informed of any new research wherein their donated material may be used.

Recent advances in different technologies have raised questions pertaining to personal data and concerns regarding the amount of control a person might have over their own information and material. Also, concerns regarding who might access such information and material have increased. In the context of medical research, "user-centric" approaches to these concerns have been propagated and applied in what is referred to as Participant-Centred Initiatives.[166] This means that a research participant is placed in the centre of decision making which may build long-term public trust in organisations carrying out health research.[167] New advances in medical research have also created numerous challenges to research governance and regulation as well as participant protection. These challenges include *inter alia* the lack of uniform consent standards in spite of the recognition of consent as fundamental. Clarity is also lacking in regard to the participant's rights over the resulting data.[168] Another challenge lies in the differences between legal, ethical[169] and regulatory requirements in different national and international

[162] Kaye, Curren *et al*. (2012) 371. See also Mason & O'Neil (2007) viii.
[163] Dynamic consent may enhance patient confidence and promote long term future patient-researcher collaborations. See Trinidad SB, Fullerton SM, Ludman EJ, Jarvik GP, Larson EB & Burke W (2011) "Research practice and participant preferences: The growing gulf" *Science* 331(6015): 287-288.
[164] Traditionally, IT mechanisms have not been employed in engaging with research participants in a way that encourages participation and dialogue between participant and researcher. See Mascalzoni, Hicks *et al*. (2009) 2.
[165] Kaye, Curren *et al*. (2012) 371.
[166] See paragraph 2.2.2 *supra* for a detailed discussion of PCIs.
[167] Kaye, Curren *et al*. (2012) 371.
[168] See in general, Wagstaff (2011) 23-29.
[169] Research ethics are mainly concerned with the protection of the research participant's interests while still allowing research to proceed. See Kaye, Curren *et al*. (2012) 371.

jurisdictions.[170] Also, as the process of whole genome sequencing[171] becomes more and more routine, and the information held by organisations such as biobanks become more interconnected, the anonymity of the concerned person may no longer be guaranteeable.[172] Further concerns exist regarding the broad consent format which has been favoured in research, as it perhaps reduces the level of trust between participants and researchers due to the fact that no secondary use was foreseen at the time of giving the consent, but such secondary use would have been covered by broad consent, and due to this persons opted out of participation due to the possibility of secondary use without their consent or knowledge.[173] As was also mentioned previously, broad consent may not be ethically sufficient at this stage and although it may be an autonomous form of consent, it is not always worthy of respect. Keep in mind that research ethics are mainly concerned with the protection of the research participants' interests while still allowing research to proceed.[174]

IT mechanisms have not been commonplace in obtaining consent for medical or research purposes, something which is quite strange considering the high-tech nature of some fields of medicine and research studies, especially stem cells and related technologies. Also, the growing aspect of human lives which is now occurring online as may be seen in social media trends raises the question as to why more aspects of medical or research interventions have not followed this digitising trend. Biotechnology for example, has, however, been greatly facilitated by advances in computing technology and bioinformatics.[175] New methods of consent and exercising choice over samples and information are required.[176] It may thus be unequivocally concluded that new research trends demand new models of consent.[177]

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[170] See in general, Schulte in den Bäumen T, Paci D & Ibarreta D (2010) "Data protection and sample management in biobanking-A legal dichotomy" *Genomics, Society and Policy* 6: 33-46. See also Kaye J (2011) "From single biobanks to international networks: Developing e-governance" *Human Genetics* 130(3): 377-382.

[171] Whole genome sequencing, full genome sequencing, complete genome sequencing or entire genome sequencing is a process whereby the complete DNA sequence of an organism's genome may be determined. It entails sequencing the entire chromosomal DNA as well as the DNA which is contained in the mitochondria. This process should not be confused with DNA profiling whereby the likelihood of the origin of DNA from a certain group is determined and does not contain additional information on genetic relationships, origin or susceptibility to specific diseases. See Ng PC & Kirkness EF (2010) "Whole genome sequencing" *Genetic Variation: Methods in Molecular Biology* 628: 215-226.

[172] See in general, Heeney C, Hawkins N, de Vries J, Boddington P & Kaye J (2010) "Assessing the privacy risks of data sharing in genomics" *Public Health Genomics* 14: 17-25. See also Kaye J (2012) "The tension between data sharing and the protection of privacy in genomics research" *Annual Review of Genomics and Human Genetics* available online at http://www.ncbi.nlm.nih.gov/pubmed/22404490 accessed 3/11/2013.

[173] See in general, Trinidad, Fullerton *et al*. (2010) 486-495.

[174] Kaye, Curren *et al*. (2012) 371.

[175] Bioinformatics may be described as the science of collecting and analysing complex biological data such as genetic codes for example. These technologies have provided new opportunities to accumulate, share, mine and integrate data sets for clinical and research purposes and provide greater growth potential in translational research. It is important to take note that the greater part of biomedical projects rely on repositories, such as a biobank, and for this reason sharing and open access is of great importance but also carries numerous implications related to privacy and thus consent.

[176] Kaye, Curren *et al*. (2012) 372.

[177] *Ibid*.

A modernised, electronic system, such as that which has been discussed in this chapter, benefits the individual, the researcher and the research project. EnCoRe and dynamic consent benefit the individual, or the potential research participant, as it makes it possible for an individual to change their mind and preferences over time, to revoke their choices, to track and audit any changes which they have made and even to choose if and how they may be re-contacted. In other words, this interface enables individuals to exercise their autonomy by enabling them to grant extremely informed consent for new uses of their samples and data in real time rather than once-off broad consent in the beginning of a venture. The benefit to the research process is that recruitment of potential donors and participants is relaxed,[178] it costs less and is more efficient; it is possible to meet the legal and the ethical requirements; the research process and its findings are more transparent and accountable and research findings may be given to the participant as a part of personalised medicine.[179] This signals a departure from manual, paper-based processes, and implementing a dynamic consent model aligns patient preferences with the needs of medical researchers. It may even silence the debate on public good versus individual autonomy and be the final break from paternalism.[180]

In the course of this thesis it was argued that the efficacy of stem cell treatments has not yet been proven to an extent where any certainty regarding the scope thereof exists. In the context of stem cell technology, treatment borders on or even consolidates with research due to the greatly uncertain scope and immense potential of any intervention and this has two implications. The first is that a patient becomes a research participant and as such, normal principles, procedures and regulatory provisions associated with patients in a treatment setting must be broadened to include those applicable to research participants. Stem cell treatment is therefore research involving human subjects. The individual may therefore be regarded as a "patient-participant." The second implication builds on this premise and relates to the most appropriate form of consent. Traditionally, informed consent is obtained in a treatment setting while broad consent is favoured in research interventions. Due to the uncertain scope of the proposed intervention, it may be argued that the validity, meaningfulness and appropriateness of informed consent is defective. This thesis sought to find a solution to this issue.

It is suggested that since the roles that an individual play have been merged by the consolidation of treatment and research, the different types of consent required in the separate settings may also be combined. This does not mean informed broad consent as this is a

[178] Dynamic consent may enhance patient confidence and promote long-term future patient-researcher collaborations. See Trinidad, Fullerton *et al*. (2011) 287-288.
[179] Kaye, Whitley *et al*. (2011) online.
[180] *Ibid*.

contradiction in terms[181] but rather, it is suggested, by taking the best elements or characteristics of both informed and broad consent and combining them, to develop a new form of consent.

It is suggested that dynamic consent is this new consent which has the potential to find real application in the context of stem cell treatment and research. It is the ultimate combination of informed and broad consent as it allows optimally for the information requirement which then includes knowledge, but it is also applicable more broadly and therefore to an uncertain future scope due to the ability to establish re- or continuous contact with the concerned "patient-participant." It also allows for true revocation options which provide for a true exercise of autonomy and for the protection of the participant. It is therefore in the introduction of this new form of consent that this thesis finds its novel value contribution.

5 CONCLUSION

In the course of this thesis it has repeatedly been stated that firstly, consent is a prerequisite which protects participants in both clinical and research settings. Secondly, consent is a fundamental element in participation and must at all times be valid, voluntary and informed. Lastly, that a participant should be able to withdraw their consent at any time. Current consent processes, however, have various problems which include *inter alia* that the process is too long and complicated for participants, there is no sure way of ensuring that participants understand the information with which they have been provided, there are no follow up processes or provision of information over time, and the right to withdraw their consent is not taken seriously.

The position of a patient, donor or research participant pertaining to the control of their samples has become a major issue in the regulation of biomedical science. Consent is internationally recognised and required, however, no consensus exists whether blanket, specific, no or broad consent is the most fitting model of consent and in practice broad consent has been adopted. Broad consent means to give consent to a framework for future research of certain types.

[181] Scholars oppose the notion that broad consent is informed consent since aspects of future research are often unforeseen and unspecified, meaning that the scope of what is being consented to is unclear and thus "informed broad consent" is seen as a contradiction in terms. See Hofmann B (2009) "Broadening consent- and diluting ethics?" *Journal of Medical Ethics* 35: 125-129. See also Hofmann B, Solbakk JH & Holm S (2009) "Consent to biobank research: One size fits all?" in Solbakk JH, Holm S & Hofmann B (eds) *The ethics of research biobanking* Springer: Heidelberg: 3-23 and Caulfield T, Upshur R & Daar A (2003) "DNA databanks and consent: A suggested policy option involving an authorization model" *BMC Medical Ethics* 4: 1. Also see in general, Árnason GÁ, Nordal S & Árnason V (2004) *Blood and data: Ethical, legal, and social aspects of human genetic databases*. Suggested further reading, Cambon-Thomas A (2004) "The social and ethical issues of post-genomic human biobanks" *Nature Reviews Genetics* 5: 866-873.

Today, an alternative to broad consent may exist due to technological developments which have made simple, two-way, cost-efficient, real-time contact with individuals regarding their preferences possible. As such, dynamic consent has been proposed as a model whereby the problems regarding consent may be resolved and it is hoped that the problem of participants not being properly or sufficiently informed may be addressed by this model of consent.

Traditionally, IT mechanisms have not been employed in engaging with research participants in a way that encourages participation and dialogue between participant and researcher. Typically, a research participant is taken through a process of consent which involves a one-on-one discussion and explanation and this process culminates in the signing of a paper-based informed consent form. This encounter focuses on obtaining a once-off consent rather than an understanding of the broader implications of participation or the interests of the participant which might evolve and change over time. Dynamic consent, however, entails a new system which would allow patients and donors to grant consent electronically, which will allow participants to monitor the possible uses of their tissue samples and personal information and to make decisions about how these may be used in future. It enables the participant to decide the amount and type of information they wish to be given or require, and also enables them to decide the level of participation and their communication preferences.

In the course of this chapter it was shown that a shift has been made towards participant-centred initiatives, placing the participant and researcher in a decision making partnership. A PCI is a tool, program and project which is able to empower a participant to engage in research processes by using IT. Dynamic consent originates from this philosophy and it may therefore be understood as not only a specific project, but also as a general concept capable of radically altering the nature of consent procedures in research. This is a result of making use of an electronic system of consent.

Consent was shown to be an unequivocal requirement in lawful treatment and research because it is a fundamental ethical and legal principle. The uncertain scope of biomedical procedures and research, however, creates problems and attempts have been made to suggest broad consent as a practical solution to informed consent's shortcomings. Broad consent is insufficient, however, since stem cell and biomedical research divert from normal, single experiment research studies but entails a request to participate in ongoing inquiries utilising multiple techniques and methods.

It was stated that since autonomy is not considered to be a static concept, neither should research participants be regarded as passive in exercising their autonomy. Consent must therefore be based on extendable information and must be rescindable. Dynamic consent is

suggested as being able to address the changing nature of autonomy as it is able to evolve along with it.

Dynamic consent was defined as a new approach for engaging individuals in the use of their information and samples and is "dynamic" in that it allows for continuous interaction over time, enables participants to consent to new studies or amend their already given consent in real time as their circumstances change and to have confidence in that these changed preferences will be adhered to. Consent becomes flexible and adaptable by providing individuals with a personalised, interactive communication interface which promotes their engagement and enables an interactive relationship with the researcher. The very essence of dynamic consent, it was shown, is a mechanism which facilitates participant-researcher communication and offers participants the opportunity to be informed and to have continuous control over their information and material.

The numerous benefits of a system of dynamic consent were discussed and included the facilitation of use and re-use of material or information; enabling individuals to grant or revoke consent in accordance with their preferences; establishing a record of transactions and interactions; enabling the approach of individuals for various types of projects; and facilitating modification of consent over time. The characteristics of dynamic consent were also identified and include the ability to easily, and in real time, consent to new research developments; the amendment of contact information and the choice of method of receiving information related to the use of material as well as in the type of information to be received. Dynamic consent was further shown to be beneficial and superior to other forms of consent as it is able to facilitate efficient re-contact, conforms to the highest legal standards, offers fine-grained revocation options, enables better communication, improves scientific literacy as well as transparency and risk management. It is also able to facilitate improved research, it involves participants in the process, is better able to respect participants' autonomy and enables meaningful consent. Dynamic consent better informs research participants, encourages participation in biomedical research, it transfers control and ethical responsibility from review boards to the participant themselves and enables the return of results and incidental findings of the research study.

