UNIVERSITEIT VAN PRETORIA
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AN ANALYSIS OF THE PROPOSED REGULATORY FRAMEWORK FOR THE PROCUREMENT AND DISTRIBUTION OF STEM CELLS

by

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submitted in partial fulfilment of the

requirements for the degree

MAGISTER LEGUM (LLM)

Prepared under the supervision of

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NOVEMBER 2010

SUMMARY

The aim of this dissertation is an analysis of the regulatory framework for the procurement and distribution of stem cells in South Africa. This research includes aspects of the law of obligations, medical law and human rights law as found in the Bill of Rights. More specifically however, this dissertation attempts to bring to attention the shortcomings of chapter 8 of the National Health Act. An examination is undertaken according to the multi-layered approach and therefore the proposed regulatory framework is examined within a constitutional framework, an ethical framework, the framework as established by common law, in this case the doctrine of informed consent and lastly within the national legislation framework as found in the National Health Act of 2003 and the regulations made in terms of the Act. This dissertation further entails a brief comparative study of the regulatory mechanisms of the United Kingdom as entrenched in the Human Fertilisation and Embryology Act of 2008 and the Human Tissue Act of 2004 and as practiced by the Human Fertilisation and Embryology Authority and the Human Tissue Authority. The analysis in this dissertation firstly provides an overview of the clinical manifestations and science of stem cell technology. Secondly, the impact of the Constitution of the Republic of South Africa is discussed with particular reference to the Bill of Rights on stem cell research and therapy. The most noteworthy conclusion to be made in this regard is that the embryo is not the bearer of constitutional rights. The ethical guidelines which act as regulatory tools in this field are then discussed with attention to general ethical principles as provided for by the Health Professions Council of South Africa as well as the Medical research Council. The doctrine of informed consent further enjoys attention as it is discussed in context of medical research and key issues are addressed regarding the process of obtaining consent in context of stem cell technologies. Certain recommendations are then made pertaining to the minimum scope required for lawful consent. Lastly a critical analysis is made of chapter 8 of the National Health Act. The findings which are made here lead to further recommendations regarding the regulation of stem cells.

Key terms and phrases: stem cells- embryo- cloning- induced pluripotent stem cells- life-dignity- constitutional rights- ethical guidelines- medical and scientific experimentation- informed consent- regulatory framework- National Health Act of 2003- regulations.

Acknowledgements

I wish to express my sincere gratitude to the following:

- My supervisor, Professor Pieter Carstens for being my mentor, for advice and guidance, patience, time and support. Thank you for the enthusiasm for the law which you have given me. Most importantly I would like to thank you for your profound wisdom and the entertainment which you have provided by your "take" on situations.
- The Department of Public Law, University of Pretoria for the opportunity to have worked there during the completion of my degree. It has been a truly interesting and entertaining experience. Thank you to my colleagues for their insight, knowledge, support and friendship. I have nothing but respect and dearness for each of you. I would especially like to thank Marozane Spamers for picking up the pieces when the challenge became too great and for your endless enthusiasm and wonderful friendship and for the coffees. Also, thank you to Lenée Veldsman and Kathleen Hardy, my co- Academic Associates.
- My family, including Mako for your support, words of encouragement and for giving me this opportunity. Mostly thank you for putting up with my temper in the course of writing this dissertation. This would not have been possible without you. I also feel it necessary to mention my dogs for sitting with me patiently and for their unconditional admiration and love.
- My friends for their motivation and patience. Thank you for believing in me, even when I no longer did and for reminding me that there is more to life than this.

Larisse Prinsen

2010

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CHAPTER 1
INTRODUCTION

1 INTRODUCTION

According to an Arab proverb a man who has health, has hope, and he who has hope has everything. Until recently, this proverb may have been labelled as idealistic and unrealistic as serious disease and illness have plagued humanity from the beginning of time. Now however, stem cells allow one to imagine a world where total health is attainable and thus hope becomes real. Stem cells have thus been described as the new form of medicine and we currently find ourselves in what could be coined a medical revolution as regenerative medicine is coming to the foreground more and more. This means is that damaged tissue no longer needs to be removed or replaced but is healed. This then leads to the prevention of degenerative illnesses and a cure for previously considered incurable diseases.

Medical scientists have, for some time known, that the body possesses certain regenerative qualities, even if only to some extent. This remarkable ability was hinted at by the generation of human skin and blood cells and in the 1950's the existence of such ability was confirmed by bone marrow transplantation. Due to this, as well as the first successful birth of a "test tube baby"[1] which proved the benefits of techniques requiring the manipulation of human biological material, the potential of regenerative medicine gave hope to millions of people suffering from disease and illness. More recently, developments such as the techniques of somatic cell nuclear transfer and induced pluripotency have promised a new form of medicine which does not only prevent or cure, but regenerate.

The promise of major medical breakthroughs has resulted in a persistent pursuit of stem cell technology, in the form of therapy and research, by physicians and scientists. Stem cell therapy gives hope to persons who suffer from cancer, diabetes, cardiovascular disease, spinal- cord injuries and many other disorders due to its potential to rebuilding or replace damaged cells and tissues. Stem cell research may also aid researchers in drug and medicine development and has provided insight into human reproductive biology and embryogenesis.

[1] Louise Brown was the first baby born as result of assisted reproduction over 25 years ago in the United Kingdom.

It is in these abilities and benefits of stem cells and stem cell research that the miracle of stem cells may be found. Stem cell therapy, however, is extremely controversial and it requires effective and proper regulation. It is then this regulation which this dissertation proposes to analyse.

2 HYPOTHESIS, PURPOSE AND PROBLEM STATEMENT OF DISSERTATION

The purpose of this dissertation is an analytical discussion of the regulation of stem cells and stem cell related technologies and practices within South Africa at the hand of various legal and ethical instruments, especially legislation and ethical guidelines pertaining to health, experimentation on humans and reproductive sciences will be discussed in the course of this dissertation. This dissertation thus begs the question of how stem cells will be regulated in South Africa.

As the biological revolution is upon us the law is confronted with two options. To lay the foundation for the scientific community to partake in this science and medicine or, frustrate scientists and medical practitioners, resulting in a wanting state for the future.[2] An attempt was made to facilitate stem cell research and technology in South Africa and thus the National Health Act of 2003 was created. The National Health Act[3] is the proposed regulatory tool whereby stem cells will be regulated but, as will be illustrated in the course of this dissertation, it is problematic, insufficient and not up to the task of regulating such an advanced subject. The reasons for this is that the legislative framework as set by the NHA is fragmented as the Act is supplemented by various regulations and ethical guidelines and thus no comprehensive regulatory tool exists, it is slow and unresponsive to new developments and it indicates a lack of scientific comprehension. This, along with the fact that the NHA has not yet come into force has resulted in a non- existent legal framework which has left South Africa in a legislative vacuum.

Other regulatory instruments are however available in the interim and thus this dissertation offers a layered approach to stem cell regulation by examining each category of alternative

[2] Jordaan DW (2007) "Science versus anti- science: The law on pre- embryo experimentation" *The South African Law Journal* 124(3): 618 at 634.
[3] Hereafter referred to as the NHA.

regulatory instruments within a layer. This dissertation thus analyses the regulation of stem cells according to the Constitutional framework, the layer as constituted by ethical guidelines and principles and the framework which is set by established medical law doctrines and then the doctrine of informed consent specifically. The NHA is then lastly discussed. It is important to note that the NHA should ideally fall within the overlapping spheres of the other layers or frameworks. It should thus correspond with the Constitution, ethics and the common law as found in South African medical law. The extent to which this is achieved is therefore analysed in this dissertation. This task has however proven difficult as stem cell science is developing at an alarming rate and therefore it is difficult to stay on the "cutting edge" thereof when one is not directly involved in the laboratory.

The title of this dissertation was chosen due to the fact that there is currently no comprehensive regulatory framework pertaining specifically to the procurement and distribution of stem cells and when the title is analysed three elements thereof may be identified:

1. The "analysis" requires a multi- layered approach as previously stated, and this entails an explanation of the science and the manifestation of stem cells as it is important to have the background and context in which the law has to function, secondly form a Constitutional point of view as the Constitution is the supreme law of South Africa and any law in conflict therewith will be invalid and it is necessary to determine whether or not stem cell technology is at all constitutional. Thirdly the ethical point of view is discussed as in the absence of in force hard law, ethics as soft law have become hard law. Also the common law is present in the form of medical law and specifically informed consent. The unique questions and areas of conflict will then also be discussed within the context of each layer and in this manner I propose to cover the playing field in which this science finds itself;

2. This dissertation attempts to analyse the "proposed regulatory framework" consisting of chapter 8 NHA and the regulations made in terms of the Act. It is the "proposed" framework due to the fact that neither chapter 8 nor the regulations have come into force; and

3. The third element of this dissertation is the fact that it is limited to the "procurement" and "distribution" of stem cells. This is done due to the fact that these two aspects are perhaps the most contested and controversial in any attempt to regulate stem cells. For the purposes of this dissertation "procurement" must be understood to mean the process by which stem cells are made available and this includes the removal or withdrawal of stem cells and also the creation thereof. "Distribution" must then be understood as being used for therapy, research or educational purposes and the practice of stem cell banking.

3 RESEARCH METHODOLOGY

In the course of this dissertation a literature study of primary legal sources as constituted by the Constitution, relevant legislation and ethical guidelines will be employed. The relevant case law will also be discussed where appropriate. Secondary sources will be used in the form of textbooks, academic writings and journal articles. The internet will be utilised as it is the fastest manner in which new information may be found and updated.

Chapter 2 follows an explanatory methodology which aims to provide a basic understanding. Chapters 3 to 5 are more discussion- orientated and cover numerous primary and secondary sources and lastly, chapter 6 is analytical in nature.

Regarding the choice of legal systems it must be stated that although the focus of this dissertation falls on the South African legislative framework regarding stem cells. Section 39(1) of the Constitution however requires that international law must be considered and foreign law may be considered in the interpretation of the Bill of Rights. International law as well as foreign law will thus influence South African law. Due to this international instruments will also be mentioned in the course of this dissertation. Foreign law becomes especially important in chapter 6 wherein it is recommended that South Africa follow a United Kingdom- model as provided for by the Human Fertilisation and Embryology Act, Act 22 of 2008 which repealed the 1990 Act and the Human Tissue Act, Act 30 of 2004. International law and foreign law offer insight into international trends in stem cell technology and is thus imperative to this dissertation.

4 OVERVIEW OF CHAPTERS

The title of this dissertation states that it is an analysis of the framework wherein stem cells will be regulated and it is thus imperative to understand stem cells. Chapter 2[4] of this dissertation will therefore explain basic biological concepts, manifestations and the science of stem cells. "Manifestations" means the different forms of stem cell. Stem cells "science" is the methods wherein stem cells are created for human application.

Chapter 3[5] outlines the constitutional framework in which stem cell research in South Africa will be required to function. Firstly, the limitation clause is discussed as any examination into the impact of the fundamental rights as enshrined in the Bill of Rights on stem cells will be null should stem cell research be found unconstitutional.

Certain issues which arise in context of stem cell research such the embryo's entitlement to constitutional rights including life and dignity, and these issues may be debated practically, legally and philosophically.[6] For this reasons argument for and against stem cell research will be made in chapter 3 of this dissertation. The constitutional provisions which may be involved in the procurement and distribution of stem cells will thus be discussed and an attempt will be made to resolve any conflicts between fundamental rights and stem cell technology.

Chapter 4[7] of this dissertation provides a discussion of the ethical regulation of stem cells as provided for by ethical frameworks and the guidelines composed by ethics bodies within South Africa. In the absence of in force hard law, ethical guidelines and principles have accrued the status of hard law even though it is soft law. This chapter then discusses the relationship between the law and ethics in context of stem cells. It is also important to keep in mind that even when the NHA, or other stem cell related legislation, comes into force ethical guidelines will play a role in providing some degree of flexibility and thus can never be ignored in health technology related matters. The NHA as pertaining to the

[4] A clinical overview of the manifestations and science of stem cells.
[5] The constitutional impact on stem cells.
[6] Lupton ML "The legal position of cryopreserved embryos" 1992 *Tydskrif vir die Suid- Afrikaanse Reg* 466 at 467 & 468.
[7] The ethical regulatory framework.

establishment of a specialised ethics council and committees will thus also be discussed in chapter 3.

Chapter 5[8] deals with consent in context of stem cells. It will therefore discuss medical law principles regarding the doctrine of informed consent. Furthermore, consent in context of research will be discussed. Consent provisions as found in the NHA and related regulations are discussed in this chapter and this will constitute the analysis of the NHA in this context. Constructing a chapter on the medical legal doctrine of informed consent in context of the procurement and distribution of stem cells pose various difficulties as it is a principle with diverse and complex implications. Chapter 5 will then also include a recommended minimum scope of consent in order to overcome these difficulties.

Lastly, chapter 6[9] constitutes an analysis of chapter 8 of the NHA which is intended to be the primary legislative regulatory tool for the procurement and distribution of stem cells. Certain problems as found in chapter 8 will be identified and recommendations will be made whereby such issues may be corrected. The United Kingdom's position is then also discussed in this chapter as it is submitted that the shortcomings of the NHA and the proposed South African framework may be corrected by following this model.

5 VALUE CONTRIBUTION AND MOTIVATION OF THIS DISSERTATION

This dissertation illustrates the ineffective and insufficient manner in which stem cells are regulated in South Africa and offers the first compendium of regulatory instruments regarding South African stem cell regulation. It further identifies certain shortcomings in the proposed future legislation regarding this subject. This research thus offers some assistance in overcoming theses problems and shortcomings and may constitute, at the very least, an academic analysis from a legal point of view of the fragmented framework for the regulation of stem cells. This will then hopefully open the doors of debate and discussion in order to affect progress in this field of law and medical science.