This chapter suggested that if dynamic consent is considered the theory or idea, technical solutions, compliance services and legal accountability are the practice. Dynamic consent thus functions as a digital system which enables participants to grant and monitor consent and their material electronically by making use of online services. EnCoRe was then discussed as such a service. Dynamic consent was described as the epitome of informed consent which also has the

capacity to solve the issues surrounding the scope of informed consent as identified in the course of this thesis.

The recent information and communication technology EnCoRe project was discussed as it examines the development and design of dynamic consent mechanisms. It was described as a patient-centric IT system which applies the dynamic consent approach and attempts to enable individuals to practise their decision to grant or revoke consent in an easy, intuitive manner which is as reliable as "turning a tap on and off."

The three objectives of the EnCoRe project were stated as: enabling organisations to adopt scalable, cost effective and robust consent and revocation methods which then allow for control of use, storage, location and dissemination of personal data and samples; establishing a mechanism which enables control in a meaningful and intuitive manner; and hoping to restore confidence in the digital economy. The four key features of EnCoRe, which render consent a web-based, bidirectional, ongoing interactive process and not a mere exercise in communication, were also identified as:

1. Preference specification by utilising an IT interface;
2. Real-time preference amendments and revocation of consent;
3. The ability to track and audit any preferences changes; and
4. The ability to prescribe when and how individuals may be contacted.

EnCoRe is able to achieve this by the development of a patient-centric IT system applying dynamic consent principles. It is further able to offer fine-grained consent by seeing consent as a combination of variable permissions and restraints which then represent changeable preferences. It thus facilitates a streamlined informational flow which promotes and maximises autonomy.

Consent is an indelible requirement in medical scientific ventures and it is the personification of a person's autonomy. Despite the importance and prominence thereof, great confusion still exists regarding the appropriateness thereof and it is unsure which consent format is best suited to interventions of a biotechnological nature such a stem cells. This led to the conclusion that new research trends demand new models of consent.

It was argued that a patient is more than a mere patient or research subject and may be described as a "patient-participant." This perspective broadens the applicable legal regulatory and ethical principles to be considered. As such, the two models of consent, namely informed and broad consent, have been discussed in detail in the course of this thesis. This chapter drew the conclusion that as the person concerned is now a merged "patient-participant," the

traditionally utilised consents should also be combined by using the strengths thereof. This entails the information requirement from informed consent as normally required in medical interventions and the open-endedness of broad consent as usually used in research settings. By so doing, concerns regarding the validity, meaningfulness and appropriateness of consent may be addressed.

As a value contribution to the field of law, dynamic consent was introduced and it was suggested that it constitutes this necessary new and improved consent and that it has real potential to find application in stem cell treatment and research. It is suggested to be the ultimate combination of informed and broad consent due to its capacity to allow optimally for information, which then includes knowledge, while also being more broadly applicable and prepared to address questions regarding the uncertain future scope of interventions by providing for continuous contact or re-contect with the concerned "patient-participant." True revocation options allowing true exercise of autonomy and protection of the participant are also provided for.

Dynamic consent has evolved in line with changing technological developments and it encompasses a range of characteristics which enable interactive methods of expressing and changing consent in a virtually immediate fashion and on an ongoing basis. An individual is therefore not limited by static, once-off, unchanging or time-consuming consent procedures. The ability to make use of technological means of maintaining ongoing engagement with patients or research participants provides significant advantages in circumstances where re-contact may be necessary. As such, dynamic consent marks a paradigmatic change from known consent systems and has considerable potential to strengthen long-term and continuous research activities. The real world implementation of this system and the actual IT services and systems as well as their development and installation is a matter of great technical complexity and falls outside the scope of this thesis. It is, however, suggested that the development of an EnCoRe-like system in South Africa, which takes cognisance of the difficulties and inequalities in both access to the health system and to technology, may form the basis of post-doctoral studies.

Ideally, implementation of dynamic consent procedures will allow contact between clinician, researcher and participant over time rather than once-off contact; it will be interactive rather than passive; multiple methods will be used such as the web, cell phones, email or even paper; and participants will be individually targeted meaning it will be preference sensitive with diverse options and tailored in such a manner that participants will be able to enact their preferences. This degree of control over the self and related matters is the true apex of autonomy.

PART E
CONCLUSION AND RECOMMENDATIONS

Part D of this thesis paid attention to the specific jurisdiction of the United Kingdom and, as such, completed the legal study of this thesis. Part E therefore contains the various conclusions drawn in the course of this thesis and offers recommendations for the regulation of consent in stem cell related interventions of a treatment-research nature.

Part E contains the conclusions pertaining to consent in South Africa, the international standing of consent and consent in the United Kingdom.

This will be followed by recommendations regarding who bears the responsibility of obtaining consent; the person from who consent must be obtained; the timing, scope and format of consent; certain recommendations pertaining to the drafting of the NHA and the regulations made under the Act; aspects identified in the course of this thesis in need of attention and lastly recommendations pertaining to possible post-doctoral studies.

Part E of this thesis consists of the following:

CHAPTER 10 - CONCLUSION AND RECOMMENDATIONS

CHAPTER 10
CONCLUSION
AND RECOMMENDATIONS

1 INTRODUCTION

At the onset of this thesis the question was posed as to with how many things are we so very close or on the brink of becoming acquainted, if carelessness or insufficient regulation did not restrain our inquiries. In attempting to answer this question the relationship between the law and science as well as medicine was analysed and it was shown that the law seeks to resolve disputes by providing for certain procedures. In context of this thesis the relevant procedure was that of consent. It was further argued that the law often plays a deciding role in what activities will be permissible to pursue and as such controls and balances various interests. It regulates a particular system and protects the persons participating in that system. It was therefore mentioned that the relationship between the law and medicine and the relationship between the law and science, is one of prescription and support. The law is, in either instance, essential in facilitating the continued progress of the field and by virtue of this, credence must be given to the word of the law. This thesis thus sought to explore the manner wherein the law as manifested by consent might support the development of stem cell therapy-research.

In the course of this thesis, it was argued that stem cells provide hope of miraculous cures of currently incurable diseases and might replace tissues and organs which have been damaged or are malfunctioning. However, in order to be able to fully pursue this wondrous technology, it must be knowledgably and strictly regulated in an informed manner. For this to be possible, it was shown that the legislator and regulator must possess some insight into a rapidly changing scientific and medical world.

This thesis therefore set out to explain briefly the most essential concepts of stem cell science and to illustrate the enormously experimental, uncertain nature of biotechnology. This was done since the hypothesis of this thesis argued that stem cell therapy is currently too novel and unpredictable due to its unproven efficacy which then renders stem cell treatment tantamount to research involving human subjects. Efficacy, it was stated, is an intervention or treatment's ability to produce a desired beneficial effect. In the context of stem cells and taking into consideration the novelty of such treatments, however, this is unfortunately too uncertain and

unproven. Working from this premise, it becomes clear that neither informed nor broad consent offers sufficient legal protection and should not be accepted as the format of obtaining consent in stem cell interventions.

In the course of this thesis, it was explained that embryonic, adult stem cells or stem cells derived from another source, are undifferentiated and unspecialised cells with the ability to renew and proliferate indefinitely and to develop into any and all cells in the human body. As a result of these abilities, stem cells may be divided into a hierarchy of totipotent, pluripotent, multipotent, bipotent and uni- or monopotent stem cells. This means that as a cell becomes more specialised, by way of differentiation, the cell's plasticity decreases from totipotency to unipotency.

However, not all human cells possess this capacity to differentiate in any which way and, as such, it was further explained in the course of this thesis that differentiated adult cells, or then undifferentiated cells found in small numbers amongst differentiated cells and tissues with decreased plasticity, may be used for therapy or research after subjecting the adult cells to processes such as SCNT or induced pluripotency. During these processes the adult cells are effectively dedifferentiated to a state of potency equal to that of an HES cell. It was, however, stated that no clinical trials using iPS cells have started and therefore no "clinical grade" iPS cells have been grown. "Clinical grade" means the standard of quality required for use in human patients. A second concern which illustrated the still experimental nature of stem cell treatment was related to cell memory and mutation of epigenomic warts.

After explaining what stem cells are and the sources or creation of stem cells, attention was given to stem cell banking techniques and practices and it was found that this branch of biotechnology will surely enjoy much attention in future. It was stated in the course of this thesis that banking is where stem cell technology moves from the scientific community to the public domain and where biotechnology becomes demystified and real. It was shown that banking entails the storage and management of material removed from the human body as well as keeping it in a frozen state until such time when it might be needed for therapeutic, research, training or educational purposes.

Tissue engineering in the form of bioscaffolding and bioprinting was also explained in the course of this thesis. Bioscaffolding, it was shown, is the process of growing tissues and organs by combining biotechnology and engineering principles. Bioprinting is a method of three-dimensionally printing tissues. It was argued that tissue engineering has made stem cell technology more concrete, literally, and will play a pertinent role in developing stem cell related

technology. It was, however, stated that bioscaffolding is clearly still in its experimental phase and is subject to a process of trial and error.

Stem cells are, as was shown, regarded as the holy grail of medical therapies and treatments in years to come. Due to this, this thesis endeavoured to address the issue of how stem cells in general might be regulated but more specifically how, in a litigious society and taking into consideration the fast development and still great uncertainties surrounding stem cells, consent may be obtained for any research or treatment or a combination thereof.

With this problem in mind, this thesis drew certain conclusions and made recommendations for addressing the hypothesised issue. In the course of this thesis, each individual chapter was comprehensively concluded and as such, the Parts comprised of these chapters are therefore brought together here.

2 CONCLUSIONS PERTAINING TO CONSENT IN SOUTH AFRICA

Consent in South Africa was addressed in Part B of this thesis which consisted of chapter 3,[1] chapter 4[2] and chapter 5.[3]

Part B of this thesis focused on the law and consent with the purpose of this Part being an inquiry into the understanding of consent in a South African context. This thesis Part flowed from an abstract and broad examination of consent to a concrete understanding of the manifestations thereof. In order to gain insight into consent, this discussion commenced by first investigating the history, rationale and development thereof.

It was shown that informed consent has a richly diverse history dually rooted in antiquity as well as modernity. Philosophically, initial legal conceptions of consent were centred on pragmatism while the idea of respect for autonomy was the moral foundation of the concept. Autonomy is the governance over a person's own agency or acting according to the law created by oneself, and it has gained popularity as the rationale underlying consent, and was discussed in detail in the course of this thesis. It was also shown in the course of this thesis that it is not necessarily the quality of a decision or the measure of autonomy in making a decision which is relevant, but rather the mere opportunity to exercise a decision which is of importance.

[1] A brief background of and introduction to consent.
[2] Specific aspects of consent.
[3] The National Health Act, Act 61 of 2003.

Although philosophy provides a reasoned and systematic approach to consent, it fails to provide actual mechanisms and procedures whereby decisions may be made. This is where the law becomes relevant and offers practicable rules to be applied. In order to understand the application of the consent concept in a South African context, this thesis thus examined the development thereof in South African case law, the Constitution and the law of obligation.

It was found that the requirement of consent for a lawful medical intervention involving a person was first pronounced in *Stoffberg v Elliot*. Two years later, *Lymbery v Jefferies* was the first case to pertinently address the duty of disclosure wherein it was held that a patient must be provided with general information in order for the patient to make a decision. The scope of disclosure was extended to include the nature, consequences and serious risks involved in a proposed procedure in *Rompel v Botha* since without this knowledge any given consent cannot constitute real consent. Instances of incapacity to consent were addressed in *Ex Parte Dixie* and it was held that consent was necessary for a lawful operation and in the event of a patient who lacks the capacity to consent, consent must be given by a person who is authorised to give consent on behalf of the incapacitated person. Consent as a prerequisite for a lawful medical intervention was also confirmed in *Esterhuizen v Administrator Transvaal* and in the absence of consent, liability may be incurred by the physician, hospital or both as decided in *Dube v Administrator Transvaal*. *In casu* it was further held that a patient must be provided with sufficiently clear and unambiguous information. The provision of information was also addressed in *Verhoef v Meyer*. It was the first case to use the term "informed consent" which was defined by the court as something which only occurs when a person understands what they are consenting to, they have been informed of what the procedure entails and where such a person is given ample opportunity to consider the risks and benefits associated with the procedure. *Phillips v De Klerk* confirmed the principle of self-determination and autonomy by recognising the right of a patient to refuse medical treatment.

The case of *Castell v De Greef* was a watershed moment in South African law as it incorporated the doctrine of informed consent into South African law and developed the concept in much detail. This included the formulation of the test for the duty of disclosure; the ousting of medical paternalism in favour of patient autonomy, and establishing the requirements of valid consent. These requirements were then elaborated on in *Oldwage v Louwrens* which held that consent is only valid where it is based on essential knowledge of the nature and effect of an intervention. Consent must therefore be informed and in order to qualify as such it must be based on substantial knowledge of the nature, effect and consequences of a proposed intervention.

The meaning of the terms "knowledge," "appreciation" and "consent" were clarified in *Christian Lawyers' Association v National Minister of Health and Others* in that knowledge means knowledge of the nature and extent of the risks or harm; appreciation suggests that the consenting person must have understanding and comprehension of the nature and extent of the risks or harm, and consent denotes that such person subjectively consents to the risks or harm and that it is comprehensive and extends to the entire transaction, which includes the risks and consequences. The capacity to consent was also addressed in *Christian Lawyers'* and it was held that only persons with the intellectual and emotional capacity to have knowledge and appreciation are truly able to consent to an intervention. The most recent *Sibisi NO v Maitin* case which once again confirmed the importance of the *Castell* case was also discussed.

As was mentioned, *Castell* incorporated consent into South African law but the ultimate recognition thereof may be found in the inclusion of a right to consent in the Constitution of the Republic of South Africa, 1996. Section 12(2)(c) was specifically discussed in the course of this thesis as providing protective measures for autonomous biomedical decision making and it was argued that this section of the Constitution gives concrete legal expression to a concept with moral and ethical roots. Two questions pertaining to section 12(2)(c) were, however, raised in the course of this thesis.

The first questioned the validity of proxy consent and was addressed making use of constitutional interpretation methods. It was shown that although the consent of the person concerned is preferred, the phrasing of section 12(2)(c) does not act as an internal limitation and that by the normal working of the law of agency, proxy consent is permissible.

The second question raised pertained to limiting the rights of an individual in favour of society's interests. Section 36 of the Constitution was applied to this issue and it was found that an individual's autonomy is not absolute and may, in compelling circumstances, be limited. For example, the autonomy of a person who lacks the capacity to consent to participation in experimentation may be limited to the extent that another person is not authorised to grant consent on their behalf and their participation may thus be limited to only studies which adhere to stringent protective measures and where no alternative to their participation exists.

The Constitution is, however, a relatively novel development in the overall South African legal framework compared to other branches of law and as such the more established law of obligation was also examined in the course of this thesis. It was found that a parallel exists between the law of contract and informed consent in that the scope and nature of the agreed upon action must be fully understood and certain. In other words, there must be knowledge, appreciation and acquiescence. Knowledge is the information with which a person must be

provided including the consequences, complications, benefits, risks *etcetera*. Appreciation is the understanding of the provided information and this is weighed against the person concerned's capacity and it will influence acquiescence. Acquiescence denotes that the relevant action is voluntary and comprehensive.

The South African experience of consent was further analysed in Part B of this thesis by examining a *capita selecta* of relevant aspects which included consent in medical law, the requirements of valid consent and the traditional distinction between therapy and research and its relation to consent practices. It was shown that consent carries a special status in the mind of ethics, medicine, research and the law and that it is closely related to the duty of a physician to disclose all information related to the scope, nature, benefits, risks, consequences and prognosis of an intervention.

This duty of disclosure, however, is not as straight forward as it may seem and in the event of medical interventions, the duty is narrower than in that of research participation. It was shown in the course of this thesis that in the context of a medical intervention, a doctor need only disclose the risks normally associated with a proposed procedure. Risks deemed too remote or unusual are regarded as immaterial and need not be disclosed. The *Castell* case formulated the materiality of risk by stating that inherent risk is material where a reasonable patient, if warned of the risk or danger, would attach significance thereto and where a physician is or should reasonably be aware that the patient, if warned of the risk or danger, is likely to attach significance thereto. Withholding of some information from a patient is referred to as therapeutic privilege and it is deemed a justifiable limitation of a patient's autonomy. The duty of disclosure and therapeutic privilege must also not be confused with the absence of consent.

In context of research participation however, the minimum standard of disclosure is full disclosure which suggests that a research participant must be fully informed of the scope, nature, duration and purpose of research participation; the anticipated benefits and advantages to the subject and society; the foreseeable risks, dangers, complications and the prognosis of any experimental treatments and that participation is voluntary and no obligation to participate exists.

As was mentioned, therapeutic privilege must not be confused with the absence of consent. Therapeutic privilege is a justifiable limitation of a person's rights while the absence of consent constitutes a violation thereof. Therefore, for consent to be valid, certain requirements must be met and in the course of this thesis the following requirements were identified:

1. The consenting person must have knowledge, appreciation and acquiescence;

2. Consent is only valid where it is based on the appropriate information pertaining to the nature and effect of the proposed intervention;
3. Consent must be legally recognised and may not be *contra boni mores*;
4. The consenting person must have the legal capacity to consent;
5. Consent must be voluntary and free from duress, coercion, fear, force or fraud;
6. The consenting person must agree to the harm, assumed risks and dangers of the intervention;
7. The information provided by the physician or researcher must be comprehensive, extend to the whole transaction and include the consequences;
8. Consent must be clear and unequivocal;
9. Consent must be obtained prior to the proposed intervention;
10. Consent must qualify as a legal act meaning that external conduct must illustrate the intention of the parties;
11. Generally, consent must be given by the person who will undergo the proposed intervention; and
12. The undertaken intervention must fall within the ambit of the given consent.

This thesis argued that the traditional distinction between medical treatment and scientific research is not applicable in context of stem cell therapy which has the implication that the traditionally advocated consent models for each are not applicable either. In order to introduce a new consent model, the finer aspects of consent were also examined in the course of this thesis including who may obtain and provide consent, when it may be obtained, what consent should include and in what format. A dynamic model of consent was also introduced for the first time in Part B of this thesis.

Pertaining to who bears the responsibility of obtaining consent, it was found that the attending physician or the relevant researcher must do so. In context of this thesis, this would then be the physician-researcher and on the condition that the patient-participant is provided with the necessary information to make a decision and there are no conflicts of interest or any interests have been disclosed. The person who must grant consent is the person who will undergo treatment or participate in research. In context of this thesis, this is the patient-participant. Where this person is an adult with capacity, they may consent themselves. Where an adult person suffers from incapacity, such as a mentally ill person, proxy consent may be obtained. A minor who has the capacity to understand what they are consenting to may do so where it is for a medical intervention. Where consent is being sought for a minor's participation in research, however, the additional consent of a parent, guardian or the Minister must be obtained. It was

argued in the course of this thesis that the additional requirements regarding the consent of a minor must be met in context of stem cell treatment as it is tantamount to research.

It was shown, with regards to the timing of consent that consent must be obtained prior to an intervention. Consent is, however, dependent on certain preferences which may change over time. This means that consent needs to be able to change as well. Granting consent as a once-off initial action is therefore not applicable in context of stem cell treatment-research.

The scope of consent was addressed in detail in the course of this Part and it was found that consent protocols, additionally to adhering to general validity requirements, must include various aspects which include the following:

1. The title of the intervention;
2. Background information, an explanation of the proposed therapy-research and the methods or techniques to be employed during treatment-research;
3. The person or institution responsible for the therapy-research;
4. Any real or potential conflicts of interest;
5. A statement of the purpose and benefits as well as of the risks and consequences involved;
6. Any alternatives available to the patient-participant;
7. Options regarding storage of material or data and any time limits attached thereto;
8. The manner in which material may be destroyed or disposed of;
9. The extent to which the privacy and confidentiality of the patient-participant will be protected;
10. The option to renew or revoke consent for any of the above and at any time;
11. Incentives to participate in the therapy-research;
12. The duration of the applicable ethics committee approval if any; and
13. Proof of the ethics committee approval.

It was also found that the patient-participant must be assured that they or their material will be used only in accordance with medical, scientific and ethical standards and they must be given the opportunity to ask any questions they may have and to participate fully in the consent process.

Attention was also given to the format of consent in the course of this Part of this thesis and various consent models were discussed. It was shown that in the context of stem cells, a concern exists that due to the uncertain nature of interventions, consent cannot be informed and this calls into question the validity of informed consent. Broad consent is therefore advocated as the

most pragmatic solution to the consent issue as it accommodates future research and new technologies. In theory, however, the best model of consent would balance the ethical responsibility of providing patient-participants with information with the need to continuously explore new scientific knowledge frontiers. It was therefore recommended that a combination of informed and broad consent be developed and as such a dynamic model of consent was introduced.

The final section of Part B of this thesis focused on an examination of the South African regulatory environment pertaining to stem cells related to both treatment and research aspects, and to consent. The Human Tissue Act of 2003 and the Regulations created under the Act were therefore dissected. It was also argued that the Act and Regulations already support a dynamic model of consent.

In general, it was mentioned that the NHA is a complex legislative document which entrenches numerous policy principles and as such it fundamentally alters South African health policy. The Act is in line with the Constitution and is firmly based thereon which renders it "the most important piece of legislation in the health sector." This furthermore emphasises the revolutionary nature whereby health policy will be formulated in future. This is exemplified by the Act's regulation of new health technologies such as stem cells and cloning.

The NHA provides some clarity regarding the legality of human cloning, stem cell therapy and research; it offers researchers unprecedented protection and promotes thorough research protocols and reviews. It is submitted that Chapter 8 of the Act, when taking into account that it is South Africa's first attempt at legislation of this nature, is a good point of departure for the regulation of biotechnology. This is due to the drafting of the NHA as framework legislation which allows for the Act to be supplemented by subordinate legislation. It was shown that a process of "fine tuning" is taking place in many of the Regulations created under the Act and that this allows for some optimism regarding the future of statutory stem cell regulation in South Africa. This issue, however, still requires much attention. This may be ascribed thereto that the NHA has fallen prey to some of the same mistakes as previous health related legislation in that it is anachronistic, slow in development and lacks a basic understanding of the science. In an attempt to remedy the failings of the Act, numerous Regulations were drafted from 2003 to 2016 but, as was shown in this thesis, this mass of legal documents has flooded the regulatory environment and created a disjointed, fragmented, confusing and contradictory framework.

Some of the sections of the NHA as discussed in the course of this thesis are of more importance to the hypothesis posed and the introduction of a new and dynamic model of consent, and must be reiterated. The first of these sections is section 6 which requires a health care user to have

full knowledge. This means that a person must be informed of their health status; diagnostic and treatment options available to them; the risks, consequences and costs of the treatment options; and their right to refuse treatment. In the event of refusal to treatment, the implications and risks of their refusal must also be explained. Currently, stem cell therapy sits more comfortably under section 11 of the Act which deals with health services for research purposes but, should it become a generally available treatment in future, the health care user will have to be informed of the treatment method, side effects, potential consequences or risks and benefits as well as costs in terms of section 6.

Section 6 of the NHA is supplemented by regulation 6 of the 2007 Human Subjects Regulations which provides for specific consent guidelines. Even though regulation 6 provides specifically for research, it applies here as this thesis posits that stem cell therapy is actually research and as such a patient is a human research participant, thereby bringing the patient-participant under the application of the Human Subject Regulations. It was shown that regulation 6 is of immense importance as it recognises the complex relationship between stem cells, consent and research and provides a consent checklist of requirements of which a participant must be informed. This includes:

1. The purpose of the research;
2. The different treatments and possibility of random assignments of each treatment where the research in fact involves treatment;
3. The methods and procedures to be utilised in the course of the research;
4. Any alternatives to participating in the proposed research;
5. Potential or real harm and risks involved in participation;
6. The expected benefits to the participants themselves and others which may result from the research;
7. The extent to which confidentiality and privacy will be protected;
8. Any available insurance in the event of injury or damage arising from participation;
9. The contact details of a person in the event of a research related injury;
10. Participation incentives as well as any differences in incentives;
11. In the event of participation in a trial, the availability of treatment beyond the duration of the trial;
12. Sponsors' details where relevant and any potential conflict of interests; and
13. Proof of ethics committee approval.

Section 7 of the Act requires that a health service may not be rendered without the informed consent of the user. Proxy consent may, however, be obtained. Section 7 also provides for a

definition of informed consent as "consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in section 6." It was argued in the course of this thesis that since the efficacy of stem cell therapy is yet to be proven, it is better described as a form of research and is still greatly uncertain. The section 7 definition makes use of the phrase *specified* health service and as stem cell treatments cannot, according to the thesis hypothesis, be specified, informed consent is not appropriate. It was submitted that dynamic consent would be a better suited consent format. It was further shown that stem cell therapy would sit better under the ambit of section 11.

A more appropriate definition for consent for the purposes of this thesis was shown to be found in the Regulations regarding the Use of Human DNA, RNA, Cultured Cells, Stem Cells, Blastomeres, Polar Bodies Embryos Embryonic Tissue and Small Tissue Biopsies for Diagnostic Testing, Health Research and Therapeutics. This much improved definition describes informed consent as "an agreement by which a participant, donor or health care user voluntarily confirms his or her willingness to participate in research, donation or treatment, after understanding all aspects of such research, donation or treatment that are relevant to his or her decision." It was argued that this definition at least foresees the possibility of research activities additionally to treatment. The requirement that the participant must, however, understand *all* aspects of the research indicates that informed consent is not sufficient as it is not possible as posited in this thesis.