[8] Consent.
[9] The proposed legislation: Chapter 8 of the National Health Act, Act 61 of 2003.

It must however be noted that at the time of publication of this dissertation, chapter 8 is under revision and all references made to sections of the NHA in the course of this dissertation refer to the provisions as they have originally appeared in the Act. It is trusted that should these revisions be given effect and the NHA amended or rewritten the NHA will be closer to what is recommended in this dissertation. The value of this dissertation will then lay in the fact that it will reflect the historical development of stem cell regulation in South Africa and provided for a record of the position in South Africa in 2010.

6 CONCLUSION

Stem cell technology confronts humanity on various levels including law and ethics. It has undoubtedly become a hot topic of debate and numerous views exist on whether such technology is legally, ethically, morally and medically permissible. An interest in the betterment of humanity by the advancement of knowledge, medicine and science must thus be balanced against the concerns regarding the use of human material in experimentation. Furthermore, the boundaries of such technology are blurred and yet it is clear that stem cell technology holds the potential to affect millions of lives in a positive manner.

In order to do this however, a comprehensive regulatory framework must be provided wherein stem cell research may be undertaken while being monitored and controlled. The Constitution will define what is permissible and legislation as well as the common law will act in a directive manner while ethics provide moral credibility to such technology. An understanding of the concepts, manifestations and science of stem cells is however imperative before any attempt can be legitimately made to regulate this technology. The following chapter thus firstly provides a clinical overview of stem cell technology.

CHAPTER 2
A CLINICAL OVERVIEW OF THE MANIFESTATIONS AND SCIENCE OF STEM CELLS

1 INTRODUCTION

Scientists have known for a long time that certain animals possess regenerative abilities and that the human body shares in this ability to some extent. Humans cannot regenerate an entire organ or appendage, but human skin cells, blood cells and other tissues are constantly renewing themselves. In the 1950's the existence of such powerful cells, stem cells, in the human body was established by the transplantation of bone marrow. This discovery raised hope in the potential of regeneration in medicine and for the first time in human history, physicians were able to regenerate damaged tissue using a new supply of healthy cells.

It is in this hope of major medical breakthroughs that stem cell research is being aggressively pursued by doctors and scientists alike. Stem cell therapies offer hope to those suffering from cancer, diabetes, cardiovascular disease, spinal- cord injuries and many other disorders as it holds the potential of rebuilding or replacing damaged cells and tissues in a regenerative manner.[1] Stem cell research is furthermore useful in the development and testing of new drugs and medicines and expands the knowledge of human biology and embryogenesis.[2] Stem cell research is thus a beacon of hope in the ideal of lessening the suffering of humans.

The title of this dissertation states that it is an analysis of the framework wherein stem cells will be regulated. In order to regulate stem cells it is however imperative to understand stem cells, even if this understanding is rudimentary. How can one dictate a subject when one is unfamiliar therewith? The purpose of this chapter is thus an explanation of the basic

[1] This means that medicine or research is no longer used to "fix" something which is broken or flawed, but "replace" it by means of new growth.
[2] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 2 available at http://dels.nas.edu/dels/rpt_briefs/Understanding_Stem_Cells.pdf accessed 3/3/2009.

concepts,[3] manifestations and science of stem cells. The word manifestations eludes to the different forms in which a stem cell may be found and thus an overview of the differing forms of stem cells will be provided according to a hierarchy of plasticity. Also, the qualities which have caused the interest in these cells will be discussed. Stem cell research and therapy is controversial due to the sources of stem cells and to be able to understand the later ethical discussion, the sources of stem cells which include embryonic stem cells, adult stem cells and created embryo or embryo-like cells are discussed. Also, the less well known sources of stem cells such as cadaveric fetal tissue, cord blood and chimeric embryos are explained.

The science of stem cells may be understood as the methods wherein stem cells are created for human application and thus somatic cell nuclear transfer and induced pluripotency must be briefly explained. To accommodate the understanding of the science and manifestations of stem cells this chapter will include illustrative figures.

The distribution of stem cells as is manifested in stem cell banking is discussed and a brief explanation is provided of how the process of banking is done. Lastly, the latest developments in stem cell technology will be mentioned in an attempt to bring this chapter "up- to- date" with the developments which have occurred in the time of writing and publishing this dissertation. In order to understand stem cells however, cognisance must be taken of the development of this peculiar and miraculous science and thus a short history and background is provided.

1.1 HISTORY AND BACKGROUND

Bone marrow experiments in the 1950's revealed the existence of stem cells in the human body and this in turn lead to the development of bone marrow transplantation. This therapy is now commonly used in medical treatment. What was and is of utmost importance of this discovery, was the hope in the potential of regeneration. After the success of the first bone marrow transplantation in 1956, scientists sought to identify cells in the embryo with the same potential, as early human development studies had indicated that all of the cells in the

[3] The definitions referred to in the course of this chapter are biological and are not the definitions which have been used in any of the legislative or ethical documents used in this dissertation.

human body could be formed by an embryo. In the 1980's stem cells were extracted from mice. In 1981 embryonic stem cells were extracted from mouse blastocysts and in 1988 hematopoietic stem cells from adult mice were purified and characterised.[4] In 1997 the first animal clone was introduced to the world in the shape of Dolly the sheep and in 1998 over 50 mice were cloned using nuclear transfer.[5] The year 1992 heralded the identification of stem cells in the human brain but not until 1998 could scientists isolate human embryonic stem cells and sustain these cells in culture without cell differentiation.[6]

In 2001 mouse embryonic stem cells were created by nuclear transfer and in 2002 pancreatic cells were derived from such cells to cure diabetes in mice. The nerve cell which is lost in the course of Parkinson's disease was produced for the first time in 2004. Human embryonic stem cells differentiated into active nerve cells when implanted into mouse brains in 2005 and in 2006 embryonic stem cells were derived from a Morula for the first time. Also, stem cells were grown without animal products in culture.[7] Induced pluripotent cells were first created using mouse cells in 2006 and in 2007 using human cells.[8] iPS cells carry an enormous risk of cancer formation, but in 2008 it was reported that the cancer causing genes could be removed from the cells after induction which increased the potential for human application.[9]

Stem cell science is developing at an alarming rate and therefore it is difficult to stay on the "cutting edge" thereof when one is not directly involved in the laboratory.[10]

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[4] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 2.
[5] See 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.
[6] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 2.
[7] *Idem* 16- 17.
[8] Stem Cell Network "Stem cell time line" available at http://www.stemcellnetwork.ca/index.php?page=stem-cell-timeline accessed 8/8/2009
[9] Los Angeles Times "Cancer threat removed from stem cells" available at http://www.latimes.com/news.nationworld/nation/la-sci-stemcell62009mar06,0,63456.story accessed 10/5/2010.
[10] See paragraph 5 *infra* for the newest developments in stem cell technology at the time of publication of this dissertation.

2 OVERVIEW OF STEM CELLS

Stem cells may be defined as "cells with the ability to divide for indefinite periods in culture and to give rise to specialised cells."[11] This definition requires further explanation. The ability to divide in a process known as cell division is the method by which a single cell divides to create two cells.[12] These two cells then become four, then eight and then sixteen as the cells exponentially multiply. Two main types of division exist, namely mitosis or meiosis.[13]

The last element of the definition of stem cells which requires explanation has regard to the formation of specialised cells. Reflection is necessary on the fact that during natural gestation of an egg cell inside the womb, the over 200 different cell types of which the human body is comprised of develop from a single fertilised embryo. For example, blood cells, liver cells, neural cells and brain cells all develop from the same origin: the embryo. The process by which cells become more specialised is referred to as differentiation. In layman's terms one can describe differentiation as the level of commitment a cell has to a certain form. Differentiation is controlled by the interaction of the cells' genes with the physical and chemical conditions outside the cell.[14] This is normally achieved by the signalling of pathways involving proteins embedded in the cells surface. This signalling of pathways is called expressing or repressing different gene subsets.[15] The possible subset of

[11] National Institutes of Health "Stem cell basics: Glossary" available at http://www.stemcells.nih.goe/staticresources/info/basics/SCprimer2009.pdf accessed 5/8/2009. Cell culture is explained in paragraph 3.6.3.1 *infra* in the discussion on induced pluripotency.

[12] National Institutes of Health "Stem Cell Basics: Glossary."

[13] Mitosis is the type of cell division which most body cells undergo by which tissues are repaired and grown. It involves the division of a single cell to create two genetically identical cells referred to as daughter cells which each have a full set of chromosomes. Meiosis is the division which occurs in a gametes maturation process so that the sex cells eventually contain only half the amount of chromosomes of the parent cell. During fertilisation the full chromosome number will be restored in the embryo in a unique combination. Daughter cells also vary genetically due to a process which is known as "crossing- over" which occurs during meiosis. Meiosis has two phases of division which is then further divided into four stages namely: prophase, metaphase, anaphase and telophase. See Family Medical (2000) *Medical dictionary* 161 & 167.

[14] National Institutes of Health "Stem Cell Basics" 20 available at http://stemcells.nih.goe/staticresources/info/basics/SCprimer2009.pdf accessed 5/8/2009.

[15] Expressing means the activation of genes while repressing means the deactivations of genes. Red blood cells for example express the genetic creator of haemoglobin, the protein which transports oxygen throughout the body while neural cells do not. See Swanepoel (2006) LLM thesis 33 footnote 37 & 38.

genes a cell is able to express becomes more limited as the cell becomes more differentiated or specialised or, stated differently the cell decreases in plasticity.[16]

Cells from different sources will then also differ in their level of plasticity and for this reason cells may be divided into a hierarchy according to the cells' stage of differentiation. This may also be referred to as the cells potency.[17] The various groupings of cells include totipotent stem cells, pluripotent stem cells, multipotent stem cells, bipotent stem cells and unipotent or monopotent stem cells.[18] The different potencies into which cells may be separated must be explained.

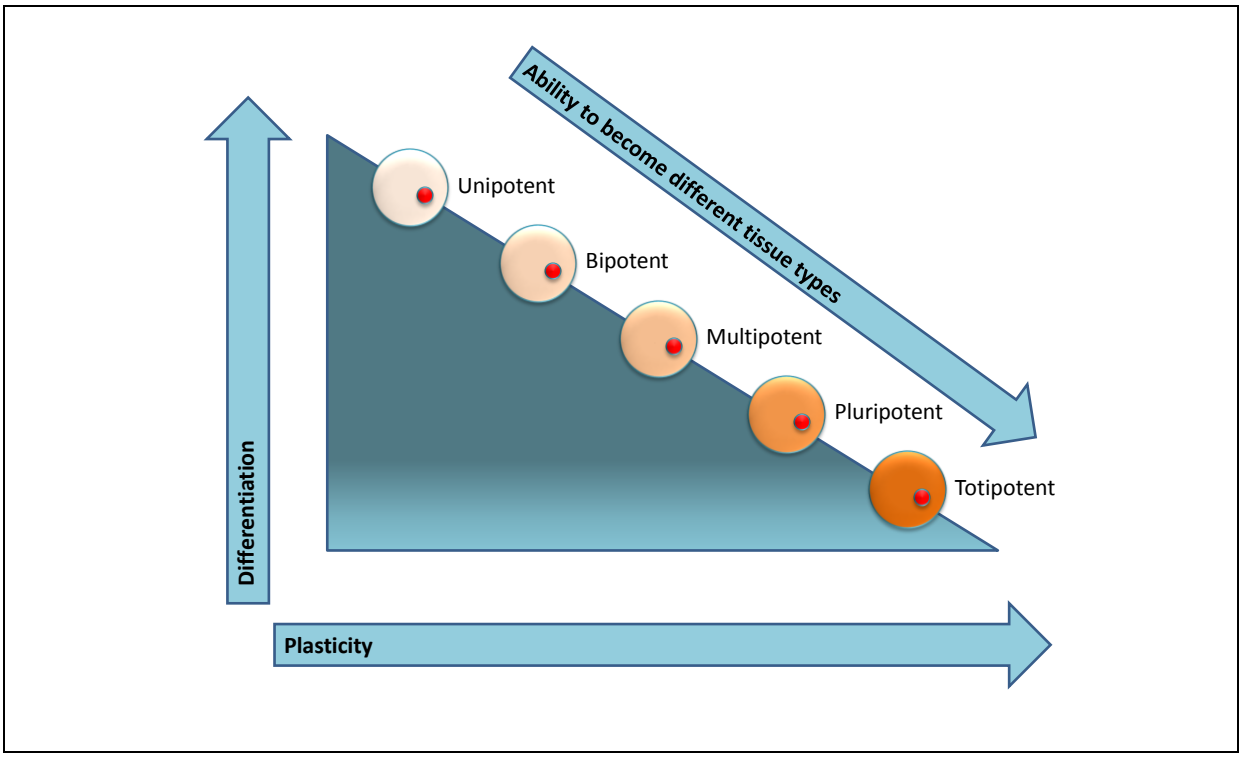

Figure A: The stem cell hierarchy

[16] Plasticity is the cells potential for differentiation. A further explanation of plasticity is that it is the cells ability to differentiate into a cell type other than the type of tissue in which it can normally be found. See The National Academies *Stem Cells and the Future of Regenerative Medicine* 71 available at http://www.nap.edu/catalog/10195.html accessed 23/4/2009.
[17] Potency is the cells ability to become a specialised cell.
[18] Swanepoel (2006) LLM thesis 34.