Section 8 gives the user the right to participate in decisions affecting their personal health and treatment. It was shown that in the context of this thesis, this may be interpreted in support of a dynamic model of consent as it necessarily suggests engaging a patient-participant at every level of decision making and in a continuous fashion.

In the course of this thesis it was mentioned a number of times that stem cell treatment might be more comfortably regulated under the ambit of section 11 of the NHA which provides for health services for experimental or research purposes. It was argued that this is due to the requirement that prior to rendering the health service, the user must be informed of the experimental or research nature of the health service. This has the implication that the user's perception regarding the intervention is shifted from the onset thereof from one of therapy to one of research participation. The user then regards himself as a participant and not a mere patient. Additionally, the user is required to grant his prior written authorisation thereto. The Act does not expressly define "authorisation" but generally this term denotes the giving of permission or consenting to an action. It was therefore suggested that the failure to specifically prescribe a particular format of consent in these instances of health services for experimental or

research purposes may be interpreted in support of the notion that a new format of consent is better suited than informed consent or broad consent.

The title of section 11 makes it clear that it provides for a certain type of health service namely experimental or research health services. This excludes services of which the efficacy has been proven. It was emphasised in the course of this thesis that this means that a patient-participant must therefore be informed of the experimental nature of the therapy-research and must understand that the health service is not a traditional medical intervention. A patient-participant must therefore be informed that the stem cell therapy they are to receive is experimental in nature and for research purposes. It was further shown that since an intervention becomes a fusion of medicine and science, the persons involved also have merged roles and become patient-participants and physician-researchers. The Regulations Relating to Human Subjects and Participants are therefore applicable and supplement section 11.

The 2007 Regulations require that a participant be well informed and make informed decisions and this is in line with the requirement of informing the patient-participant that the health service is for research or experimental purposes. The 2013 Regulations expressly require that the bodily integrity of the patient-participant be respected, similar to section 12(2)(c) of the Constitution which also provides the right to consent prior to medical or scientific experimentation. It was also shown that the 2014 Regulations provide that health research involving human participants depends on the appropriate consent and that a patient-participant has the freedom of choice regarding participation in research. It was shown to mean that where a potential patient-participant is informed that the proposed stem cell therapy is experimental in nature and for research purposes, they retain the freedom to decide to participate or to withdraw from the research.

Section 71 was also discussed in the course of Part B of this thesis as it specifically provides for research or experimentation with human subjects. This section requires that research or experimentation involving human subjects may only be conducted once the objects of the research have been explained to the participant and consent has been obtained. Unfortunately, the Act does not specify the consent format needed in these circumstances and it was therefore submitted that this suggests that a dynamic model of consent may be appropriate.

Section 71 further provides for research involving minors and makes a distinction between therapeutic and non-therapeutic research. It was argued in the course of this thesis that this distinction should fall away in context of stem cells. It was shown that when working from this premise it becomes possible to merge the distinctive requirements in order to establish one comprehensive set thereof for research involving minors. It was therefore suggested that the

following requirements should be met when involving minors in research, namely that participation must be in the best interests of the minor; research may only be conducted in and under the prescribed manner and under the conditions; with the consent of a parent or guardian of the minor; with the consent of the minor where the minor is capable of understanding all relevant aspects of their participation in the research; and with Ministerial consent where appropriate.

The 2007 Research on Human Subjects Regulations also offer valuable supplementation to section 71 and were discussed as such in the course of this thesis. The Regulations require that a research participant be well informed and make an informed decision regarding their participation in research. The prescribed aspects which the subject must be informed of include the risk and benefits of participation, and the Regulations therefore require that the risks and benefits of a research study must be analysed prior to the research being undertaken.

It was also shown that the Regulations provide for mentally ill persons, an area which section 71 fails to address. It was found that research which involves mentally impaired persons and which necessitates their involvement in the research, must be sufficiently justified; that proper procedures for evaluating and confirming the true incapacity of the participant are in place; that it must be ensured that the consent was free from coercion; and that it involves no or minimal risk. Where minimal risk is involved, the anticipated benefits to the participant must outweigh the risk.

It was also shown in the course of this thesis that the most substantial contribution made by the 2013 Human Subjects Regulations was the recognition of proxy consent by a legally authorised person on behalf of a research subject. The 2014 Regulations then reiterated the requirement of appropriate consent prior to health research involving human subjects and it was argued that the failure to specify a preferred consent format may be interpreted as support for the argument that neither informed nor broad consent is suitable. The Regulations also stipulate that participants have the freedom to withdraw from participation. In context of this thesis, it was shown to support consent as a flexible concept which is not stagnant and which should be responsive to changing patient-participant preferences.

The last South African legislative document discussed in Part B of this thesis and which needs to be mentioned again at this juncture is the Regulations relating to Human Stem Cells of 2007. The Regulations require that informed consent must be obtained from a stem cell donor where the cells are intended for therapeutic, research or educational purposes and that these stem cells must have been voluntarily donated. In the context of this thesis, it was suggested that informed consent is not appropriate and that it ought to be replaced by a more dynamic consent

format. After having extensively examined the South African understanding of consent, the international experience was addressed in Part C of this thesis.

3 CONCLUSIONS PERTAINING TO THE INTERNATIONAL POSITION OF CONSENT

The international position of consent was addressed in Part C of this thesis which consisted of chapter 6.[4]

Part B of this thesis set out the South African position relating to consent which included a discussion of the Constitution. The Constitution mandates international legal comparison. Part C of this thesis therefore focussed on international instruments and the consent provisions contained therein.

It was shown that the Constitution, as the supreme law of South Africa, establishes a constitutional imperative to consider international law in interpreting the South African Bill of Rights and that an interpretation which is consistent with international law is preferential to one which is not. It was therefore argued that international law may influence national law and may be insightful in developing new legal regimes. In order to gain as much insight as possible, numerous international instruments were discussed in the course of this thesis.

The Nuremberg Code which conflates treatment and research ethics and human rights to some extent, provides for certain tenets to ensure that medical research is conducted in an ethical and lawful manner. The Nuremburg Code, it was shown, states that:

1. The physician-researcher and patient-subject are equal;
2. Consent is an absolute requirement;
3. A patient-subject must possess the legal capacity to grant consent;
4. The patient-subject must exercise their choice freely without force, fraud, deceit, duress or coercion. Consent must therefore be voluntary;
5. There must be sufficient knowledge and comprehension on the part of the patient-subject to make an informed decision;
6. The patient-subject should be informed of the following prior to granting consent:
    - The nature of the study;
    - The duration and purpose of the experiment;
    - The method and means of experimentation;
    - Any inconveniences and hazards reasonably expected; and

[4] Consent in international instruments.

- The effects on the subject.

7. It is the physician-researcher's responsibility to ascertain the quality and thus validity of the consent; and
8. A patient-subject may withdraw their participation and thus consent at any stage of the research.

The International Bill of Human Rights provides that everyone has the right to life, liberty and security of person, meaning that it corresponds with section 12 of the South African Constitution and as such includes the right not to be subjected to medical or scientific experiments without consent. It therefore confirms the necessity of prior consent and reiterates that in the absence of such consent no medical or scientific activity will be lawful.

Vulnerable groups are dealt with in the Declaration of the Rights of the Child and the Declaration on the Rights of Disabled Persons. It was shown that according to the Declaration of the Rights of the Child children need not be excluded from medical treatment or research merely because they are minors. Protective measures, however, need to be in place for their participation. Consent is one such protective measure and is therefore a prerequisite in treatment or research involving minors.

The Convention on the Rights of the Child also provides for matters pertaining to minors. A child is defined as a person below the age of 18 in terms of the Convention, and in any activity involving such a child, their best interests are of paramount importance and must always be considered. A child who is deemed capable of understanding must be given the required information as well as the opportunity to express their opinions on matters related to them or their health, treatment or research participation. A child may thus grant consent themselves and where a child does not wish to do so, their choice and best interest must be considered and respected.

The Declaration on the Rights of Disabled Persons provides a definition of "disabled person" as "any person unable to ensure by himself or herself, wholly or partly, the necessities of a normal individual and/or social life, as a result of deficiency, either congenital or not, in his or her physical or mental capabilities." The Declaration further provides that disabled persons are entitled to medical, psychological and functional treatment. Persons with disabilities therefore have the right to medical treatment regardless of the fact that they have deficient capacity.

The Universal Declaration on the Human Genome and Human Rights provides specifically for research on the human genome but may also be more generally applied to other forms of research on human material and subjects. It was shown that the Declaration requires a prior

and rigorous assessment of the risks and benefits involved in genome research as well as the prior, free and informed consent of the person concerned. Also, an incapacitated person may only be involved in research where they will receive a direct health benefit and subject to authorisation and protective conditions prescribed by law. The law must also prescribe the conditions under which consent may be limited as well as specify compelling reasons to limit consent.

The CIOMS Guidelines are a set of ethical principles regarding human experimentation and state that consent is a voluntary decision made by a competent individual who has received all the necessary information and who understands this information and then arrives at a decision after taking some time to consider the given information. It was also shown that consent is not a mere event but a process which commences when initial contact is made with a potential subject and continues throughout the course of the research. Also, in terms of the CIOMS Guidelines, consent ought to be sufficiently documented and in the event of material changes to the research procedures or conditions, the physician-researcher is obliged to renew the originally granted consent. Where secondary research use of human material or information is foreseeable or feasible, additional consent is usually required. It was suggested that dynamic consent offers a method of continuously changing and renewing or revoking consent and is therefore in line with the CIOMS Guidelines.

An interesting feature of the CIOMS Guidelines was shown to be the requirement that where a researcher withholds information from a participant, it needs to be with the consent of the subject. This is due to the need to ensure the validity of a study and the researcher therefore has the obligation, additionally to providing the subject with information prior to the study, to obtain consent to withhold certain information from the research subject.

Vulnerable persons are also provided for in the CIOMS Guidelines. In the course of this thesis it was found that it must be established that the research necessitates the participation of vulnerable persons; that the purpose of the obtained knowledge is relevant to the particular health needs of the vulnerable group; that the consent of each subject has been freely obtained to the extent of their ability to understand and that any refusal or objections on their part is respected; and that where the potential subject is completely unable to consent an authorised person must grant consent on their behalf.

The next instrument that was discussed in the course of Part C of this thesis was the Universal Declaration on Bioethics and Human Rights and it was found that the interests and welfare of an individual, such as the exercise of autonomy and the freedom to make decisions, must always enjoy priority above those of science. This Declaration therefore once again emphasised the

primacy of prior, voluntary consent based on adequate information, with the option to be withdrawn.

It was also shown that the Declaration reiterates consent as a requirement in all instances of medical or scientific interventions involving humans and especially where they do not have the capacity to consent themselves. In such instances, authorisation for such interventions must be obtained according to the best interest of the person concerned and they may be involved in the decision making process to whatever extent possible. Persons who lack certain capacities were then once again addressed in the discussion pertaining to the Convention on the Rights of Persons with Disabilities. It was found that the definition of disability in terms of the CRPD is broad enough to include mental disability which may have an effect on granting consent. Disabled persons may, however, not be excluded from enjoying the highest attainable standard of health merely due to their disability and as such they may be permitted to receive certain treatments and to participate in research provided that protective measures are in place.

The duties and obligations of the physician and therefore the physician-researcher may be found in the Declaration of Geneva read with the Hippocratic Oath, the International Code of Medical Ethics and the Declaration of Helsinki. Physicians must act in a manner that is humane, must have respect for a competent patient's refusal to treatment, respect the rights and preferences of patients as well as other health care professionals, and respect for domestic and international codes of ethics. A physician must also have respect for human life and act in the best interests of the patient when providing medical care. A further duty also exists to promote and safeguard the health, well-being and rights of patients which include those involved in medical research. It was also shown that physician-researchers must protect the dignity and right to self-determination of their research subjects.

In the course of this Part of this thesis it was found that although the primary purpose of research lies in the generation of new knowledge, the purpose of the research may never take precedence over the rights and interests of the research subjects. This, it was found, means that in instances of combined medical research and care, physicians ought only to involve patients to a justifiable extent. Participation in research may be justified by the potential preventive, diagnostic or therapeutic value of the research. A physician must therefore have good reason to believe that the patient's participation will not adversely affect their health. It was further found that research involving human subjects is only permissible where the burdens involved are outweighed by the importance thereof. Research must therefore be preceded by an assessment of the predictable risks and burdens compared with the foreseeable benefits.

Lastly Part C examined some of the regional African instruments which may be relevant to stem cells, biotechnology and consent. It was found that the African Bioethics Resolution recognises bioethics as a priority and provides individuals with the right to benefit from scientific progress. It also refers to "enlightened consent" and it was suggested that this phrasing accurately enunciates the need for consent to be associated with a process of gaining knowledge.

At the close of Part C it was noted that although this thesis argues that informed consent is insufficient and the international instruments discussed refer to informed consent, these instruments are still relevant. This is due to the fact that these instruments repeatedly illustrate and confirm the importance of consent as well as the information and knowledge component of the consent process. Information and knowledge were shown to be highly valued aspects of consent according to the dynamic consent format introduced in the course of this thesis, and international instruments therefore provide a solid foundation for developing a new consent format. After discussing the broader international guidelines relevant to this thesis, the focus was then narrowed and attention was given to the laws of the United Kingdom.