2.1 TOTIPOTENT STEM CELLS

The cells found in the human body may be divided into germ cells,[19] egg cells,[20] sperm cells[21] and somatic cells which are all the cells of an organism except the germ cells and are made up of two sets of chromosomes.[22] Fertilisation is the union of an egg and sperm cell and after fertilisation the fertilised egg begins a process of cell division which is "[a] method by which a single cell divides to create two cells."[23] If any of these cells were to be isolated and continued to develop, a new embryo would form as is the case when twins are born.[24] Totipotent cells have an unlimited capacity and can differentiate into an embryo,[25] placenta[26] and tissue and may also contribute to each and every cell type in the human body[27] such as heart cells, brain cells and liver cells.[28] This period of totipotency is however short and after three days of embryonic cell division the cells will become more specialised and possess less potency.[29] The cells therefore become pluripotent.

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[19] Germ cells are "gametes (ova or sperm) or cells that give rise directly to gametes." Gametes are "(1) any germ cell, whether ovum or spermatozoon, (2) a mature male or female reproductive cell." See Holland S, Lebacqz K & Zoloth L (eds) (2001) *The human embryonic stem cell debate: Science, ethics and public policy* 244.

[20] An egg cell is also known as an oocyte. It is "a cell in the ovary that undergoes meiosis to produce an ovum, the female reproductive cell." See Family Medical (2000) 184.

[21] "The mature ,male reproductive cell or gamete." The sperm cell consists of a head with the Haploid nucleus and contains half the chromosome number and an acrosome which helps in the penetration of the egg cell. Below the head is mitochondria which provides the sperm with energy and a tail which propels it forward. See Family Medical (2000) 239.

[22] Holland, Lebacqz & Zoloth (2001) 245.

[23] National Institutes of Health "Stem cell basics: Glossary."

[24] Twins are born due to a process wherein genetically identical organisms arise from a symmetrical division and separation of totipotent cells. See in general Revolution Health "Where do twins come from?" available at http://www.revolutionhealth.com/healthy-living/pregnancy/first-concerns/multiples/facts accessed 22/4/2010.

[25] "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 *Stem Cells and the Future of Regenerative Medicine* 68.

[26] Placenta is "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* as presented at the Stem Cell Seminar held at the Innovation Hub, University of Pretoria, Pretoria 27/5/2009. Hereafter referred to as the Stem cell seminar.

[27] Holland, Lebacqz & Zoloth (eds) (2001) 245.

[28] Miller J (2003) "A call to legal arms: Bringing embryonic stem cell therapies to market" *Albany Law Journal of Science & Technology* 13(2): 555 at 558.

[29] 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): 514 at 515.

2.2 PLURIPOTENT STEM CELLS

Pluripotent stem cells are present in the early stages of embryo development and can generate all cell types capable of self- renewal in the fetus and adult, but cannot develop into a complete organism.[30] Pluripotent cells can however form differentiated cells and even tissues and although the gene expression of the cell is different to that of the pluripotent stem cell the genome remains unchanged.[31]

The blastocyst[32] forms on roughly the fourth day after fertilisation of the egg cell and is a sphere of cells which comprise of an outer layer of cells known as the trophoblast,[33] a fluid-filled cavity named the blastocoel[34] and a cell cluster inside the blastocyst known as the inner cell mass.[35] Embryonic stem cells are derived from the inner cell mass of the blastocyst.[36] The cells from the blastocyst are pluripotent and therefore have the ability to develop into any of the cells of the human body whether endoderm,[37] mesoderm[38] or ectoderm.[39] As stated above however pluripotent cells cannot become a fetus should it be

[30] Holland, Lebacqz & Zoloth (eds) (2001) 244.
[31] Kidson (2009) Stem cell seminar.
[32]The blastocyst is an embryo of about 150 cells produced by cell division following fertilisation. See National Institutes of Health "Stem cell basics: Glossary."
[33] 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." See National Institutes of Health "Stem cell basics: Glossary."
[34] "The fluid- filled cavity inside the blastocyst, an early... stage of the developing embryo." See National Institutes of Health "Stem cell basics: Glossary."
[35] *Ibid*. See also The National Academies *Stem Cells and the Future of Regenerative Medicine* 67.
[36] See paragraph 3.4 *infra* for a further discussion on the derivation of embryonic stem cells from blastocysts.
[37] Endoderm is "one of the three primary germ cell layers... in the very early embryo." The endoderm is the innermost layer and differentiates to give rise first to the embryonic gut, the respiratory lining, digestive tracts, the liver and pancreas. See MedicineNet.com available at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=endoderm accessed 3/5/2010.
[38] Mesoderm is the middle layer of the three primary germ layers and differentiates to gives rise to a number of tissues and structures which include bone, muscle, connective tissue, and the middle layer of the skin. Some cells in these tissues retain the capacity to differentiate into different tissue types. See MedicineNet.com available at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=mesoderm accessed 3/5/2010.
[39] Ectoderm is the outermost of the three germ layers which make up 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, and 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 however, has indicated that certain cells within ectodermal structures retain their ability to differentiate into other tissues. See MedicineNet.com available at http://search.medicinenet.com/search/search_results/default.aspx?Searchwhat=1&query=ectoderm accessed 3/5/2010.

implanted into the uterus of a woman.[40] The pluripotent cell continues to develop into more specialised cells which are known as multipotent cells.

2.3 MULTIPOTENT STEM CELLS

Multipotent cells are cell capable of becoming only a few types of tissues. Umbilical cord stem cells and bone marrow cells are prime examples of this as they can become different types of cells such as blood cells.[41] These cells therefore have a specified function and are regarded as organ- specific. Multipotent cells form during fetal development and may still be found in adult humans, thus most adult cells are multipotent in nature, although not in such vast amounts.[42]

2.4 BIPOTENT CELLS

A bipotent cell can become one of two things.[43] It may also be noted that bipotent cells may produce endoderm and mesoderm and is useful in the production of pancreatic islets.[44]

2.5 UNIPOTENT OR MONOPOTENT CELLS

Fully differentiated cells are unipotent and most of the somatic cells in the body fall under this category.[45] A skin cell will create more skin cells and thus a unipotent cell has almost no plasticity and will only ever create more of its own type of cells.

[40] See Moore KL & Persaud TVN (2003) *Before we are born: Essentials of embryology and birth* defects 41- 48 & 60.
[41] Kidson (2009) Stem cell seminar.
[42] Slabbert (2003) *JLM* 514 at 515.
[43] Kidson (2009) Stem cell seminar.
[44] "A culture of bipotency" *Development* 132(19) of 1 October 2005 available at http://dev.biologist.org/content/132/19/e1905.full.pdf+html accessed 3/5/2010.
[45] Kidson (2009) Stem cell seminar.

2.6 THE UNIQUE PROPERTIES OF STEM CELLS

Stem cells are not like other cells in the human body. Herein lays the interest in, importance of and potential miracle of stem cell research. Stem cells possess three unique characteristics which separate them from other cells, namely:

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

Each of these unique characteristics deserves some further explanation and will now be briefly discussed.

2.6.1 Proliferation and Self- Renewal

Stem cells, unlike other cells in the body have the ability to replicate repeatedly and this is referred to as proliferation.[46] In this way one can almost describe the cells as immortal as a small subset of cells could produce millions of cells if allowed to proliferate for many months in culture. This immortality of cells is called homeostasis.[47] The cells naturally become more specialised and therefore have therapeutic application but should these cells remain unspecialised and are able of creating other unspecialised cells, they are referred to as being capable of long term self- renewal.

[46] Proliferation is explained in the discussion pertaining to induced pluripotent stem cells. See paragraph 3.6.3 *infra*.
[47] Laurie G (2004) "Patenting stem cells of human origin" *European Intellectual Property Review* 26(2): 59 at 60.

2.6.2 Unspecialised

Stem cells are essentially "blank slates" as they do not carry a tissue- specific structure or encoding which provides for the cell to perform a certain function. Stem cells can however give rise to cells and tissues with specialised functions such as heart muscle or nerve cells.[48]

2.6.3 Give Rise to Specialised Cell Types

When stem cells as blank or unspecialised cells give rise to specialised cells the process is referred to as differentiation. Differentiation is therefore "the process whereby an unspecialised early embryonic cell acquires the features of a specialised cell such as a heart, liver or muscle cell."[49] Differentiation is triggered by the cells internal and external signals and not much is known of this process as of yet. What is known is that the internal signals are controlled by the genes in the cells DNA[50] which carries the instructions of the functions and structures of the cell. The external signals are much more circumstantial and include physical contact with surrounding cells, the chemicals these neighbour cells secrete and the micro- environment of the cell in certain cases.[51] This process and the control thereof by scientists will feature as a key element in any cell- based therapy in the future. It is further interesting to note that the process of differentiation is reversed in the procedure which produces induced pluripotent stem cells.[52]

2.7 THE POTENTIAL OF STEM CELLS

Stem cells offer the prospect of cell- based therapies due to their unique characteristics as discussed above. Cell- based treatments include the reparation or replacement of damaged tissues and the prospective treatment of neurodegenerative diseases such as Alzheimer's,

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[48] 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): 547 at 551.
[49] The National Academies *Stem Cells and the Future of Regenerative Medicine* 69.
[50] DNA or deoxyribonucleic acid is "a nucleic acid and primary constituent of chromosomes." See Family Medical (2000) 69.
[51] [51] Swanepoel (2006) LLM thesis 37.
[52] See paragraph 3.6.3 *infra* for a discussion in induced pluripotent stem cells.

diabetes or Parkinson's.[53] What is even more astounding is the potential miracle of engineering organs such as hearts, kidneys or livers.[54] Drug testing, cancer research and embryonic development research, are further fields that would benefit from more understanding of this particular science. Gene therapy would become a practicable method of medicine and revolutionise medical treatment.

It is submitted that benefits which could not be obtained in any manner other than embryo research may be divided into four categories:[55]

1. The improvement of infertility treatment;
2. Developing further knowledge into factors which give rise to congenital disease;
3. Developing more effective contraceptive methods; and
4. Pre-implantation detection of gene or chromosome abnormalities.

Stem cell therapy holds the potential to treat degenerative, malignant or genetic diseases or even injuries caused by inflammation, infection or trauma. Due to this stem cell therapy has been hailed to be capable of treating diabetes, Parkinson's disease, Alzheimer's disease, spinal cord injury, heart failure or failure of bone marrow.[56] At this juncture it is however important to note that there exists many arguments for and against research conducted on embryos in general. They may be conducted on philosophical, legal and practical grounds.[57] The arguments will however be discussed in the course of this dissertation and will not be examined in detail in this chapter.[58]

[53] Holland, Lebacqz & Zoloth (2002) 3.
[54] Gavaghan H (2001) "The promise of stem cells" *Bulletin of the World Health Organisation* 79(8): 800 at 800.
[55] Tanner JM (2005) "Medici stry nog oor foetuses se pyn" *Perspektief* 4. See also Carstens P & Pearmain D (2007) *Foundational Principles of South African Medical Law* 198.
[56] Lerou PH & Daley Q (2005) "Therapeutic potential of embryonic stem cells" *Blood Reviews* 19: 321 at 321. See also The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 13- 17, National Institutes of Health "Stem Cell Basics" 1-2 and Swanepoel (2006) LLM thesis 39- 41.
[57] Lupton ML 1992 "The legal position of cryopreserved embryos" *Tydskrif vir Suid- Afrikaanse Reg* 466 at 467 468. See also Carstens & Pearmain (2007) 198.
[58] See chapter 4 of this dissertation.

3 THE SOURCES OF STEM CELLS

Human stem cells may be derived from a variety of sources or potential sources which include the following:[59]

1. Human embryonic stem cells. These cells are created in the process of *in vitro* fertilisation;[60]

2. Cadaveric fetal tissue or embryonic germ cells. This is derived from what remains after spontaneous or elective abortion;

3. Cloned human embryos. The process of somatic cell nuclear transfer is relevant in this regard;[61]

4. Cloned chimera embryos where the somatic cell of a human is implanted into an enucleated[62] animal egg cell; and

5. Adult cells. Adult cells are generally obtained from the bone marrow, blood or skin of the donor.

For the purpose of this dissertation human embryonic stem cells, adult stem cells and created embryos are of most importance. It is however imperative to briefly mention the other sources of stem cells, namely cadaveric fetal tissue, chimeras and cord blood cells.[63]

3.1 CADAVERIC FETAL TISSUE

Cadaveric fetal tissue is obtained after an abortion is carried out. This may be spontaneous or elective but since spontaneous abortions, which include miscarriages and ectopic pregnancies, often have pathological flaws the tissue from elective abortion is preferred.[64] Cells are withdrawn from fetuses which are aborted five to nine weeks after fertilisation.

[59] Slabbert (2003) *JLM* 514 at 516.
[60] *In vitro* means "in glass" and is the opposite of *in vivo* which is a biological process. See Family Medical (2000) 133.
[61] Somatic cell nuclear transfer is discussed in further detail in paragraph 3.6.2 *infra*.
[62] "Enucleated" means that the nucleus of the cell has been removed.
[63] Carstens & Pearmain (2007) 191.
[64] Castell (2001) *U Mich JL Ref* 574 at 549- 550.

Obviously there are many ethical concerns regarding the use of aborted fetal tissue and this subject has become highly contentious and emotionally loaded.