4 CONCLUSIONS PERTAINING TO CONSENT IN THE UNITED KINGDOM

Consent in the United Kingdom was addressed in Part D of this thesis which consisted of chapter 7,[5] chapter 8[6] and chapter 9.[7]

Part C of this thesis analysed relevant international instruments and Part D therefore paid attention to the more specific foreign legislation of the United Kingdom. The purpose of Part D was an analysis of the laws of the United Kingdom with the ultimate goal of introducing a dynamic consent format.

To understand the specialised, the general must be understood, and it was shown in the course of this thesis that the United Kingdom consists of three separately identifiable legal systems spanning the four countries comprising the United Kingdom namely England, Wales, Scotland and Northern Ireland. This thesis therefore set out to provide some insight into the complexities of each system and the interplay between them.

It was shown that England has a combined system of statutory and common law derived from numerous primary sources such as legislation, case law, equity, custom, European law, treaties and other sources of law including Canon law, Roman law, textbooks and legal writing. Welsh

[5] The law of the United Kingdom: An introduction to the legal systems of the United Kingdom.
[6] The Human Tissue Acts 2004 and 2006, the Human Tissue Authority and other relevant regulatory instruments.
[7] Dynamic consent.

law is law made in terms of the devolved authority granted by the Government of Wales Act 2006 and is constituted of both primary and secondary legislation created by the National Assembly for Wales. The law of Northern Ireland, similar to English law, is the system of statutory law and common law and has been in use since the partition of Ireland in 1921. Northern Irish statutory law consists of various different Acts including Acts of the Parliament of the United Kingdom which apply to Northern Ireland, Acts of the Northern Ireland Assembly and statutory instruments created and enacted by different departments of the Northern Ireland Executive and the Government of the United Kingdom. The Scottish legal system was shown to be the most independent of the different systems since it was granted a measure of autonomy by the Acts of Union 1707. It is therefore separate while also co-existing with the laws of England, Wales and Northern Ireland. The Parliament of the United Kingdom of Great Britain and Northern Ireland, or as it is also known, Westminster, is the legislature of the United Kingdom.

The 1998 Scotland Act provides for devolved powers of the Scottish Parliament and further delineates legislative competence by explicitly specifying "reserved" powers of the Parliament of the United Kingdom. Any issues which are not explicitly reserved, automatically fall to the Scottish Parliament. It was shown that due to this devolved legislative competency, Scotland is able to create its own legislation such as the Human Tissue (Scotland) Act of 2006.

In order to form a complete and holistic view of the UK's regulatory regime and understanding of consent, certain key consent related cases were discussed. Consent, it was found, is the cornerstone of the Human Tissue Acts of 2004 and 2006 and thus the multi-layered approach to analysing this concept would be incomplete without paying attention to judicial opinions on the matter.

In the course of this discussion it was found that the *Bolam* test, which is used when determining the appropriate standard of care expected of skilled professionals, holds that a medical professional will not be liable where he acted in accordance to what is considered the proper practice by a responsible body of medically skilled men in that same particular art. It was shown that this test was subsequently applied in the case of *Sidaway v Bethlem Royal Hospital Governors* and that it was held that a physician's failure to disclose information only establishes negligence where all reasonable practitioners find such failure to be unacceptable in that same field. Furthermore, it was found that providing a patient with too much information is as detrimental to making a decision as too little information. Patients must therefore be provided with enough information to make a balanced decision. The *Sidaway* case also emphasised a patient's right to decide to either receive or refuse medical treatment. In giving

effect to this right, a patient must therefore be provided with all material information to enable him to make a decision. Information is deemed material if a reasonable person in the shoes of the patient might regard the information as significant.

The *Gillick* and *Re C (Adult Refusal to Treatment)* cases were also discussed in relation to competence to consent. It was found in *Gillick* that a child is not incompetent to provided consent by virtue of their age and that their treatment may continue in the absence of parental control where the treating physician is satisfied that the child concerned has the intelligence to fully understand the proposed intervention. Adult competence was addressed in *Re C (Adult Refusal to Treatment)* which held that competence entails three aspects, namely, firstly, comprehension and retaining of information regarding the treatment, secondly, belief of and trust in the information and lastly, a process of weighing up the information to come to a decision.

It was found that a significant risk which may potentially affect a reasonable patient's judgment must be disclosed to the patient as part of a physician's normal responsibilities and it is therefore an essential part of the scope of consent and allows a patient to make decisions regarding their course of action in the *Pearce and Pearce* case. The case of *Re B (Consent to Treatment: Capacity)* also examined the need for a patient to make his own decisions and in the course of this thesis it was shown that this case held that a physician may not allow his own dislike of or emotional reaction to his patient's choices to cloud his judgment in the determination of the capacity of the patient to make a decision, regardless of the seeming irrationality of the patient.

It was shown that the *Simms* case held that a person ought not to be excluded from pioneering therapies due to their inability to give consent. The rights of a patient are therefore important and in the *Chester v Afshar* case this, the right to be informed in particular, was emphasised. It was shown that a patient has the right to receive information and that a physician therefore has a duty to respect this right and to provided such information. This, it was found, is in line with the idea of dynamic consent as introduced in the course of this thesis.

The last UK case discussed in the course of this thesis was the *Montgomery v Lanarkshire Health Board* case which addressed issues pertaining to risk and information. It is regarded as an important case and marks a shift in the consent law of the United Kingdom by departing from the precedents set in *Bolam* and *Sidaway*. The materiality of risk was described as being either a risk which a reasonable person in the patient's position would be likely to attach significance to, or a risk which the physician ought reasonably to be aware would have significance attached to by the concerned patient. It was shown that this decision has resulted therein that patients now

determine the scope of information to be provided, rather than physicians. Collectively, it was shown, these cases confirm the importance of consent and the provision of full information as was propagated in the course of this thesis.

As the South African Constitution obliges comparative study of foreign law, the law of the United Kingdom offers an insightful comparison as it was found that the legal environments of South Africa and the United Kingdom are sufficiently similar that they might encounter the same dilemmas regarding consent. Workable solutions applicable in the United Kingdom might therefore be applicable in South Africa. It was also argued that South African medical law is influenced by the laws and common law of the United Kingdom and since biomedical issues have been regulated in the UK since the 1970's, it was considered an ideal source of comparison.

In the course of this thesis, the Human Tissue Act 2004 as well as the Human Tissue (Scotland) Act 2006 were discussed in relation to the scope of the Acts, the activities permitted under the Acts, consent or authorisation provisions and the existence of any exemptions to the requirement of consent or authorisation and the offences under the Acts.

The 2004 Human Tissue Act is an Act of the Parliament of the United Kingdom and does not extend to Scotland. It contains provisions regarding the removal and storage of human organs and other tissue, the regulation of activities involving human tissue which includes licensing, codes of practice and even trafficking and lastly miscellaneous and general provisions. The 2004 Act is divided into three Parts which provide for the removal, storage and use of human organs and other tissue for scheduled purposes; the regulation of activities involving human tissue and miscellaneous and general provisions.

It was shown that Part 1 of the Act relates to consent and establishes the requirements for obtaining appropriate consent for the activities regulated under the Act. It was found that appropriate consent is defined with reference to the consenting person or nominated representative who makes decisions on his behalf. Importantly, it was found that consent is the cornerstone of the 2004 Act and is as a foundational principle to a number of the Act's provisions.

It was found in the course of this thesis that the 2004 Act requires consent for research in three situations. The first is where tissue from a living person will be utilised and the sample is identifiable, the second is where a sample from a living person has been anonymised but the research study has not been approved by a Research Ethics Committee and the third is where the tissue is collected from a deceased person and has been anonymised or is identifiable.

In terms of the 2004 Act, adults with capacity to do so must consent to an activity themselves but where adults lack capacity, consent must be obtained in accordance with the Mental Capacity Act 2005. Consent may also be deemed to exist in certain instances such as where a deceased adult had not given consent prior to his death and a nominated representative of that person grants consent to an activity on his behalf. A spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half sibling or longstanding friend may act as a nominated representative.

The age of majority in the UK differs from the South African age of majority and the 2004 Act further makes a distinction between living and deceased children. The parent or person with parental responsibility for a living child below the age of 16 who is incompetent or cannot make decisions must consent on their behalf to proposed activities. A person with parental responsibility may also grant consent where a child below the age of 16 died before granting his consent to an activity or where he was incompetent to do so. Where no person with parental responsibility exists, a spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half sibling or longstanding friend may do so.

It was noted that the position set out in the 2004 Act is similar to the South African and international position on consent concerning new medical treatments with unproven efficacy meaning that it borders on research involving human subjects. It was further noted that once again consent is given primacy as regulatory instrument yet the preferred format is not specified.

The 2006 Scottish Act is an Act of the Scottish Parliament and creates broad rules providing for transplantation, post-mortem examinations and tissue samples or organs no longer needed for Procurator Fiscal purposes. It regulates research using organs, tissues and samples from deceased persons but not research using tissue from living donors. The 2006 Act was, however, still of informative value regarding the person from whom consent may be obtained.

The Scots Act refers to authorisation rather than consent but it was shown that these terms carry the same meaning. The 2006 Act requires authorisation, for the removal and use of post-mortem tissue samples intended for research. In Scotland, adults are persons over the age of 16 and they may authorise such removal, use and storage of organs, tissue or samples for research purposes themselves. An incapacitated adult may nominate a person or a nearest relative to grant authorisation on their behalf. The Scots Act then also permits children over the age of 12 to authorise activities themselves on the condition that they are competent to do so. A nominated person or person with parental responsibility may grant authorisation on behalf of a child where the child is not competent.

It was, however, found in the course of this thesis that the 2004 and 2006 Acts do not regulate matters related to human tissues and cells on their own and various other legal instruments are in place regarding these issues in the UK including the Human Tissue (Quality and Safety for Human Application) Regulations of 2007, the *Guide to Quality and Safety Assurance of Human Tissue and Cells for Patient Treatment*, the European Union Tissue and Cells Directives as well as certain Codes of Practice.

It was shown that the Q&S Regulations fully implemented the EUTCD and thereby extended the remit of the Human Tissue Authority by bringing the regulation of procurement, testing, processing, storage, distribution, import and export of cells and tissues under the regulatory authority of the HTA. The Q&S Regulations, however, do not specifically provide for consent and this aspect is provided for in the Q&S Guide.

The Q&S Guide provides for compliance with the 2004 Act and the HTA Codes of Practice. It establishes the requirement that all licensed establishments under the HTA ensure information is provided to a donor prior to donation and in a manner as prescribed under the 2004 Act and the Code. It was also found that such licensed establishment ensure that the donor is provided with information by trained personnel in an easily understood manner, that the donor is informed of the necessity of obtaining their prior consent, and that the donor must be informed of at least the following:

1. The purpose and nature of their donation;
2. The consequence and risks involved;
3. Any analytical tests that are to be performed;
4. The manner of recording and protection of their donor data and medical confidentiality;
5. Any therapeutic purposes and potential benefits of their donation; and
6. Information on the applicable safeguards intended to protect the donor.

In the course of this thesis the European Tissue and Cell Directives were also discussed and it was found that the procurement of human tissue or cells may only be authorised after all consent requirements have been met including providing the donor with the appropriate information. The donor of tissue or cells must be informed of the necessity of consent in order to proceed with the procurement; the nature and purpose of the procurement; the consequences and risks involved in their donation; the possibility of analytical tests; all aspects related to the recording and protecting of donor data and medical confidentiality; the therapeutic purposes and potential benefits which may potentially arise from the donation; information on safeguards intended to protect the donor, and that they have the right to receive

any confirmed results of the analytical tests which were run and also to have these tests clearly explained to them.

It was shown that the HTA prepares Codes of Practice which serve as practical guides to persons involved in carrying out the activities permitted under the 2004 Act. The Code clarifies the details regarding when and how consent should be sought and what information should be provided. In the course of this thesis, six central issues related to consent were identified and addressed and are summarised here:

1. Regarding the issue of whether or not consent is required, it was found that generally, consent is required where human bodies or relevant material is intended to be stored, used or removed;
2. Regarding the issue of what constitutes the appropriate consent in the particular circumstances, it was shown that the 2004 Act clearly provides for what constitutes appropriate consent and it is defined in terms of the consenting person for a particular purpose;
3. Regarding what constitute valid consent, it was found that in terms of the 2004 Act and the Code, consent is a positive act and must be voluntarily given by the appropriate person with the capacity to understand the purpose of and the risks involved for it to be valid. To render an activity lawful, consent must have been obtained prior to the removal, storage or use of materials, and prior consent presupposes that the consenting person was provided with the necessary information and time to make a decision;
4. Regarding the issue pertaining to the scope of consent, it was found that the scope of consent will vary according to the circumstances and may be generic or specific. Generic consent is suited to research scenarios and specific consent is better suited to medical treatment interventions;
5. Regarding the duration of consent, it was shown that the Code states that it may be enduring or time-limited. Enduring consent remains in force until it is revoked and a person may also specify a time-limit wherein consent will remain in force; and
6. Regarding withdrawal, it was found that the Code provides that consent may be withdrawn at any time.