3.2 CORD BLOOD CELLS[65]

After birth, the umbilical cord may be used to extract cord blood cells. Also, postnatal stem cells and haematopoietic stem cells may be procured at this time.[66] This is an especially important source of mesenchymal cells. It has been suggested that a national cord blood "bank" be established in order to harness the medical potential of cord blood stem cells. These cells would be useable in not only the donors' therapy but in any other patients treatment and would be a source of stem cells which scientists could use in the course of their research.[67]

3.3 CHIMERIC EMBRYOS[68]

Chimeras have been mentioned previously in the course of this chapter and thus some attention must be paid thereto. Animals are often relied on in research for medical purposes as well as research which examines developmental processes in organisms and disease.[69] The implantation of human cells into animals, especially mice, has been common practice in order to test the safety and efficacy of new medicines and treatments before human testing is undertaken and in context of stem cells, animal testing is used to ensure that stem cells incorporate into tissue, that there are no harmful consequences and that stem cells then

[65] See also paragraph 4 *infra* for a discussion of cord blood banking.
[66] Swanepoel (2006) LLM thesis 45 & 55.
[67] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 14.
[68] See in general Karpowics P, Cohen CB & Van der Kooy (2005) "Developing human- nonhuman chimeras in human stem cell research: Ethical issues and boundaries" *Kennedy Institute of Ethics Journal* 15(2) 107- 134.
[69] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 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.

function in cooperation with the rest of the functions of the body. Animal studies may then also illustrate how human cells differentiate during normal development.[70]

Organisms which contain cells or tissues from different species are referred to as chimera. A chimera is thus an organism which has two or more genetically different groups of cells which originate from different organisms.[71] Somatic cell nuclear transfer is used to create chimera embryos and entails the somatic cell of a human, being implanted into an enucleated ovum of an animal. These embryos may be used in stem cell based treatments and could be a form of relief to the supply of spare IVF embryos.[72] These embryos are then used in stem cell- based treatments[73] and may lessen the burden placed on spare eggs.[74]

There is however an underlying objection to this practice as it involves mixing genetic material from different species. Ethical issues surrounding the moral status of such a hybrid embryo may however be less difficult to overcome than those associated with the moral status of the embryo.[75] The creation of chimeras has unique ethical implications and these must thus be briefly discussed.[76]

Kant was of the opinion that man does not have any duty towards animals. Animals are a mere means while man is the end. Man does not have a direct duty to animals but rather an indirect duty towards humanity.[77] One of the researchers duties towards society however, is to respect life and thus to treat all living objects, humans and animals, with the necessary and appropriate respect. Animals should therefore not be used in research which will

[70] 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.
[71] Medical News Today (2006) "Permission to create chimeras, not hybrids, for stem cell research" available at http://www.medicalnewstoday.com/articles/56266.php accessed 3/11/2009.
[72] Swanepoel M (2007) "Constitutional, legal and ethical issues regarding the regulation of cloning in South Africa" *SA Public Law* 22(2): 336 at 341.
[73] 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.
[74] Slabbert MN (2003) *JLM* 514 at 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, Adams NA (2004) "Creating clones, kids and chimera: Liberal Democratic compromise at the crossroads" *Issues in Medicine and Law* 20(1): 3- 27.
[75] Dhai A, McQuiod- Mason & Rodeck C (2004) "Ethical and legal controversies in cloning for biomedical research: A South African perspective" *South African Medical Journal* November 94(11): 906 at 908.
[76] This discussion will focus greatly on the ethical guidelines as provided for by the HPCSA and will thus constitute the "ethics layer" regarding animals in context of this dissertation.
[77] Kant I (1930) "Duties toward animals" in Huhse H & Singer P (eds) (2006) *Bioethics: An anthology* 2nd edition 564 at 564.

require them to be harmed or sacrificed where alternative methods, such as computer-generated models, could be used to achieve the same results.[78]

Health researchers thus have duties to animals used in research which include to accept responsibility for the care of the animals used in research and respect their welfare and to take active measures and use procedures which minimise both the incidence and severity of pain and suffering experienced by the animals and researchers must demonstrate that research is justifiable and scientifically based and must follow the ethical and regulatory guidelines which are established at an institutional level concerning the use of animals by professional associations and governmental authorities. Lastly, researchers should use inanimate objects instead of animals when appropriate. In situations where the use of animal species is scientifically necessary, researchers must use lower animal species, which may be less susceptible to pain and suffering, without compromising the integrity of the research. Also, the minimum possible amount of animals should be used.[79]

Animal testing raises numerous issues and thus researchers must always consider the importance of the knowledge sought and the importance of using animals in the search for that knowledge. The MRC have provided the following rules in this regard:[80]

1. Research must preferably benefit humans, animals and the environment;
2. Animals may only be used where no appropriate alterative could be found;
3. Optimal standards of animal health and care should be observed to provide good quality results which will in turn enhance credibility and reproducibility;
4. The three "R" principles of replacement, reduction and refinement must be adhered to during the planning and conducting of studies on animals;
5. The use of animals is dependent on the maintenance of public confidence in the mechanisms and processes used to ensure that experiments are justified and humane; and
6. Laboratory animals are protected by law in South Africa and accordingly the use of animals in education, research and testing must be justifiable.[81]

[78] HPCSA "General ethical guidelines for health researchers" *Guidelines for good practice in the health care professions Booklet 6* 9 available at http://www.hpcsa.co.za/hpcsa.default.aspx?id+152 accessed 8/7/2009.
[79] *Idem* 11.
[80] MRC "Guidelines of ethics for medical research: Use of animals in research and training" Book 3 available at www.mrc.ac.za accessed 12/7/2010.

The National Health Act, Act 61 of 2003 is silent on the use of chimeras and thus attention must be given to Regulations Relating to Research on human Subjects as it is currently the only legislative tool in context of stem cells dealing with the use of animals in research intended for human application.[82]

Chapter 3 of the Human Subjects Regulations deal with research involving animals and states that where animals are used for research purposes which will ultimately benefit humans, the proposal for such research must be submitted to an animal research ethics committee and the proposed researcher must consult with and comply with the regulations and guidelines for such research as prescribed by the National department of Agriculture.[83]

It is important to note however, that much ethical concern is raised regarding the combination of species and that the risks and potential risks thereof are still greatly uncertain. Cells may be combined in the early stages of development[84] or after full development.[85] It is clear though, that the use of chimeras in research is essential as human testing may not be done unless conclusive animal testing has been performed.[86]

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[81] See in general HPCSA "General ethical guidelines for biotechnology research" *Guidelines for good practice in the health care professions Booklet 7* 26- 28 available at http://www.hpcsa.co.za/hpcsa.default.aspx?id+152 accessed 8/7/2009.

[82] Regulations Relating to Research on human Subjects No. R135 in Government Gazette No. 29637 of 23 February 2007 10. Hereafter referred to as the Human Subjects Regulations. This discussion then constitutes the "legislative layer" concerning animals in stem cell research.

[83] Regulation 9 of the Human Subjects Regulations.

[84] Introducing human cells into a mouse blastocyst in order to observe the development thereof.

[85] Implanting human stem cell- derived pancreatic cells into mice to test the functioning thereof inside the body.

[86] The ethical issues surrounding the creation of chimeras will not be discussed in much further detail in the course of this dissertation. It may now however be noted that some are of the opinion that research on animals is permissible as long as the animal has no level of human consciousness and therefore any research which makes it possible to produce a brain 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.

See The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 21- 22.

3.4 HUMAN EMBRYONIC STEM CELLS

Human embryonic stem cells or HES cells[87] may be defined as "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."[88] It can therefore be said that HES cells are immortal and have almost endless developmental potential.[89] Due to the fact that HES cells can proliferate indefinitely in cell culture, they have the ability to produce an unlimited source of specified adult cells such as bone or blood cells.[90]

HES cells, as is suggested by the name, are derived from early embryos, specifically during the blastocyst stage of development. It is however extremely important to note that the embryos used for this purpose are not naturally fertilised embryos but rather "extra" embryos which have not been used for *in vitro* fertilisation.[91] HES cells may otherwise be obtained from aborted fetuses and for this reason HES cells have sparked great ethical issues.[92]

In order to understand the source of embryonic cells, one must first understand the basic development of an embryo. The embryo is the developing organism from the moment of fertilisation[93] of the egg cell until the end of the eighth week of development at which time it is referred to as a fetus.[94] Differently stated an embryo is the entity which comes into

[87] This abbreviation as well as embryonic stem cells will be used interchangeably in the course of this dissertation.
[88] National Institutes of Health "Stem cell basics: Glossary."
[89] 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.
[90] University of Wisconsin- Madison (2001) "Embryonic stem cells: Research at the University of Wisconsin-Madison" available at http://www.news.wisc.edu/packages/stemcells/facts.html accessed 6/8/2009.
[91] Slabbert (2003) *JLM* 514 at 517.
[92] The ethical dilemmas surrounding stem cell research in general will be discussed in detail in chapter 4 of this dissertation.
[93] Fertilisation is the union of the male and female gamete. See The National Academies *Stem Cells and the Future of Regenerative Medicine* 67. The moment of fertilisation is difficult to determine since it cannot be observed within the human body. See also Moore & Persaud (2003) 2 and Swanepoel (2006) LLM thesis 43.
[94] National Institutes of Health "Stem cell basics: Glossary." See also Family Medical (2000) 93, where a fetus is described as "an unborn child after the eight week of development." It is important to note that in the course of this dissertation this will be the accepted spelling of fetus although the form "foetus" is also commonly accepted.

being due to *in vivo* or *in vitro* fertilisation[95] of an egg cell by a sperm cell.[96] Embryonic development can be set out in the following seven stages:[97]

1. Fertilisation of the egg cell. Fertilisation takes place in the oviduct of the uterus when a female egg is fertilised by male sperm and human fertilisation normally occurs within the first 12 hours after ovulation[98] but no later than 24 hours as the oocyte[99] start to degenerate after such time and male sperm have a general life span of about 48 hours inside the female genital tract.[100] Fertilisation is the culmination of numerous biological processes and steps and the ultimate result thereof is the formation of a zygote[101] which carries the necessary genetic information to form an individual. Half the genes are provided for by each parent.[102]

2. Cell division. Approximately 36 hours after fertilisation, the process of cell division comes into action. At this stage all the cells are identical and thus totipotent, meaning that in the proper environment, each cell has the capacity to develop into an individual.[103] The zygote exponentially divides, meaning that at first it divides into two blastomeres, which then divide into four, which in turn become eight. At this stage the cells reshape and change their formation to form a ball of cells known as a Morula.[104] The Morula is sometimes referred to as the "morus mulberry" due to its mulberry- like appearance. Three days after fertilisation the Morula enters the

[95] *In vitro* fertilisation or IVF is "the process of fertilising an ovum outside the body". The first successful live birth utilising this technique was in 1978 and caused the term "test- tube baby" to be coined. See Family Medical (2000) 133.
[96] Swanepoel (2006) LLM thesis 43.
[97] For the purpose of this dissertation, only the first three stages are relevant and have been illustrated in figure B *infra*.
[98] Ovulation is when 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.
[99] An oocyte is a cell in the ovary. It produces an ovum which is the female reproductive cell. See Family Medical (2000) 184.
[100] Holland (2002) *Nat Geogr Mag* 18. See also Moore & Persaud (2003) 26.
[101] "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 into the uterine wall and becomes an embryo. See Family Medical (2000) 283.
[102] Odendaal HJ (1989) *Ginekologie* 21- 23.
[103] The National Academies *Stem Cells and the Future of Regenerative Medicine* 13.
[104] Moore & Persaud (2003) 31.

uters where the fluid inside the cavity of the Morula increases and the trophoblast and inner cell mass[105] are separated.

3. The fertilised embryo then becomes what is known as a blastocyst and consists of 100 to 150 undifferentiated cells. The trophoblast later forms the extra embryonic structures such as the placenta and umbilical cord.[106] The inner cell mass is the primary source of HES cells and therefore the blastocyst is often also referred to as a "pre- implantation embryo" or an "early embryo." Cells are harvested from the blastocyst and cultured in order to obtain stem cells.[107]

4. A week after fertilisation the early embryo, which still contains relatively undifferentiated cells or pluripotent cells, implants into the womb of the female and this process is usually completed before the second week after fertilisation. Should this not occur, the blastocyst undergoes no further development.[108]

5. After two weeks the embryo consists of approximately 2000 cells and only at this stage of development do the cells start differentiating into more specialised cell types.[109] It is also at this stage that the primitive streak[110] which forms the central nervous system appears.[111]

[105] 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. They are the source of embryonic stem cells." See The National Academies *Stem Cells and the Future of Regenerative Medicine* 70.
[106] The umbilical cord connects the embryo and later the fetus, to the placenta and is normally connected near the centre of the fetal surface. The placenta is the primary source of nutrients and aids gas exchange between the mother and fetus. Together the placenta and umbilical cord 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.
[107] See figure C *infra* for an explanation of cell culturing.
[108] The Merck Manuals Online Medical Library Home Edition for Patients and Caregivers "Stages of development" available at http://www.merckmanuals.com/home/sec22/ch257/ch257c.html accessed 5/5/2009.
[109] *Ibid*.
[110] The primitive streak may be defined as a "dense area on the central posterior region of the embryonic disk. It is formed by the morphogenetic movement of a rapidly proliferating mass of cells that spreads between the ectoderm and endoderm, giving rise to the mesoderm layer. This seam like elongation indicates the cephalocaudal axis along which the embryo develops, and it corresponds to the blastopore of lower animal groups. Also called primitive line." See The Free Medical Dictionary available at http://medical-dictionary.thefreedictionary.com/primitive+streak accessed 5/5/2009.
[111] Odendaal (1989) 23.

6. The individual organs become apparent after about eight weeks and at this time the embryo becomes a fetus. At this stage growth and differentiation of organs, tissues and bodily systems take the primary developmental role.[112]

7. Nine months, normally 38 weeks, after fertilisation the fetus is born as a baby. At this stage stem cells such as haematopoietic stem cells, may be harvested from the cord blood which is left in the umbilical cord and postnatal stem cells can be derived from the placenta or afterbirth.[113]

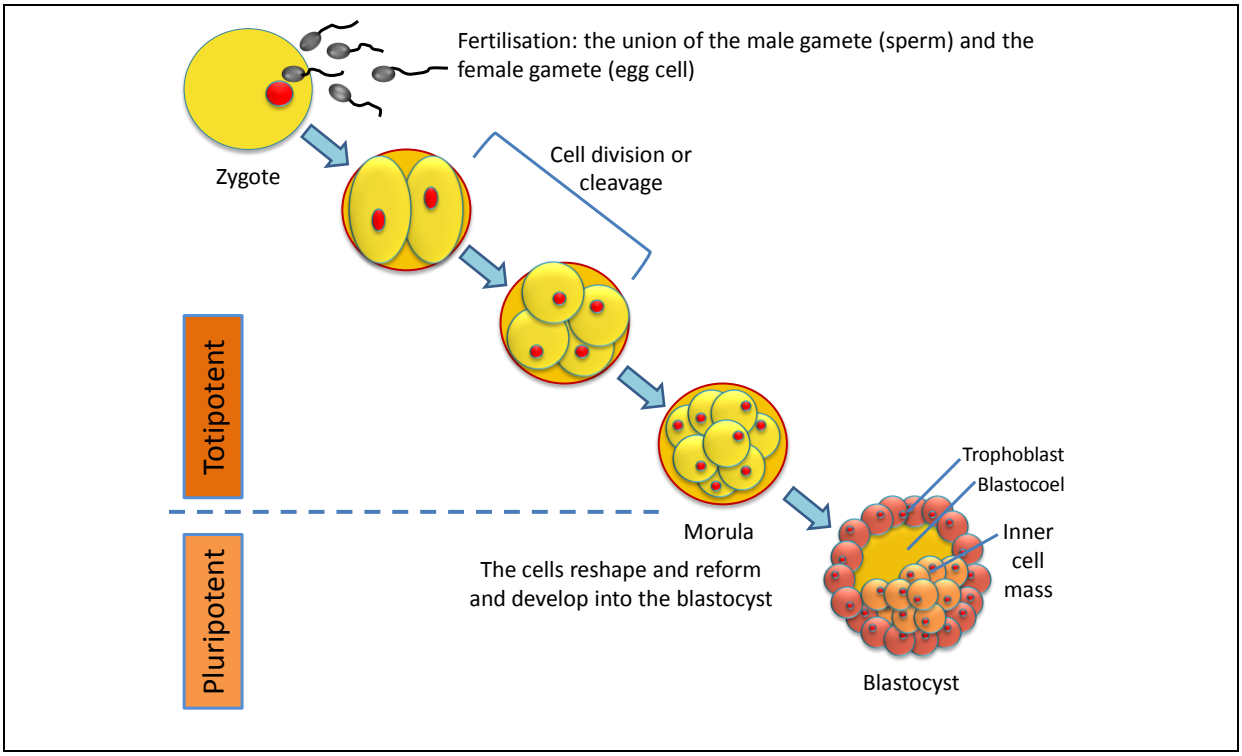

Figure B: Early embryonic development

As mentioned above, the inner cell mass of the blastocyst is the primary source of HES cell and it is important to explain the process whereby these cells are cultured. After the inner cell mass has been removed from the blastocyst, the cells are planted into a petri dish. This dish contains a feeder layer which is comprised of embryonic mouse skin cells which provides firstly for an adhesive service whereon the planted cells may attach and proliferate and secondly, it provides nutrients to the cells. Further nourishment is provided to the planted cells by a culture medium which is also placed in the petri dish.

[112] Moore & Persaud (2003) 78.
[113] See paragraph 4 *infra*.

After the cells have been planted in the petri dish they are allowed to proliferate and spread across the inner surface of the dish. Once the dish is crowded with cell, cells are removed from the dish and planted into a new one. This new cycle of culturing is referred to as subculturing and each new cycle of subculturing is known as a passage.[114] An embryonic stem cell line will be established after six months of proliferation without the cells differentiating and thus remaining pluripotent.

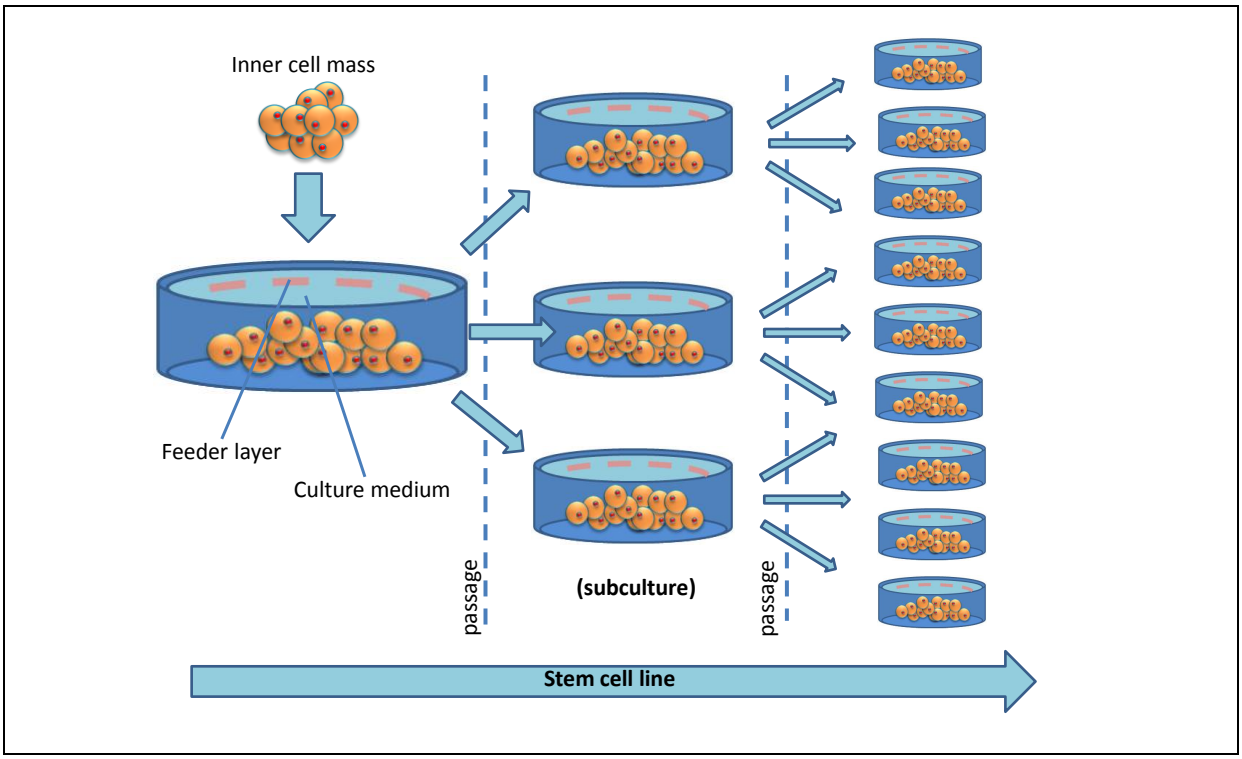

Figure C: Stem cell culturing

The use of HES cells is the root of the controversy in stem cell research and thus adult stem cells are important to acknowledge as alternative. The following section of this dissertation thus focuses on an explanation of adult stem cells.

3.5 ADULT STEM CELLS

[114] National Institutes of Health "Stem Cell Basics" 5.

During the 1960's researchers discovered that bone marrow comprised at least two differing cell types: haematopoietic stem cells[115] and bone marrow stromal cells[116] and thus adult stem cell research was born.[117] Adult stem cells may be defined as "an undifferentiated cell that is found in differentiated tissue, can renew itself, and can (with certain limitations) differentiate to yield all the specialised cell types of the tissue from which it originated."[118]

Stem cells, as explained above,[119] possess different degrees of plasticity and due to this a stem cell of a certain tissue type may give rise to cells of a different kind of tissue.[120] Certain processes must however be followed to accommodate this and will be discussed in the course of this chapter.[121]

A stem cell generally produces an intermediate cell before becoming fully differentiated and this cell is referred to as a progenitor cell.[122] The function of an adult stem cell is to maintain and repair the hosting tissue and unlike embryonic stem cells, the origin of adult stem cells is unsure as found in mature tissue.[123] Adult stem cells are however only found in very small numbers and therefore the identification thereof is quite difficult. Scientists do also not agree on the best method to identify and test adult stem cells and one of the following methods is normally employed:[124]

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[115] "A stem cell from which all red and white blood cells evolve." See The National Academies *Stem Cells and the Future of Regenerative Medicine* 69.

[116] "Stromal cells are a mixed population of cells that generate bone, cartilage, fat and fibrous connective tissue." See Swanepoel (2006) LLM thesis 53 footnote 150.

[117] Weise E (2007) "Stem cell discovery hailed as milestone" available 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 at http://www.newscientist.com/article/dn1826-ultimate-stem-cell-discovered.html accessed 5/05/2009.

[118] The National Academies *Stem Cells and the Future of Regenerative Medicine* 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): 47 at 48- 63.

[119] See footnote 16 *supra* for more on the plasticity of cells.

[120] Weiss R (2005) "The stem cell divide" *Nat Geogr Mag* available at http://ngm.nationalgeographic.com/ngm/0507/feature1/index.html# accessed 6/05/2009.

[121] The referred to processes include somatic cell nuclear transfer and induced pluripotent stem cells. See paragraphs 3.6.2 and 3.6.3 *infra*.

[122] Progenitor cells are differentiated to some extent and are committed to a specified cell type and give rise to differentiated cells during cell division. See Swanepoel (2006) LLM thesis 54.

[123] Stayn J (2005) "The new Massachusetts stem cell research law" *Boston Bar Journal* 49(4): 16 at 17.

[124] Walsh P (2005) "Stemming the tide of stem cell research: the Bush compromise" *John Marshall Law review* 38(3): 1061 at 1063- 1066.

1. Using markers to label cells in living tissue and then determining the cell types that are generated by the labelled cell;

2. Labelling cells in culture after removal from a live animal and then transplanting the cells into a different animal to examine whether the cells repopulate the tissue from which they originate; or

3. Isolating cells, culturing them and then manipulating the cells[125] to determine the cells into which they differentiate.

3.6 CREATED EMBRYOS OR EMBRYO- LIKE CELLS

The following section of this dissertation focuses on stem cells which are not naturally derived in a pluripotent state but must be reverted to such a state by way of some process. This includes cloning, somatic cell nuclear transfer and induced pluripotency.

3.6.1 Cloning

In 1997 Ian Wilmut along with his colleagues at the Roslin Institute in Scotland announced that they had successfully cloned[126] a sheep and the phenomena of Dolly took the world by storm. In 1998 Dolly was no longer a "clone alone" as scientists in Hawaii published their report stating that they had cloned over 50 mice by using nuclear transfer.[127]

Today however cloning is a tired subject, unless taken into account that the same process used to clone animals could be applied to stem cell therapies or cell based regenerative medicine. This then sparks ethical issues but it is nonetheless important to discuss for the purpose of this dissertation as embryonic stem cell lines can be derived from embryos which have been specifically created to be used in stem cell research. One must also note that

[125] This is done by adding growth factors or introducing new or different genes into the cell. See Swanepoel (2006) LLM thesis 55.
[126] Cloning is defined as "to generate identical copies of a region of a DNA molecule or to generate genetically identical copies of a cell, or organism." See National Institutes of Health "Stem cell basics: Glossary."
[127] See Swanepoel (2006) LLM thesis 56.

cloning may have a therapeutic or reproductive function.[128] It is therefore important to shortly discuss therapeutic and reproductive cloning.

3.6.1.1 Therapeutic cloning

Cloning and embryonic stem cell technology may be combined in the process and application of therapeutic cloning. Therapeutic cloning is "the process of using somatic cell nuclear transfer to produce cells that exactly match a patient."[129] By combining the nucleus[130] of a somatic cell of a patient and an enucleated egg scientist can harvest cells which will match the patient's body, thereby eliminating the risk of rejection by the patient's immune system. One could almost say that these cells are tailor made to suite the patient's body.

Many other arguments in favour of therapeutic cloning exist and should be mentioned in spite of naysayers stating that alternatives exist. Embryonic stem cells have desirable characteristics and are regarded as ideal for research purposes. Adult stem cells have already committed to specialised tissue types and are less in numbers than embryonic stem cells. The potential for development is therefore restricted. For cloning to reach its "medical promise," early embryo research is required and then also on embryos specifically created for that purpose.[131]

3.6.1.2 Reproductive cloning

Reproductive cloning is "the process of using somatic cell nuclear transfer to produce a normal, full grown organism genetically identical to the organism that donated the somatic cell nucleus."[132] This would then require implanting the resulting embryo into the uterus

[128] This subject is however ethically controversial and is discussed in further detail in chapter 4 of this dissertation.
[129] National Institutes of Health "Stem cell basics: Glossary."
[130] The nucleus may be defined as "the large, membrane-bounded organelle that contains the genetic material, in the form of multiple linear DNA molecules organized into structures called chromosomes." In layman's terms the nucleus is thus the central point of a cell and it contains DNA. See Biology Online available at http://www.biology-online.org/dictionary/Nucleus accessed 6/5/2009.
[131] Gusman A (2005) "An appropriate legislative response to cloning for biomedical research: The case against a criminal ban" *Annals Health Law* 14(2): 361 at 265. See also Goldberg D (2006) "Cloning around with cells" available at http://www.abc.net.au/science/slab/stemcells/default.htm accessed 7/5/2009.
[132] National Institutes of Health "Stem cell basics: Glossary."

where it would then undergo normal development and become an independent being. It could also be said that reproductive cloning is cloning which is aimed at the birth of an individual being born who is genetically identical to a person in a previous generation.[133]

The difference between therapeutic cloning and reproductive cloning thus lays in the procedure and intention thereof. Although the steps taken up until the blastocyst stage are the same the embryo is allowed to develop to term in the case of reproductive cloning but for the purpose of therapeutic cloning, it is only grown to the blastocyst stage and aims at generating embryonic stem cells which are only to be used for direct treatment and therapy applications. The distinction therefore lies in the later procedures following somatic cell nuclear transfer and also in the purpose of the procedure.[134] Reproductive cloning is highly controversial and unethical and has thus been nationally and internationally prohibited.