Attention was also given to the Human Tissue Authority in the course of this thesis. It was shown that the HTA operates as a watchdog without which the UK's legal instruments would be of little effect. The Authority is concerned with ensuring that valid consent is obtained, that donors understand the risks involved in donating material, donate of their own free will and not due to coercion or duress, and that no reward is offered or sought for any donations. It was

submitted in the course of this thesis that a South African counterpart to the Authority be established in order to exercise similar functions.

It was also shown during the course of the discussion on the UK position that certain other lessons may be learnt from the United Kingdom's regulatory regime. It was possible to describe consent as permission, and the giving of consent or authorisation is therefore a positive act meaning that it must be given voluntarily by a person who is capable of making an informed decision. This person must be given all the relevant information in order to enable him to make the best decision. Recognising the role that time plays in decision making was shown to be important in the course of this thesis as a person's preferences change over time and this influences the validity of consent.

It was also shown that certain rules regarding the obtaining of consent may be inspired by the United Kingdom. The following were identified in the course of this thesis:

1. Consent must be obtained prior to any proposed removal, storage or use of a donation in both treatment and research. In the context of this thesis, it was argued that consent must therefore be obtained prior to carrying out stem cell therapy-research involving a patient-participant;
2. It is the responsibility of a trained health care professional to obtain consent in clinical treatment-focused settings. It was therefore submitted that in research situations, it is the relevant researcher who must obtain consent from the participant. It was further submitted that for stem cell therapy-research, it is the duty of the physician-researcher to obtain consent and to inform the proposed patient-participant of the risks, benefits, consequences and other relevant aspects;
3. The person from whom consent must be sought will differ depending on the circumstances. Consent should not be a rigid, inflexible concept whereby participants are excluded from participation in certain activities. It was argued that in context of this thesis, consent must be adaptable in accordance to the circumstances at hand; and
4. Consent may be enduring or may be time-limited and may be withdrawn or revoked at any time. In context of this thesis, it was argued that consent may be amended or ended, depending on the preferences of the patient-participant from whom it was obtained; however
5. No specific consent format is prescribed and it was therefore suggested that a dynamic format of consent be followed.

The final section of Part D of this thesis then turned its attention towards the introduction of a new format for consent into South African law by suggesting that different types of consent may be combined to develop a new dynamic consent format.

In the course of this thesis it was repeatedly stated that consent is a prerequisite protecting participants in both clinical and research settings and that it is a fundamental element in participation and must be valid, voluntary and informed at all times. It was further shown that a participant should be able to withdraw their consent at any time. However, current consent processes are greatly problematic as the process is too long and complicated, no sure manner of ensuring that participants understand the information provided exists, follow up processes or provision of information over time are non-existent and the right to withdraw consent is not taken seriously.

It was shown that the position of patients, donors or research participants relating to the control of their samples has become a major issue in the regulation of biomedical science. Although consent is internationally required in this field of activities and in spite of the shortcomings of informed consent being recognised, no consensus exists regarding the most appropriate alternative format of consent. As such broad consent has been adopted as a pragmatic solution but it was shown in this thesis that it is not ideal.

This thesis argued that an alternative to broad consent exists and dynamic consent was proposed as a consent model for addressing and resolving problems regarding consent. Dynamic consent entails a new consent system which allows patients and donors to electronically grant consent, which allows participants to monitor the possible uses of their samples and personal information, and to make decisions regarding how these might be used in future. It enables participants to decide the amount and the type of information they are given or require and also enables them to make decisions regarding their level of participation and communication preferences.

In the course of this thesis it was shown that a shift has been made towards participant-centred initiatives which place the participant and researcher in a partnership. A PCI empowers a participant to engage in research processes by using IT mechanisms. It was shown that dynamic consent originates from this philosophy and may therefore be understood as a specific project and, more importantly in the context of this thesis, a general concept which is capable of radically altering the nature of consent procedures in research.

It was shown in the course of this thesis that autonomy is not static and that research participants should not be regarded as passive in exercising their autonomy. As such, consent

must also not be regarded as a static concept and should be based on extendable information as well as be rescindable.

To this end, dynamic consent was defined as a new approach for engaging individuals in the use of their information and samples and which is "dynamic" in that it enables continuous interaction over time, allows participants to consent to new studies or to amend already given consent in real-time as their preferences change, and then to have confidence that these altered preferences will be adhered to. It was shown that the very essence of dynamic consent is a mechanism which facilitates participant-researcher communication and offers research participants the opportunity firstly to be informed and secondly, to have continuous control over their information and material. The characteristics of dynamic consent were also identified in the course of this thesis and it was found that this system may be characterised by the ability to easily and in real time grant consent to new research developments; the amendment of contact information; and the option of methods of receiving information related to the use of material as well as the type of information to be received.

The various benefits of a dynamic system of consent were discussed in the course of this thesis and were shown as including the facilitation of use and re-use of material or information; enabling individuals to grant and revoke consent according to their preferences; establishing a record of transactions and interactions; to enable approaching individuals for various types of projects and facilitating modification of consent over time. In a similar vein to this, it was argued that dynamic consent is beneficial and superior to other forms of consent as it is able to facilitate efficient re-contact; it conforms to the highest legal standards; it offers fine-grained revocation options; enables better communication; it improves scientific literacy and transparency as well as risk management. Dynamic consent is also able to facilitate improved research; involves participants in the research process; it is able to respect a participant's autonomy in a better manner and enables meaningful consent. It was further shown that it is able to better inform research participants, encourage participation in biomedical research, it transfers control as well as ethical responsibility from review boards to the participants themselves and to enable the return of results and incidental findings of the research study to the participants. Due to the numerous advantages discussed in the course of this thesis, it was found that dynamic consent may be described as the epitome of informed consent but also has the capacity to solve the problems surrounding the scope of informed consent as identified in the hypothesis of this thesis.

The EnCoRe project, amongst others, was also discussed in Part D of this thesis and was described as a patient-centric IT system which applies the dynamic consent approach. It

attempts to enable an individual to exercise their decisions to grant or revoke consent in an easy, intuitive manner which is as reliable as "turning a tap on and off."

The hypothesis of this thesis recognised that consent is an indelible requirement in medical scientific ventures and it personifies a person's autonomy. Despite the importance and prominence thereof, however, great confusion exists regarding the appropriateness of which consent format is best suited to interventions of a biotechnological nature. This led to the premise that new research trends demand new models of consent.

It was argued in the course of this thesis that a patient is more than a mere patient or research subject and may be better described as a "patient-participant." Working from this perspective, the applicable legal regulatory and ethical principles to be considered are broadened. In line with this the two models of consent, informed and broad consent, were discussed in detail in the course of this thesis. This thesis then drew the conclusion that since the concerned person is combined into "patient-participant," the traditionally applied consents ought also to be combined by using the strengths thereof. This entailed the *information* requirement from informed consent as normally applied in medical interventions and the *open-endedness* of broad consent as normally applied in research settings. By so doing, concerns regarding the validity, meaningfulness and appropriateness of consent were addressed.

Dynamic consent was introduced as a value contribution to the field of South African law and it was suggested that it constitutes a necessary new and improved consent which may find real application in stem cell treatment and research, or then therapy-research. It was suggested that dynamic consent is the ultimate combination of broad and informed consent as it is broadly applicable and prepared to address questions regarding the uncertain future scope of interventions by providing continuous contact or re- contact with a patient-participant and due to its capacity to optimally allow for information**.**

Dynamic consent evolved concurrently with changing technological developments and encompasses a range of characteristics which enable interactive methods of expressing and amending consent in a virtually immediate manner and on an ongoing basis. The individual is therefore not limited by static, once-off, unchanging or time-consuming consent procedures. The ability to use technological means of maintaining ongoing engagement with patient-participants provides significant advantages where re-contact may be necessary. As such, it was shown that dynamic consent marks a paradigmatic shift from traditional consent systems and possesses considerable potential to strengthen long-term and continuous research activities. The actual real world implementation of this model along with the IT services and systems as well as their development and installation is, however, a matter of great technical complexity

and was found to fall outside the scope of this thesis. It was, however, suggested that the development of an EnCoRe-like system in South Africa, taking into account the difficulties and inequalities faced in both access to the health system and to technology, may form the basis of post-doctoral studies.

Finally, it was found that the implementation of dynamic consent procedures might allow for contact between clinician, researcher and participant over time rather than once-off contact; it would be interactive rather than passive; it would utilise multiple methods such as the web, cell phones, email and even paper based formats, and participants may be individually targeted which means it would be preference sensitive with a diversity of options and tailored in such a manner that participants would be able to enact their preferences. This degree of control over the self and related matters, it was shown, is the true apex of autonomy.

5 RECOMMENDATIONS

In the course of this thesis it was argued that stem cell treatment is tantamount to human subject research due to its untested efficacy and the still greatly experimental nature and scope of such interventions. It was shown that due to this merger of the intervention or the fusion of medicine and research, the persons involved and their roles are also combined and they therefore become a patient-participant and a physician-researcher. This, it was argued, is a new trend in and form of research and as such a new model of consent is necessary. Working from this hypothesis and after conducting the study which ultimately resulted in this thesis and the conclusions drawn in the writing thereof, it became possible to make the following recommendations.

5.1 RECOMMENDATIONS PERTAINING TO WHOM BEARS THE RESPONSIBILITY OF OBTAINING CONSENT

Normally, a physician is tasked with obtaining consent in instances of medical interventions. In a research setting, it is normally the task of the relevant researcher to obtain consent. In the context of this thesis it is therefore the physician-researcher who bears the responsibility of obtaining consent in instances of therapy-research. This is subject to the condition that a patient-participant be provided with the necessary information to make a decision and there are no conflicts of interest, or any interests have been disclosed to the patient-participant. It is

important that this person obtaining consent is sensitive to the situation and has a good understanding of the purpose for which consent is sought.

Procedures ought to be in place setting out the responsibilities of the person who obtains consent. They ought to be able to answer any questions the patient-participant has and must have successfully completed training in the relevant field.

5.2 RECOMMENDATIONS PERTAINING TO THE PERSON FROM WHOM CONSENT MUST BE OBTAINED

5.2.1 Fully Capacitated Adults

Patient-participants themselves grant consent.

5.2.2 Incapacitated and Mentally Ill Persons

A person need not be excluded from therapy-research merely because they have deficient capacity. A mentally ill person may grant consent themselves to the extent that they are capable of understanding all relevant aspects of their consent and, where they are unable proxy consent must be obtained. A spouse, partner, child, sibling, grandparent, grandchild, niece or nephew, step parent, half sibling or longstanding friend may act as a nominated representative on behalf of the incapacitated person. It is, however, important that an incapacitated person is only involved in research where they will receive a direct health benefit.

Research involving mentally ill persons should, however, only be permitted where it is essential to the research that such persons participate and their participation is indispensable to the object of the study. Stringent requirements ought then to be met, such as that it must be sufficiently justified; proper procedures for evaluating and confirming the true incapacity of the participant are in place; it has been ensured that the consent was free from coercion and that the research involves no or minimal risk. Where minimal risk is involved, the anticipated benefits to the participant must outweigh the risk involved.

The knowledge, understanding and acquiescence of the participant should be the deciding factor in assessing his participation, and his mental health status, which includes strength of character, resilience and general attitude or personality, should be taken into account.

5.2.3 Minors

A person need not be excluded from research merely because they are of minor age. As such, a child may grant consent to participation in an intervention themselves and should a child wish not to participate, his decision must be considered and respected. It is, however, a requirement that in an activity involving a child, his best interests are of paramount importance and are always taken into account.

Also, therapy-research ought only to be conducted in the prescribed manner and under the prescribed conditions, with the consent of the parent or a guardian of the minor, with the consent of the minor himself where his is capable of understanding all relevant aspects of his participation and with Ministerial consent where appropriate.

5.3 RECOMMENDATIONS PERTAINING TO THE TIMING OF CONSENT

Consent must be obtained prior to an intervention, be it a medical treatment or participation in scientific research or then therapy-research. Once consent has been obtained it must be flexible and able to be continuously changed throughout the course of the intervention and over time as the preferences of the consent-giver change. Consent ought ideally also to be amendable in real time.

Prospective patients, research subjects or then patient-participants ought to be furnished with sufficient time and opportunities to ask any questions that they might have regarding a proposed intervention and to fully take part in the consent process. This allows such persons to identify information they might deem relevant and which might have an influence on their preferences and decision making. Consent ought to be able to be amended or withdrawn depending on the preferences of the patient-participant from whom it was obtained at any time.