3.6.2 Somatic Cell Nuclear Transfer[135]

Somatic cell nuclear transfer, or SCNT, is "the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed."[136] In other words it is a technique whereby an enucleated egg and the nucleus of a somatic cell are combined to make an embryo. SCNT can be used therapeutically or for reproductive purposes, as the process which combines an enucleated egg and a somatic cell are identical."[137] It is important to note that this is a highly contentious subject as it is more commonly referred to as cloning.[138] Ethical considerations regarding egg donation, informed consent and the destruction of the blastocyst arise and many people fear the misapplication of the technique of SCNT for reproductive cloning purposes.[139]

The production of embryonic stem cells by SCNT is however not the same as reproductive cloning. Where nuclear transfer is used to develop disease- specific stem cells it is referred

[133] See Swanepoel (2006) LLM thesis 60.
[134] *Ibid*.
[135] See in general Chung Y & Becker S (2006) "Embryonic stem cells using nuclear transfer" *Methods in Enzymology* 418: 135- 147.
[136] The National Academies *Stem Cells and the Future of Regenerative Medicine* 71.
[137] National Institutes of Health "Stem cell basics: Glossary."
[138] See paragraph 3.6.1 *supra* regarding cloning technology.
[139] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 7.

to as "research cloning" or "therapeutic cloning."[140] These terms must be distinguished from reproductive cloning where a cloned embryo is intended to develop to term inside the womb of a woman. It is also the technique by which Dolly the sheep was created. Animal reproductive cloning has become common practice but human reproductive cloning is wide and actively discouraged and prohibited.[141]

3.6.2.1 The process of SCNT

The process involves removing the nucleus, thus all 46 chromosomes,[142] from a somatic or adult cell. The rest of the cell is then discarded. At the same time an unfertilised egg is enucleated and this enucleated egg is referred to as an oocyte. The previously removed somatic cell nucleus is then planted into the oocyte and the oocyte then enters the process of division and embryogenesis[143] after shock- stimulation. It is important to note that the egg cell now contains the genetic code or DNA of the donor cell and is reprogrammed. The implanted egg cell is then cultured in the same manner as HES cells and produces a blastocyst with almost identical DNA to the original somatic cell donor.[144]

This method is used to create patient specific pluripotent cells and eliminates the risk of rejection. SCNT cells are genetically matched to the donor and genetically customised cell lines can be created to target certain diseases.[145]

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[140] 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.

[141] The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 7.

[142] "The rod- like structures, present in the nucleus of every body cell, that carry the genetic information or genes". Every cell in the human body contains 23 pairs of chromosomes excluding the sperm and ova, half received from the mother and the other half from the father. A chromosome is made up of a coiled double filament, which is called a double helix, of DNA and linearly carries the genetic information of the cell. All the characteristics of the individual are determined by the information contained in the DNA, for example 22 of the chromosomes are identical in the male and female but the 23rd determines the sex of that individual. Males have an x- chromosome while females have a y- chromosome. See Family Medical (2000) 46.

[143] Embryogenesis is "the processes leading to the development of an embryo from egg to completion of the embryonic stage." See Biology Online *supra*.

[144] Peters T (2007) *The stem cell debate* 13. See also The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 6.

[145] Semb H (2005) "Human embryonic stem cells: Origin, properties and applications" *Acta Pathologica, Microbiologica et Immunologica Scandinavica* November 13(11-12): 734. See also Hadjantonakis AK &

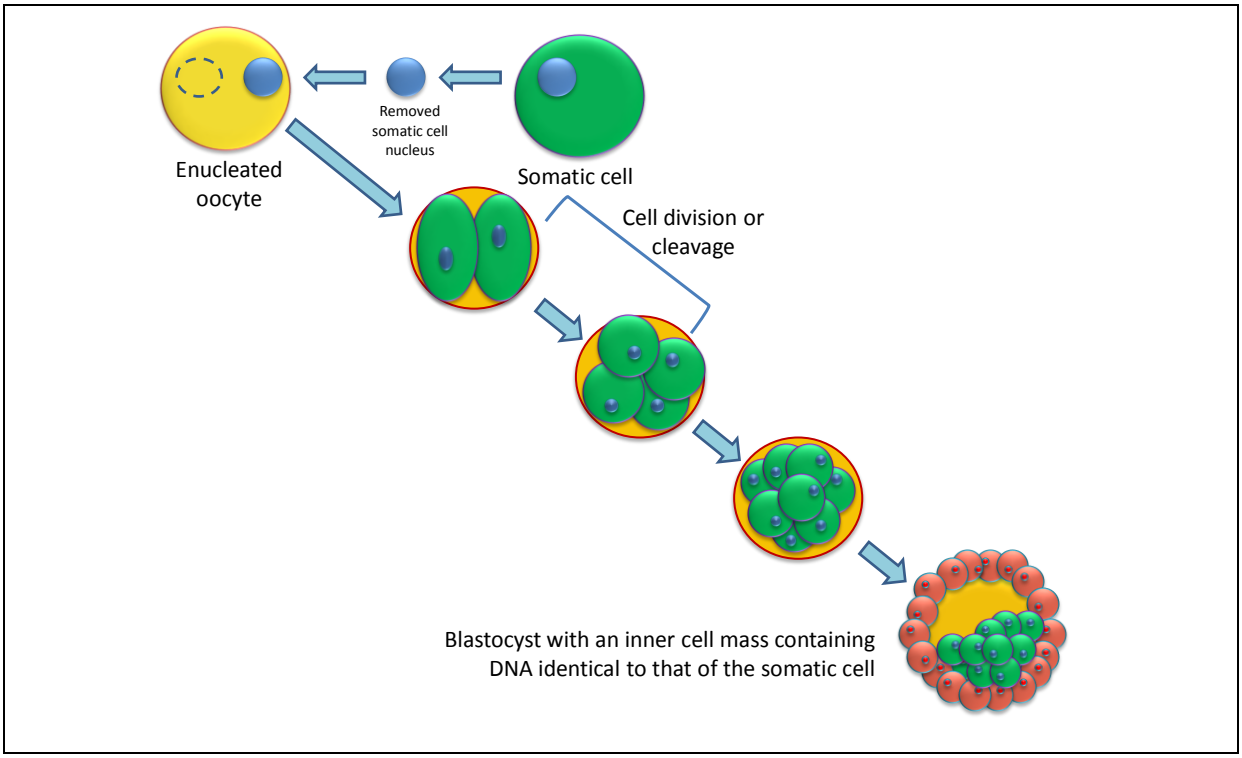

Figure D: Somatic cell nuclear transfer

3.6.2.2 SCNT in stem cell research

Researchers may use SCNT in stem cell research with the objective of obtaining stem cells that are matched genetically to the donor of the somatic cell. This is especially important in eliminating immune system rejection in medical treatment and creating disease- specific cell based- therapies. When considering stem cell based therapy, immunological rejection becomes particularly important as the human body rejects cells which it does not recognise as its own. This is done primarily to protect the body from diseases. This problem will have to be overcome and there currently exists three ways of avoiding rejection:[146]

1. The use of immune- suppressing drugs. Drugs have been used for many years in organ transplantation but they often leave the patient open to infection and must be taken for the rest of the patients lifetime;

Papaioannou VE (2002) "Can mammalian cloning combined with embryonic stem cell technologies be used to treat human disease?" *Genome Biology* July 3(8): 1023- 1023.6.

[146] Swanepoel (2006) LLM thesis 58 footnote 171.

2. The use of matching tissue. Finding a matching donor is highly unlikely but having regard to the fact that stem cells can be cultured indefinitely the possibility does exist to establish a stem cell bank in which the population may be sufficiently represented; and
3. Using the patient's own tissue or cells. This is regarded as the safest option and also the surest method of avoiding rejection. This would involve creating a zygote from the patient's adult cell's nucleus and growing it to the blastocyst stage. The resulting cells would then be used for implantation.

3.6.2.3 Limitations and controversy

Embryonic stem cells created by SCNT may be advantageous over the use of embryonic stem cells derived form *in vitro* fertilised embryos as the risk of rejection is reduced or even eliminated. SCNT furthermore has great value in the researching of dedifferentiation as currently this is the only method whereby the factors which affect DNA marking during differentiation could be identified and removed.[147]

SCNT does however have certain limitations. Enormous stress is placed on the egg cell and nucleus which leads to high losses of created cells. This process is labour intensive as it cannot be automated and the biochemistry involved in reprogramming or dedifferentiating cells is still uncertain. Mitochondrial DNA is also not completely transferred and this hybrid of mitochondrial structures lead to imperfect copies which in turn leads to immune system rejection.[148]

Various ethical and moral issues are also present. Some of these issues include the fear that allowing SCNT will eventually lead to reproductive cloning as it involves the same procedure.[149] Socio- economic concerns also arise as the source of the required human egg

[147] Swanepoel (2006) LLM thesis 58.
[148] Campbell KH, Mcwhir J Ritchie WA & Wilmut I (1996) "Sheep cloned by nuclear transfer from a cultured cell line" *Nature* March 380(6569): 64 at 64.
[149] This is however unfounded. See The National Academies "Understanding stem cells: An overview of the science and issues from the National Academies" 7. See the discussion pertaining to the "slippery slope argument" as discussed in chapter 4 paragraph 2.2.2 *infra*.

cells is women and this could lead to exploitation or the commercialisation of eggs cells.[150] These issues and concerns will be further discussed in the course of this dissertation. It is important to note that the method of induced pluripotent stem cells nullifies the need to make use of SCNT and must therefore be discussed.

3.6.3 Induced Pluripotent Stem Cells

Induced pluripotent stem cells or iPS cells are "a type of pluripotent stem cell, similar to an embryonic stem cell, formed by the introduction of certain embryonic genes into a somatic cell."[151] This means that they are cells which are artificially derived from adult or somatic cells, usually multi- or unipotent, and reprogrammed to a pluripotent state by forcing the expression of certain genes essential to the maintenance of pluripotent cells.[152] Induced pluripotent cells are therefore believed to be identical to natural pluripotent cells such as human embryonic stem cells.[153] Induced pluripotent cells were first created in 2006 using mouse cells and thereafter in 2007 using human cells. The significance of this development cannot be understated as iPS cells have the ability to be used in further research, the potential to be therapeutically applied and may eliminate the use of embryonic stem cells and in so doing, reduce at least some of the controversy surrounding human stem cell research.

The use of iPS cells is however not without risk and this could lead to limited use in humans. This reprogramming of genetic material may trigger the activation cancer- causing genes known as oncogenes. The latest developments in this field have however found that cells are able to be induced by specific proteins, thereby removing the formation of oncogenes.[154]

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[150] See chapter 4 paragraph 2.4.1 *infra* for a discussion on exploitation in context of stem cells.
[151] National Institutes of Health "Stem cell basics: Glossary."
[152] Kidson (2009) Stem cell seminar.
[153] Baker M (2007) "Adult cells reprogrammed to pluripotency, without tumors" *Nature Reports Stem Cells* available 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.
[154] See paragraph 5 *infra* for a discussion on the latest developments.

3.6.3.1 The production of induced pluripotent stem cells

The induction of cells involves a process of de- differentiation[155] and this is done via transfection. Transfection involves infecting of a cell with viral vectors such as retroviruses[156] or purified viral nucleic acid, which results in the subsequent replication of the cell. The genes used to de- differentiate the donor cell are Oct3/4, c- Myc, Sox2 and Klf4 but this was not always the case. During the development of this method of induction one finds two generations. Each of these developmental stages will shortly be discussed.

3.6.3.1.1 *First generation iPS cells*

Kyoto University's Shinya Yamanaka first generated iPS cells in 2006[157] using mouse fibroblasts,[158] retroviruses and genes found to be essential in embryonic stem cells. The genes used by this team were Oct3/4, c- Myc, SoX2 and Klf4 and the cells were isolated by Fbx15^{+} cells. The iPS cell lines produced in this manner however demonstrated DNA errors and did not produce viable chimeras when tested by injection into developing embryos.[159]

[155] De- differentiation may be understood as reverting the cell back to a less specialised cell type.
[156] A retrovirus is an "RNA virus (a virus composed not of DNA but of RNA)." Retroviruses possess an enzyme called reverse transcriptase which gives them the unique property of transcribing RNA, their own, into DNA. This DNA can integrate into the chromosomal DNA of the host cell and be expressed. HIV, human immunodeficiency virus, which casues AIDS is an example of a retrovirus. See MedicineNet.com at http://www.medterms.com/script/main/art.asp?articlekey=5344 accessed 3/5/2010.
[157] SABioscience (2009) "Induced pluripotent stem cells- Quik facts" *Pathways Magazine* 9. See also Pei XT (2010) "iPS cells: Alternative pluripotent cells to embryo stem cells" *Science China Life Sciences* January 53(1): 154- 156.
[158] A Fibroblast may be defined as "a cell ubiquitous in connective tissue that makes and secretes collagen." See MedinceNet.com at http://www.medterms.com/script/main/art.asp?articlekey=24766 accessed 3/5/2010.
[159] See in general 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* January 18(1): 51–54.

3.6.3.1.2 *Second generation iPS cells*[160]

Yamanakas team as well as groups from Harvard, MIT[161] and The University of California published findings in June 2007 indicating the successful reprogramming of mouse cells without the previous DNA errors. It was further shown that viable chimera were produced.[162] The difference was the replacement of the genetic marker Fbx15^{+} with Nanog which is an important gene in embryonic stem cells and major determinant in pluripotency.[163] Unfortunately this process was still not efficient as c- Myc is oncogenic and some of the chimeric mice developed cancer.[164]

3.6.3.2 Human iPS cells

November 2007 marked a milestone in the science of iPS cells as two independent groups published studies on the creation of iPS cells from adult human cells. The first was published by James Thomson and Junying Yu at the University of Wisconsin,[165] and the second by Yamanaka and his colleagues at Kyoto University.[166] Both groups had used the same

[160] See in general Kritikou E (2007) "Introducing the next generation" *Nature Reviews Molecular Cell Biology* July 8 available at http://www.fbae.org/2009/FBAE/website/images/PDF%20files/stem%20cells/Reprogramming%20Embryonic%20Stem%20Cells.pdf accessed 7/8/2009.

[161] Michigan Institute of Technology.

[162] Akst J (2009) "iPS cells yield live mice" available at http://www.the-scientist.com/blog/display/55835/ accessed 7/11/2009.

[163] Takahashi K & Yamanaka S (2006) "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors" *Cell* 126: 663. See also Okita K, Ichisaka T & Yamanaka S (2007) "Generation of germline-competent induced pluripotent stem cells" *Nature* July 448: 313-7, 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* July 448: 318-24 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.

[164] 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* April 10: 484- 486.

[165] 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* December 318(5858): 1917.

[166] 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* November 131 1–12.

essential genes as used in the mouse studies but Yamanaka had further used a retroviral[167] system. Thomson and Yu had used Oct4, SoX2, Nanog and Lin28 with a lentiviral[168] system. Concerns were raised regarding the potential therapeutic application of such created iPS cells due to an inclination to form tumors as a result of the transfection system used to insert genes randomly into the hosts genome and both research groups expressed the need to develop a new method of delivery.[169]

Konrad Hochedlinger and his research team at Harvard University successfully overcame this problem by using an adenovirus[170] to transport the required genes into the DNA of lab mice. This resulted in the formation of cells identical to embryonic stem cells.[171]

The current process of producing iPS cells requires donor cells to be isolated and cultured in the same manner as HES cells.[172] The four genes associated with embryonic stem cells are then transfected into the donor cells via viral vectors. This causes the subsequent replication of the cell and these cells are then cultured and harvested in the same manner as embryonic stem cells.[173] A small subset of the transfected cells will then become similar to pluripotent

[167] A retrovirus is "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 available at http://medical-dictionary.thefreedictionary.com/retroviral accessed 7/6/2009.
[168] A Lentivirus is "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 at http://medical-dictionary.thefreedictionary.com/lentiviral accessed 3/5/2010. See in genaral SABiosciences "Lentivirus- based signalling pathway reporters" available at http://www.sabiosciences.com/pathwaymagazine/pathways9/lentivirus-based-signaling-pathway-reporters.php accessed 6/5/2009.
[169] Swaminathan N (2007) "Stem Cells:This time without the cancer" *Scientific American News* available at http://www.sciam.com/article.cfm?id=stem-cells-without-cancer accessed 6/6/2009.
[170] This 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 available at http://medical-dictionary.thefreedictionary.com/adenovirus accessed 7/6/2009.
[171] Stadtfeld M, Nagaya M, Utikal J, Weir G, Hochedlinger K (2008) "Induced pluripotent stem cells generated without viral integration" *Science* September 322: 945. See also Stein R (2008) "Scientists find way to regress adult cells to embryonic state" *Washington Post* available at http://www.washingtonpost.com/wp-dyn/content/article/2008/09/25/AR2008092502099.html accessed 6/7/2009. Regarding the Hochedlinger method see Ahn JY (2010) "Are iPS cells and ES cells identical twins or distant cousins?" available 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.
[172] Cell culture has been explained previously.
[173] See figure B *supra*.

cells, morphologically and also biochemically, and generate embryonic stem cell- like cells which may be used in the same manner as natural embryonic stem cells.[174]

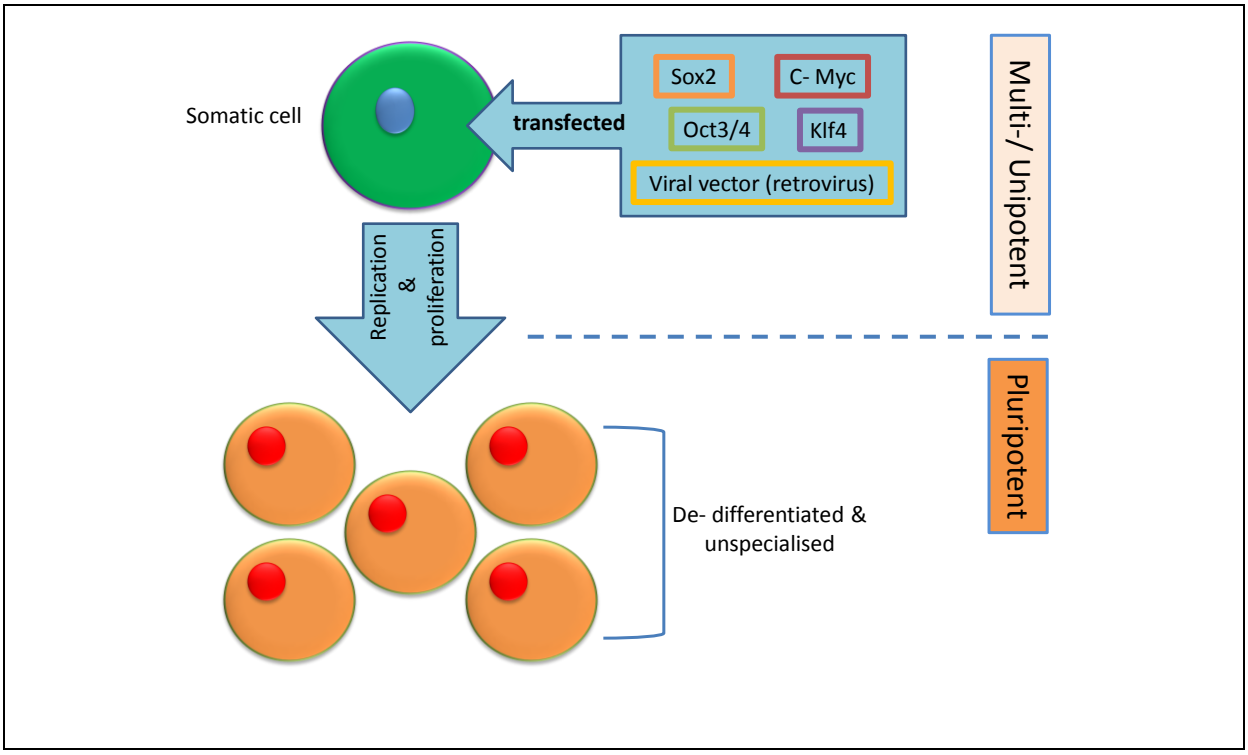

Figure E: Induced pluripotent stem cells

As stated above, the genes used are Oct3/4, c- Myc, SoX2 and Klf4 and the induction of adult cells would not be possible without the use thereof. For this reason it is important to briefly discuss each:[175]

1. Oct3/4 is a crucial transcription regulator as it aids in maintaining pluripotency. The absence of Oct3/4 in blastomeres and embryonic stem cells leads to differentiation of the trophoblast. Oct3/4 is seen as an exclusive gene as other members of the Oct family fail to have the same results in pluripotency maintenance.
2. c-Myc is a member of the Myc family of genes and are proto- oncogenes. This means that c- Myc is implicated in the formation of cancer and the usage thereof is troubling. By using different genes such as N- Myc and L- Myc however,

[174] National Institutes of Health "Stem Cell Basics" 2, 13 & 14. See also Swanepoel (2006) LLM thesis 57- 61 and Baker M (2007) *Nature Reports Stem Cells*.
[175] 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 volume 174: Stem Cells* 2 at 8- 12.

pluripotency may be induced as efficient but with a lesser risk of tumor formation.

3. SoX2 is also a transcription regulator which maintains pluripotency in a similar fashion as Oct3/4. SoX genes are however generally associated with multi- or unipotent cells and thus lacks the exclusivity of Oct3/4.
4. Klf4 aids in the generation of human iPS cells.

It is also important to note the role of the genetic markers used in the process of creating iPS cells, namely Nanog or Lin28. Nanog promotes pluripotency and Lin28 is an mRNA[176]binding protein which is expressed by embryonic stem cells and it is associated with differentiation and proliferation of the cell.

3.6.3.3 Similarities between HES cells and iPS cells

The miracle and medical potential of iPS cells lays in their similarity to naturally pluripotent stem cells such as HES cells. Holland stated that "many suspect that new kinds of adult stem cell may be found that are as versatile as those found in embryos," and by inducing pluripotency, embryonic stem cells will become obsolete.[177] There are three main categories of likeness which will now be discussed.[178] The first is related to the cellular biological properties of iPS cells. The cell morphology or appearance is identical as well as the surface markers. iPS cells express genes normally expressed by HES cells. Furthermore, he growth properties[179] and telomerase activity was also alike.

[176] RNA or ribonucleic acid is "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, namely ribosomal (r), transfer (t) and messenger (m) RNA. It forms the genetic material in some viruses. See Family Medical (2000) 225. Cytoplasm is "the substance within the cell wall that surrounds the nucleus and contains a number of organelles." See Family Medical (2000) 61.

[177] Holland as mentioned in Weiss (2005) "The stem cell divide" *Nat Geogr Mag*.

[178] See 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* September 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* August 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* August 461: 91.

[179] Such as self- renewal, proliferation and cell division.

The second area of comparability concerns pluripotency and iPS cells have the ability to differentiate, like HES cells into fully differentiated tissue. Lastly, the epigenetic reprogramming of iPS cells was parallel to that of HES cells.

iPS cells are therefore a viable alternative to the use of embryonic stem cells and a more ethically acceptable method of creating embryos than SCNT. The future of stem cell research will most probably be centred on this procedure and thus its importance may not be underestimated. A further aspect of stem cells which will enjoy much attention in future is the process of stem cell banking. The following section of this dissertation thus deals with the procedure and important elements of decision making of stem cell banking.

4 STEM CELL BANKING

Stem cell banking is rather a misnomer and it should rather be referred to as umbilical cord blood banking as this is currently the material which may be "banked." Cord blood has lead to a rapid change in regenerative medicine. As this dissertation focuses on the procurement and distribution of stem cells, attention must be given to the distribution thereof which takes place by way of banking. In context of this dissertation, distribution must thus be understood as the process whereby stem cells are made available and banking may be included under this. For this reasons, banking must be briefly discussed.

After the birth of a child, the umbilical cord is cut and the remainder of the cord as well as the placenta is discarded of as cord blood has, until now, been viewed as medical waste.[180] Blood however remains in the cord and this blood is rich in stem cells. These stem cells could then be utilised in the treatment of serious diseases.[181] The cord blood is collected after the cord has been cut by inserting a needle into the section of the cord which is still attached to the placenta. The placenta is thus still inside the uterus of the mother. This is the extracted into a tube and this is said to be painless as no nerves are found within the

[180] See in general Kent A (2008) "Cord blood: Medical waste?" *Obstetrics & Gynaecology Forum* October 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.

[181] Cox SR (2008) "Cord blood banking: What's it all about?" *Journal of Midwifery & Women's Health* March 53(2): 161 at 161. Stem cells derived from cord blood may be applied in the treatment of leukaemia and other diseases which affect the immune system.

cord. The collected blood is then packaged, frozen and sent for storage at the chosen banking facility.[182]

The practice of banking is however not as uncomplicated as it would seem. There are certain health risks which should be considered. Health care providers are sometimes of the opinion that the cord blood should be allowed to flow into the new born as this may prevent anaemia and later illnesses. Given that stem cells may be derived from other sources, it may be argued that this is an unnecessary risk.[183] Also, the chances of the new born needing the stem cells in treatment are not high enough to always justify the high costs involved in stem cell banking.[184] It is thus imperative to seriously consider banking prior to the birth.