5.4 RECOMMENDATIONS PERTAINING TO THE SCOPE OF CONSENT

A patient-participant ought to be informed of the following aspects prior to consenting to participation in any treatment-research:

1. The title of the intervention;
2. Background information, an explanation of the proposed therapy-research and the methods or techniques or procedures to be employed during treatment-research;
3. The person or institution responsible for the therapy-research;

4. Any real or potential conflicts of interest;
5. Sponsors' details where relevant and any potential conflict of interests pertaining to them;
6. The purpose and benefits as well as the risks and consequences of the therapy-research;
7. The expected benefits to the participants themselves as well as others;
8. The expected side effects and potential change in quality of life;
9. The range of treatments available and applicable to the specified disease should be explained to the patient-participant as well as the disease's specific treatment processes, method and side effects;
10. Any alternatives available to the patient-participant;
11. The different treatments and possibility of random assignments of each treatment where the research in fact involves treatment;
12. Options regarding storage of material or data and any time limits attached thereto;
13. The manner in which material or data may be destroyed or disposed of;
14. The extent to which the privacy and confidentiality of the patient-participant will be protected;
15. The option to renew, review or withdraw consent and at any time;
16. Incentives to participate in the therapy-research as well as differences in incentives;
17. Any alternatives to participating in the proposed therapy-research;
18. In the event of participation in a trial, the availability of treatment beyond the duration of the trial;
19. Any available insurance in the event of injury or damage arising from participation;
20. The contact details of a person in the event of a therapy-research related injury;
21. The experimental nature of the therapy-research as well as that the health service is not a traditional medical intervention;
22. That they retain the freedom to withdraw from therapy for experimental or research purposes and may decide to participate or not;
23. In the extraordinary event that it may be necessary to withhold information from the patient-participant, the consent of the person concerned must be obtained to do so;
24. The duration of the applicable ethics committee approval if any; and
25. Proof of the ethics committee approval.

5.5 RECOMMENDATIONS PERTAINING TO THE FORMAT OF CONSENT

Informed consent is an acceptable consent format for procedures of which the efficacy or scope has been determined such as therapeutic cloning. Broad consent on the other hand is acceptable for traditional research models using single experimental procedures that do not entail an ongoing inquiry with multiple questions and methods and unknown risks. Broad consent is consent to certain information frameworks. A framework entails the aims, conditions of use and governance of a research project. Where any of these components change, the foundation of the framework changes and re-consent is required in order to lawfully continue using the participant's material or data. The moment an activity is considered outside the framework consented to, new consent must be sought.

Consent in the context of stem cell related matters ought to be explicit and written due to the moral and emotional significance of the material. Also, since it is not always desirable to de-identify material or data, the de-identification of such biological material ought only to be permitted where it has been specifically consented to. Ideally, a dynamic consent format ought to be utilised.

Consent must be flexible and changeable and ought to be regarded as a living and constantly altering process which ought to be continually revised, renewed or where appropriate, revoked. The ideal format of consent is a combination of informed and broad consent and is therefore dynamic in nature.

5.6 RECOMMENDATIONS PERTAINING TO THE DRAFTING OF THE NHA AND THE REGULATIONS MADE UNDER THE ACT

Numerous drafting issues were encountered in the course of the examination of the Act and the Regulations made in terms of the Act, and a list of the recommendations pertaining to these issues is provided here for convenience:

1. Interpretation of relevant sections of the Act indicates the possible application of dynamic consent. This is due to ambiguity, contradictory provisions or the failure to specify a particular consent format such as either "informed" or "broad" consent in instances where, for example, health services are provided for research or experimental purposes.
2. Chapter 8 of the NHA (Control of Use of Blood, Blood Products, Tissue and Gametes in Humans) might not be suited to the regulation of stem cells, stem cell therapy or stem cell

research. Considering that the efficacy of stem cell treatment is untested and, as argued in the course of this thesis, it borders on research, stem cell treatment is better provided for under section 11 of the NHA, which provides for health services for research or experimental purposes which falls under Chapter 2 of the Act (Rights and Duties of Users and Health Care Personnel).

3. A system of institutional self-regulation must be implemented for the regulation of biotechnology and related matters. Insight may be drawn from the United Kingdom in this regard and the Human Tissue Authority may be used as an example on which to model an independent South African statutory authority serving this function. One of the first aspects to be addressed by such an authority will have to be providing for adult stem cell specific regulatory instruments and drafting guidelines for the process whereby consent ought to be obtained. This thesis contributes, it is hoped, to this aspect.
4. The general ambit of the NHA and/or Chapter 8 thereof ought to be broadened in order to enable the Act to accommodate new technological advances such as bioprinting and scaffolding, for example as these aspects are currently unregulated. Alternatively, specialised legislation and/or Regulations providing for this matter ought to be drafted.
5. Chapter 8, for now, remains the primary proposed regulatory tool of stem cell therapy and research in South Africa and as such the title ought to be amended to expressly include stem cells, either by direct use of the term or by use of an umbrella term.
6. Excessive control and power by the Minister must be addressed and minimised. Excessive power such as this is problematic for two reasons. Firstly, Ministers are appointed by the ruling party and if stem cells or related matters do not "sit well" with the party, the Minister will be able to negatively influence stem cell policy in this regard, and secondly, stem cells are highly specialised and do not easily fit into South Africa's health priorities meaning that it will not be given the amount of resources and attention it requires.
7. Hospitals have no part in the trade of human materials and must only apply or use such material as appropriate. Such a ban on trade activities should be implemented to ensure a decrease in conflicts of interest in the treatment of health care users. Section 60 of the NHA must therefore be redrafted to correct the entitlement of hospitals to receive payment in connection with tissue, blood, blood products or gametes.
8. Section 56 of the NHA should be amended by expansion as well as contraction. The ambit thereof should be expanded by the addition of "research" as permissible use of material. Also, stem cells or at least an umbrella term ought to be added to the usable material named in this section. The ambit of this section must then be contracted by the removal of "blood products." Blood products cannot be removed from the human body and the

inclusion thereof is therefore indicative of the lack of technical knowledge on the part of the legislator pertaining to stem cell technology. An amendment such as this would constitute a massive development in stem cell regulation.

9. Section 54 of the NHA allows the Minister to designate any authorised institutions and provides for the activities which these institutions may undertake. Storage, processing and analysis of human material is, however, not provided for and it is suggested that it ought to be brought under the ambit of section 54 of the Act. This would ensure a more comprehensive and inclusive regulatory regime pertaining to human biological materials.
10. The definitions provided for by the Human Tissue Act of 1983, and those relating to the terminology found in Chapter 2 of the NHA in particular, are deemed scientifically and medically more accurate and should have been directly transferred to the NHA.
11. The first definition of stem cells is provided in the 2007 Regulations regarding Use. It defines stem cells as "any embryonic stem cell, circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, hematopoietic cell or any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell." It is, however, suggested that "one of the body's master cells with the ability to become any of the body's over 200 cell types" may be a more user-friendly definition and it is broad enough to accommodate adult stem cells. The definition provided in the 2011 Use of Human Biological Material Regulations which reads "any cell that is capable of replicating (proliferating) and giving rise to a differentiated cell," however, is also acceptable as it is broad enough to accommodate adult or somatic stem cells.
12. A definition of "health status" should be added to the NHA and should be drafted in a manner which is inclusive of all aspects of a person's physical and mental health.
13. The first reference to stem cells in the NHA is only found in section 56(2)(a)(iv). Stem cells are not defined in the Act itself and a definition ought to be provided within since reliance on Regulations to provide such a definition is unsatisfactory considering the NHA is deemed to be the regulatory instrument for stem cell related matters in South Africa. Section 1 of the Act, however, defines tissue as "human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or gametes." A new definition may perhaps be drafted which includes gametes and cells, particularly stem cells, as falling under tissue. Since the NHA does not provide for a definition of stem cells, embryonic or adult, it is further recommended, perhaps in the alternative, that at the very least an umbrella term must be provided under which stem cells may be brought under the field of application of the NHA in a direct manner. Such an umbrella term may then perhaps also include DNA and RNA as well as other genetic materials.

14. The definition of blood products as found in the NHA is not medically accurate. It states that it is "any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells." A blood product, however, cannot be removed from the human body. It must be removed from *blood* which is withdrawn from a person's body and a separate provision ought therefore to be made for an institution where blood products may be generated. Blood products should rather be defined as any processed or manufactured product derived from blood which is intended for therapeutic purposes, but excludes stem cells and genetic material.
15. The amendment of the title of the 2014 Human Participant Regulations from what was previously referred to as the Human Subjects Regulations in 2013 suggests a shift in the perception of the role of the person participating in the research and is more humane and consumer friendly. It further indicates that the researcher and participant are on a more equal footing than previously thought.
16. The definition of embryo as found in the 2011 Import and Export Regulations which currently reads "a human offspring in the first eight weeks of conception" might be amended to read "human offspring in the first fourteen days from conception" in order to bring the South African definition in line with internationally used definitions.
17. The 2011 Import and Export Regulations contain no definition of "export" and it ought therefore to be added to the Regulation. In line with the definition provided for "import," it may be said to mean "to export out of the Republic in any manner."
18. The meaning of "more than minimal risk" and "minor increase over minimal risk" as contained in the 2007 and the 2013 Human Subjects Regulations is in need of clarification.
19. The 2007 Stem Cell Regulations only refer to "clone" as a noun and fails to describe it as a verb. An explanation or a definition of the activity of cloning ought to be provided.
20. The Regulations state that individuals may only be reimbursed for reasonable expenses incurred in order to affect a donation. This means a person may not "sell" biological material and the donor may not be involved in any trade aspect of stem cells. It also supports the argument that informed consent transfers ownership of material. This concurs with the ethical position that there should be no financial incentives in donation in order to protect persons from exploitative practices. It seems exploitative nonetheless since stem cell research has definite monetary implications and gains but the beneficiaries are the stem cell institutions, hospitals, stem cell banks and the persons involved therein. It is recommended that the financial aspect of stem cell technology and transfer of ownership deserves further study and should be reconsidered. This thesis argued that a person who donates material maintains an interest in their material and

should still have a measure of control in the uses thereof. This is in line with the argument that control is a separate aspect from ownership.

5.7 RECOMMENDATIONS PERTAINING TO OTHER RELATED ASPECTS IDENTIFIED IN THE COURSE OF THIS THESIS

Numerous recommendations pertaining to a vast array of matters were made in the course of this thesis and have been listed here for convenience:

1. The word "experimentation" means an investigative process of a certain specified research nature. Research may then include numerous experiments. Medical experimentation therefore means medical research and scientific experimentation means scientific research. Science, however, is broader than medicine and may in fact include medicine although the converse is not always true.
2. Autonomy, and by extension the rights associated with autonomy, is not absolute and may be limited in certain prescribed circumstances.
3. Autonomy is the superior rationale underlying informed consent and is regarded as the foundation of the requirement of informed consent requirement. However, it is not necessarily the quality of a decision or the measure of autonomy which is relevant, but rather that an individual was able to make such a decision which is of importance.
4. Decision making is less about processing vast amounts of information and more about identifying the most relevant information. This means that to make an autonomous decision a person ought to identify information likely to affect their willingness to participate in an intervention or not.
5. Although the consent of the person concerned is preferable, the use of the word "their" in section 12(2)(c) is not an internal limitation. Proxy consent is constitutionally permissible and as such a legally authorised person may grant consent on behalf of a research participant and such consent must then be recognised as lawful on condition that it meets all other requirements for valid consent.
6. Therapeutic research is of direct benefit to the research participant or subject, similar to medical treatment. Non-therapeutic research is beneficial to general scientific knowledge and does not directly affect the subject. This distinction is based on the potential of direct benefit which may potentially arise from participation by a subject. The object of both therapeutic and non-therapeutic research, however, is the acquisition of knowledge and not personal treatment. The distinction has, however, become obsolete in biotechnology. Also, medical treatment on the one hand is an activity with the object of benefitting the

patient concerned and is not future or community orientated, much like therapeutic research. A medical treatment which goes beyond the norm of clinical care may, however, qualify as research. Research, on the other hand is future orientated and contributes to the understanding of a topic, similar to non-therapeutic research. In the context of stem cells, the distinction between medicine and research becomes obsolete since therapy borders on research due to the unproven efficacy and uncertain nature and scope of stem cell applications.

7. The minimum standard of disclosure for stem cell treatment, like participation in research, ought to be full disclosure and for this reason therapeutic privilege is not applicable to stem cell therapy.
8. Prior to consenting to a research intervention, a person must be informed of the risk and benefits involved. The risks and benefits of a research study ought therefore to be analysed prior to the research being undertaken.
9. Consent procedures may at times vary in differing circumstances and, as such, the requirements for valid consent should also be variable. Consent ought to be adaptable in accordance with the circumstances at hand.
10. Various submissions were made regarding biological material banking in the course of this thesis. It is recommended that an expert panel be compiled to assess this matter and find viable solutions to the issues raised regarding the debate surrounding public versus private banks.
11. In time, electronic and information technology will become more prominent and the law ought to anticipate this shift in patient-subject behaviour and establish procedures, methods and protocols enabling this development in the interim.
12. IT mechanisms ought to be incorporated into consent processes.
13. Although the EnCoRe project currently focusses mostly on an individual's data and information, its functionality may be broadened to include actual human biological material as well.
14. Research applications in biology, genetics and medicine must endeavour to offer relief from suffering and to improve the health of the individual and humankind as a whole and no research in the fields of biology, genetics or medicine may ever prevail over respect for the human rights, fundamental freedoms and human dignity under any circumstances.

5.8 RECOMMENDATIONS PERTAINING TO POSSIBLE POST-DOCTORAL STUDIES

It might be useful to considered separating the concepts of "control" and "ownership" of data and material. This aspect is related to the commercial aspects of stem cells as well as the intellectual property issues which may arise. As such, it falls outside the ambit of this thesis. A further investigation into this topic, however, might form the basis of post-doctoral studies.

Also, the development of an EnCoRe-like system in South Africa, which takes into account the unique difficulties and inequalities faced in this country regarding access to the health system and to technology, may form the basis of post-doctoral studies as it is of a technical nature which falls outside the ambit of this thesis.

6 CONCLUDING REMARKS

Several regulatory issues exist regarding stem cells and the massive gap between the law and science or medicine seems to grow by the day as the amazing field of biotechnology regularly expands almost exponentially. This matter is complicated even more when considering that legislation in this field ought to endeavour to regulate and enable scientific progress without being constrictive, confusing or incorrect while still protecting the public and their confidence and interests. Although the science of stem cells is astounding and holds the potential to greatly decrease human suffering, the public interest and potential benefit must not be underestimated as it is the most important foundation and justification for pursuing this science. Stem cell therapy and research face numerous challenges which include, but unfortunately are not limited to, the potential of over-commercialisation of human material, patenting practices, ethical issues, moral objections, the classification of stem cell therapy, regulation of safety and efficacy, issues surrounding storage and the protection of information, and of course the issue of consent in stem cell related interventions. All of these issues require attention and must be addressed sufficiently for stem cell therapy and research in all forms to fulfil its promise. Sadly, there are no short cuts to solving the various issues arising in this field of bioscience. It is, however, hoped that this thesis serves as a first step and point of departure for the issues surrounding consent and that it therefore contributes positively to the stem cell regulatory environment.

BIBLIOGRAPHY

1 EXPLANATORY NOTE ON REFERENCING METHOD

- In the following explanatory note regarding the referencing method used throughout this thesis the numbering indicates:

  1 : Reference used in first relevant footnote of chapter.
  2 : Subsequent references to same source.
  3 : Reference as it appears in the Bibliography.

- It must be noted that each chapter may be regarded as its own entity in relation to the references used in the relevant chapter. For this reason, references start anew and footnotes begin with "1."
- The Figures which appear throughout this thesis were created and designed by the author and are therefore not referenced.
- No table of abbreviated journal titles has been provided as the full title of the journal is provided.
- Suggested further reading is provided throughout the course of this thesis for persons interested in certain aspects mentioned in the relevant discussion.

1.1 BOOKS

- Where more than two persons are authors, only the surnames of the first two authors are used in subsequent references. The remainder of authors are referred to as "*et al*."
- Where a person has authored more than one publication in the same year, an abbreviated title of the publication is provided in order to distinguish.
- Publications authored by institutions make reference of the full name of the institution as author in the first reference thereof and the recognised abbreviated name of the institution in subsequent references.

a. Books by single or multiple authors

1 : Author(s) Surname Initial (year) *Title of book*: relevant page.
2 : Author Surname (year) relevant page.
3 : Author(s) Surname Initial (year) *Title of book Volume*/Edition Publisher: Place of Publication.

b. Books compiled by editor

1 : Editor(s) Surname Initial (year) *Title of book*: relevant page.
2 : Editor Surname (year) relevant page.
3 : Editor(s) Surname Initial (year) *Title of book Volume*/Edition Publisher: Place of Publication.

c. Books, booklets or guidelines authored by institutions

1 : Full name of institution (year) *Title of book/ booklet/ guideline* relevant page.
2 : Abbreviated name of institution (year) relevant page.
3 : Full name of institution (year) *Title of book/booklet/guideline Volume*/Edition Publisher: Place of Publication.

1.2 DISSERTATIONS AND THESES

1 : Author Surname Initial (year) *Title of dissertation/thesis* (LLM/LLD dissertation/thesis unpublished, University where obtained): relevant page.
2 : Author Surname (year) relevant page.
3 : Author Surname Initial (year) *Title of dissertation/thesis* (LLM/LLD dissertation/thesis unpublished, University where obtained).

1.3 ARTICLES

- Where more than two persons are authors, only the surnames of the first two authors are used in subsequent references. The remainder of authors are referred to as "*et al*."
- Where a person has authored more than one publication in the same year, an abbreviated title of the publication is provided in order to distinguish.
- Publications authored by institutions make reference of the full name of the institution as author in the first reference thereof and the recognised abbreviated name of the institution in subsequent references.

a. Articles by single or multiple authors

1 : Author(s) Surname Initial (year) "Title of article" *Name of Journal* volume(number): relevant page.
2 : Author(s) Surname (year) relevant page.
3 : Author(s) Surname Initial (year) "Title of article" *Name of Journal* volume(number): first page of article.

b. Articles or essays as contribution in books compiled by editor

1 : Author(s) Surname Initial (year) "Title of contribution" in Editor(s) Surname Initial *Title of book*: relevant page.
2 : Author Surname (year) in Editor(s) Surname relevant page.
3 : Author(s) Surname Initial (year) "Title of contribution" in Editor(s) Surname Initial *Title of book Volume*/Edition Publisher: Place of Publication.

c. Articles, essays or guidelines authored by institutions

1 : Full name of institution (year) "Title of article/ essay/ guideline" *Name of Journal* volume(number): relevant page.
2 : Abbreviated name of institution (year) relevant page.
3 : Full name of institution (year) "Title of article/ essay/ guideline" *Name of Journal* volume(number): relevant page.

1.4 PAPERS AND LECTURES

- Where a certain paper or lecture is referred to more than once, an abbreviated reference is provided as "hereafter referred to as."

1 : Presenter(s) Surname Initial (year) *Title of paper/ lecture* as presented at Name of conference/seminar/workshop/lecture series, Venue, Place, date. Hereafter referred to as Abbreviated name.
2 : Presenter(s) surname (year) Abbreviated name.
3 : Presenter(s) Surname Initial (year) *Title of paper/ lecture* as presented at Name of conference/seminar/workshop/lecture series, Venue, Place, date.

1.5 ONLINE SOURCES

a. Online sources authored by person in form of booklet

1 : Author Surname Initial (year) *Title of booklet* available online at full URL accessed /da/te/.
2 : Author Surname (year) online relevant page.
3 : Author Surname Initial (year) *Title of booklet*
Full URL.

b. Online source authored by person in form of article

1 : Author Surname Initial (year) "Title of article" *Name of website* available online at full URL accessed /da/te/.
2 : Author Surname (year) online relevant page.
3 : Author Surname Initial (year) "Title of article" *Name of website*
Full URL

c. Online sources authored by institution

1 : Name of institution (year) "Title of article" *Name of institution/website* available online at full URL accessed /da/te/.
2 : Abbreviated name of institution (year) online.
3 : Name of institution (year) "Title of article" *Name of institution/website*
Full URL

d. Online source in the form of magazine or newspaper article

1 : Author Surname Initial/Magazine/Newspaper (year) "Title of article" *Name of Magazine/Newspaper*, date available online at full URL accessed /da/te/.
2 : Author Surname/Magazine/Newspaper (year) online.
3 : Author Surname Initial/Magazine/Newspaper (year) "Title of article" *Name of Magazine/Newspaper*
Full URL

1.6 SOUTH AFRICAN LEGISLATION

a. Acts

1 : Name of Act, Act number of year.
2 : Name of Act year.
3 : Name of Act, Act number of year.

b. Regulations

1 : Name of Regulation of date. Hereafter referred to as abbreviated name of year.
2 : Abbreviated name of year.
3 : Name of regulation in Government Gazette No. of date.

c. Notices and proclamations

1 : Notice/Proclamation No. in Government Gazette No. of date.
2 : Notice/Proclamation No. of date.
3 : Notice/Proclamation No. in Government Gazette No. of date.

1.7 SOUTH AFRICAN CASE LAW

1 : *Full name of case* reported citation.
2 : *Abbreviated case name supra.*
3 : *Full name of case* reported citation.

1.8 INTERNATIONAL INSTRUMENTS

- A table of international instrument is provided for in the text of the relevant chapter pertaining to international instruments. The table provides the creator of the instrument, the name of the instrument and the date thereof. As such, a brief form of referencing was used.

1 : Name of Instrument (Abbreviated name).
2 : Abbreviated name.
3 : Name of Instrument year.

1.9 FOREIGN LEGISLATION

- It must be noted that each jurisdiction in the United Kingdom have a separate manner of referencing certain legislative documents. A complete explanatory note on the citation of United Kingdom legislation has been provided and this section therefore merely explains the referencing method used in the text of this thesis for sources repeatedly referenced.

a. Acts

1 : Name of Act year (chapter/aspect). Hereafter referred to Abbreviated name.
2 : Name of Act year OR Abbreviated name.
3 : Name of Act year (chapter/aspect).

b. Directives

1 : Directive citation of the European Parliament and of the Council of date on Name of Directive. Hereafter referred to as Abbreviated name.
2 : Abbreviated name.
3 : Directive citation of the European Parliament and of the Council of date on Name of Directive. Hereafter referred to as Abbreviated name.

1.10 FOREIGN CASE LAW

1 : *Full name of case* reported citation.
2 : *Abbreviated case name supra.*
3 : *Full name of case* reported citation.

2 EXPLANATORY NOTE ON THE CITATION OF UNITED KINGDOM LEGISLATION

Since 1890 each Act has a long as well as short title. Older legislation was given a short title by the Short Titles of 1896. In the course of this thesis the short title of each relevant Act was referred to. A distinction may be made between public general, private or personal and local Acts. This thesis made reference to public Acts.

The full official citation of a public general Act is comprised of the short title, a year and a chapter number. Until 1963, this was always the regnal year, meaning the year of the Monarch's reign. The chapter number is a continuously running number ascribed to Acts during a year. The chapter number is indicated after the year by making use of the letter "(c.)" For example, the Irish Appeals Act 1783 (23 Geo. 3. c.28) was the 28th Act passed in the 23rd year of the reign of King George III. As of 1963 however, the citation of these Acts has been simplified and now makes use of the calendar year. For example, the Human Tissue Act 2004 (c.30) indicates that the Human Tissue Act was the 30th Act passed or assented to in the year 2004.

A distinction may also be drawn between the Acts passed by the devolved legislative bodies found in the United Kingdom. The citation of legislation of each of these bodies is explained briefly.

2.1 NATIONAL ASSEMBLY FOR WALES (SINCE 2006)

The primary legislation made by the National Assembly for Wales is referred to as Measures and is cited by making use of the short title, the year and then the National Assembly for Wales number in the form of "(nawm)." For example, the National Health System Redress (Wales) Measure 2008 (nawm 1). The title itself will indicate that it is a Welsh Act as may be seen from the given example.

2.2 PARLIAMENT OF NORTHERN IRELAND (1921-1972)

The citation of the Acts of the former Parliament of Northern Ireland is similar to the system used by United Kingdom general public legislation. It differs however in that the transition from regnal to calendar year occurred earlier, in 1944. In Westminster legislation, Northern Irish Acts are cited with "(NI)" appended to the chapter number. For example, the Charities Act (NI) 1964 (c.33).

A distinction is further drawn between Acts passed in Northern Ireland by the Parliament of Northern Ireland and Acts passed by Westminster relating to Northern Ireland. This distinction is indicated by the placement of the word "Act." For example, the Departments Act (Northern Ireland) 2016 (c.5) was passed by the Parliament of Northern Ireland whereas the Judicature (Northern Ireland) Act 1978 (c.23) was passed by Westminster.

2.3 NORTHERN IRELAND ORDERS IN COUNCIL

Northern Ireland Orders in Council are a species of subordinate legislation made at Westminster, though they are also the constitutional equivalent of Acts that could be enacted by the Northern Ireland Parliament or the Northern Ireland Assembly. The main difference between Orders and Acts is procedural insofar as Northern Ireland legislation that was made by way of Order in Council is not subject to the same levels of accountability and control that one would expect with "Acts". For example, the Children (Northern Ireland) Order 1995 (S.I. 1995/755 (N.I. 2)).

2.4 NORTHERN IRELAND ASSEMBLY (SINCE 1999)

Acts of the Northern Ireland Assembly, established in 1998, are cited by referencing the short title followed by "(Northern Ireland)" and then the year in which the Act was passed. For example, the Departments Act (Northern Ireland) 2016 (c.5).

2.5 SCOTTISH PARLIAMENT (SINCE 1999)

Acts of the Scottish Parliament are cited by referencing the short title of the Act and year followed by an indication that it is such an Act by the use of the acronym "asp" and lastly, the running number of the Act. For example, the Human Tissue (Scotland) Act 2006 (asp 4) indicates that the Act was the 4th Act passed by the Scottish Parliament in 2006 with application to Scotland only.

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