Aspects which will have to be considered are whether to bank with a private or public bank and then to whom such banked material may be made available. Private banking allows for the preservation of material for autologous family use which then ensures accessibility. This is referred to as directed donations.[185] Public banks make material available to those who need it and thus material cannot be reserved. Some may however choose a public bank due to ethical citizenship and altruistic reasons.[186] This is then referred to as altruistic unrelated donations.[187] Another aspect which must be considered is that the material will undergo testing which may lead to the discovery of troubling results such as paternity, infectious diseases or the predisposition to genetic illnesses.[188] Such information as is necessary regarding testing and the corresponding confidentiality measures must thus be provided to the deciding woman. It is submitted that women must also be informed of the alternative

[182] Cox (2008) *JMWH* 161 at 161. 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: 126 at 128- 132 and also see Warwick R & Armitage S (2004) "Cord blood banking" *Best Practice and Research Clinical Obstetrics and Gynaecology* 18(6): 995 at 1002- 1005.
[183] Cox (2008) *JMWH* 161 at 161.
[184] *Idem* 162.
[185] Warwick & Armitage (2004) *Best Pract Res Clin Obstet Gynaecol* 995 at 997.
[186] Louw VJ & Heyns A (2010) "The role of the state in establishing a public cord blood stem cell bank" *South African Medical Journal* May 100(5): 292 at 292.
[187] Warwick & Armitage (2004) *Best Pract Res Clin Obstet Gynaecol* 995 at 999.
[188] 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* 277 at 278.

uses, such as research, which may be done utilising the material. In conclusion, it is thus important to mention the advantages and disadvantages of cord blood banking.[189]

The advantages of cord blood banking are:

1. Cord blood units may be more rapidly available than bone marrow;
2. Cord blood entails less risk in the collection thereof;
3. The potential number of donors is high;
4. The risk of graft versus host disease is decreased;
5. Cord blood does not have to be HLA matched to be used;[190] and
6. The risk of infectious disease is eliminated as such blood is tested and screened for any such diseases.

The disadvantages of banking are then:

1. Platelet fragmentation is prolonged;
2. The cell dose found in umbilical cord blood is insufficient for the treatment of adults; and
3. Hereditary diseases, which may not be detected at birth, may be transmitted to the recipient of the material.

5 LATEST DEVELOPMENTS

As mentioned above, stem cell research is developing at a rate which precludes a person who is not directly involved in the laboratory from having the "most up- to- date" information and knowledge. It is necessary to briefly discuss the developments which have occurred in the period this dissertation was written and published. This is done in order to paint the most complete possible picture of the science and manifestations and also plays a role in reflecting the historical position and context of this dissertation.

[189] Gunning J (2005) "Umbilical cord cell banking: Implications for the future" *Toxicology and Applied Pharmacology* 207: s538- s543. See also Warwick & Armitage (2004) *Best Pract Res Clin Obstet Gynaecol* 995-1011.

[190] HLA is Human Leukocyte Antigen and this is the name of the major histocompatibility complex of human beings.

In 2009, it was indicated that iPS cells could be generated without the alteration of the adult cell. This is done by channelling specific proteins into the cell by poly-arginine anchors. This induced pluripotency and is referred to a protein- induced pluripotent stem cells or pips cells.[191] Andras Nagy first reported that a method had been found wherein iPS cells could thus be created without the use of retroviruses. [192]

6 CONCLUSION

Stem cells offer the hope that in future, diseases thought to be incurable may be cured and damaged tissue may be replaced. However, for stem cell research and therapy to reach this ideal goal, stem cell technology will have to be regulated and such regulation must be knowledgeable and informed. The legislator and regulator must possess a certain amount of insight into this rapidly changing science in order to properly provide therefore in law. A basic understanding of stem cell manifestations and the science thereof is thus pertinent in any discussion related thereto.

In the course of this chapter an attempt was made to explain the basic concepts, manifestations and scientific processes which stem cell technology entail. It was explained that stem cells are cells which have the ability to indefinitely renew and proliferate which means that these cells are immortal. What is even more impressive regarding stem cells is that they have the ability to become any other cell in the human body as a stem cell itself is unspecialised. Herein lays the value of stem cells.

Not all stem cells however possess these unique qualities and it was explained that stem cells differ in plasticity which translates into the cells ability to become different cell types. The less plasticity a cell possesses the fewer cell or tissue types it may become. Stem cells may thus be divided into a hierarchy ranging from the completely potent totipotent cells to

[191] Cell Stem Cell "Generation of induced pluripotent stem cells using recombinant proteins" at http://www.cell.com/cell-stem-cell/fulltext/S1934-5909(09)00159-3 accessed 10/5/2010. See also Stem Cell Network "Stem cell time line" and ScienceWatch (2010) "New hot papers: Andras Nagy on stem cells" available at http://sciencewatch.com/dr/nhp/2010/10marnhp/10marnhpNagy_LE/ accessed 25/11/2010.

[192] Woltjen K, Michael IP, Mohseni P, Desai R, Mileikovsky M, Hamalainen R, Cowling R, Wang W, Liu PT, Gertsenstein M, Kaji K, Sung HK & Nagy A (2009) "piggyBac transposition reprograms fibroblasts to induced pluripotent stem cells" *Nature* April 458(7239): 766.

pluripotent cells which are used in stem cell research and therapy, to multi-, bi- and unipotent cells.

Further, the sources from which stem cells may be derived were discussed and it was pointed out that currently human embryonic stem cells are the most commonly used but that adult stem cells may soon replace them. This would be a welcome development as embryonic cells carry various ethical issues which would be totally mitigated by the use of adult cells. Also, a distinction was made between embryonic and adult stem cells on the one hand, which are naturally pluripotent and cells which must be programmed into such pluripotent state. Techniques which may be used in order to do this were mentioned as cloning, somatic cell nuclear transfer and induced pluripotency.

Cloning has always been, and will remain, ethically difficult and may retard the development of stem cell technology. Somatic cell nuclear transfer uses the same technique as cloning and thus offers no alternative. The process of induced pluripotent stem cells however provides a viable alternative and it is submitted that this will take centre stage in future activities surrounding stem cell research, therapy and regulation. Currently however, this is an extremely risky endeavour as the genes used to dedifferentiate somatic cells may cause cancerous growths. The development of induction without such retroviruses, which is the latest development, is thus of great importance and a keen eye must therefore be kept thereon in future.

In conclusion, it is submitted that stem cells are seen as the holy grail in future medical treatments and therapies and although this may be true and stem cells my save countless lives and lessen human suffering, stem cells are also a complex and controversial subject which leads to various legal and ethical questions. Many of these questions will be answered in the course of this dissertation and in any attempt to regulate stem cells the Constitution of the Republic of South Africa will play a valuable role. The following chapter will thus deal with the applicable provisions as found in the Constitution which may have a bearing on the future development and regulation of stem cells.

CHAPTER 3
THE CONSTITUTIONAL IMPACT ON STEM CELLS

1 INTRODUCTION

In a regulatory process, such as the regulation of stem cell which is the focus of this dissertation, the impact of the Constitution[1] cannot be ignored or underestimated. There are three reasons for this importance. The first is due to the fact that the Constitution is considered the supreme law in South Africa.[2] The obligations imposed thereby must be adhered to and any legislation or conduct, which is inconsistent therewith, is invalid to the extent of the conflict.[3] Secondly, section 8(1) of the Constitution states that the Bill of Rights applies to all law and is binding upon the executive, legislature and judiciary as well as all organs of state. The spirit, objects and purport of the Bill of Rights must be promoted[4] by any court, tribunal or forum when interpreting legislation or developing the common law.[5] Lastly, the Bill of Rights further requires that the state may not violate fundamental rights when exercising any powers allocated thereto by the Constitution. In the context of stem cell research however, certain fundamental rights which are constitutionally protected become relevant as these rights may be violated or limited. For this reason the limitation

[1] The Constitution of the Republic of South Africa, Act 108 of 1996. Hereafter referred to only as the Constitution.

[2] Section 7(1) of the Constitution states "This Bill of Rights is a cornerstone of democracy in South Africa. It enshrines the rights of all people in our country and affirms the democratic values of human dignity, equality and freedom."

[3] Section 2 of the Constitution. Any sections referred to during the course of this chapter must be understood as sections of the Constitution unless otherwise indicated.

[4] Section 7(2) elaborates on the states duty and states that the state must respect, protect, promote and fulfill the rights in the Bill of Rights.

[5] Section 39: **Interpretation of Bill of Rights**

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.

For more on the interpretation of the Bill of Right see Du Plessis L (2002) "Interpretation of the Bill of Rights"chapter 32 in Woolman S, Roux T & Bishop M (eds) *Constitutional law of South Africa* 2nd edition. Hereafter referred to as CLoSA. See also Devenish GE (2005) *The Constitution of South Africa* 27- 30.

clause, section 36, of the Constitution is of importance as it is imperative to determine whether an infringement upon fundamental rights could nevertheless be justified.[6] In so doing one determines whether or not stem cell research is constitutionally valid at all.

In the context of stem cell research certain issues arise including to what point research on embryos should be permitted, whether the creation of embryos for research purposes should be allowed, what are the uses of embryonic or fetal tissue as well as various complexities surrounding stem cell banking. These issues may be debated on a practical, legal and philosophical level[7] and for this reason the arguments for and against research on embryos or, for the purpose of this dissertation stem cell research, must shortly be discussed.

Arguments justifying this research are the following:

1. Assisted reproduction would benefit greatly as would infertility treatment and method of prevention for inheritance or genetic disorders. Gaining knowledge regarding factors leading to congenital diseases, the development of more effective contraceptives and the detection of gene and chromosome abnormalities are further examples of benefits which could be obtained exclusively through such research;[8]

2. It may be said that the embryo has no morally relevant physical or other characteristics and it may even be said that the embryo does not have the interest to be preserved or the capacity to be harmed;[9]

3. Legal capacity and status is only afforded to human persons by the law;[10]

4. The human embryo is entitled to a greater degree of respect than animal embryos but this respect is not absolute and must be weighed against the benefits of knowledge gained which may arise from such research. Furthermore, human

[6] Currie I & De Waal J (2005) *The Bill of Human Rights Handbook* 26.
[7] Lupton ML "The legal position of cryopreserved embryos" 1992 *Tydskrif vir die Suid Afrikaanse Reg* 466 at 467 & 468.
[8] Carstens P & Pearmain D (2007) *Foundational Principles of South African Medical Law* 198.
[9] Charles Foster has stated that the embryos autonomy has been promoted by embryo and stem cell research. For more on this however see chapter 5 paragraph 3.1 *infra* of this dissertation.
[10] An embryo is not considered a person. This will be illustrated throughout the course of this chapter.

material such as the embryo cannot be substituted in research concerning human beings; and

5. It is possible to control research by the institution of regulations and measures which must be met. The occurrence of brain birth, which is seen as a requirement for human existence,[11] could be an alternative to the much vied for 14- day cut- off.[12]

The flip side of the "constitutional coin" must however be examined and the arguments against stem cell research is summarised as followed.

1. Some argue that the embryo is in fact human and therefore it could never be justifiable to undertake research thereon;

2. Due to the potential for human life, the embryo may be given the same status as a child or adult;

3. Taking a life is never justifiable as the right to life is a fundamental right;[13]

4. Where harm or death could be caused to a child or adult, research is completely unacceptable.[14] Furthermore, research cannot be permitted where no prior informed consent has been obtained.[15] The embryo can obviously never consent and research is thus unacceptable; and

5. Many people instinctively feel opposed to research which involves meddling with the creation of human life.[16]

The embryo protection trend does lead to the regression of constitutional values and therefore a new approach is necessary.[17] For this reason it is important to discuss the constitutional aspects involved in the procurement and distribution of stem cells. Conflicts between fundamental rights such as human dignity and human life now require resolution

[11] Lupton (1992) *TSAR* 466.
[12] For a discussion on the 14-day rule, see chapter 4 paragraph 2.1.2 *infra*.
[13] The fetus is not a bearer of the constitutional right to life. For a more detailed discussion see paragraph 5 *infra*.
[14] See chapter 5 paragraph 5.3 *infra* for a discussion on the risk involved in research on minors.
[15] See chapter 5 paragraph 2.5 *infra* for a discussion on the absence of consent.
[16] See chapter 4 paragraph 2.2.1 *infra* for an explanation of the wisdom of repugnance.
[17] Carstens & Pearmain (2007) 199.

as part of interests which are contemplated by the limitation clause.[18] Also the legitimacy of stem cell research must be argued on the basis of the limitation clause.[19]

The purpose of this chapter therefore is to outline the constitutional framework in which stem cell research in South Africa will be required to function. As starting point, the limitation clause must be discussed as any further examination into the implications of the fundamental rights as stipulated by the Bill of Rights on stem cell research would be superfluous should stem cell research over all be found to be unconstitutional.

2 SECTION 36: THE LIMITATION CLAUSE[20]

The fundamental rights, as provided for by the Bill of Rights are not absolute as they may be limited. The limitation clause provides for specific limitation criteria before fundamental rights may be restricted and any limitation must be extremely compelling.[21] An infringement or limitation will only be constitutionally valid where it can be justified in an open and democratic society based on human dignity, equality and freedom.[22]

A discussion of what section 36 entails is necessary. The limitation clause in general may be described as the inherent restriction of human rights and liberties by the duty, which is an

[18] O' Sullivan M (2002) "Reproductive rights" chapter 37 in CLoSA.
[19] Section 7(3) states that the rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill.
[20] 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.

[21] Currie & De Waal (2005) 163 & 164. See in general Woolman S & Botha H (2002) "Limitations" in CLoSA. See also Devenish (2005) 179- 184.
[22] A distinction must be made between the interpretation and limitation of fundamental rights. Where a claim is made that a right has been infringed, the court is required to determine whether or not the right has in fact been infringed. This is done by interpretation. See 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.

inherent counterpart of the corresponding right, to respect the rights of others.[23] This includes the state as the traditional purpose of the Bill of Rights is to protect individuals against the abuse of state power due to the fact that the relationship between the state and the individual is one of unequal footing. The Constitution in section 8[24] however specifically states that the Bill of Rights has horizontal and vertical application and section 38 states that the listed persons in the section may approach a competent court and may be granted relief where an allegation is made that a fundamental right has been threatened or infringed upon.[25] This relief includes a declaration of rights.

Rights in the Bill of Rights may, according to section 36, only be limited in terms of law of general application. This is known as the "rule of law."[26] "Law" includes legislation, common law[27] and customary law according to *Khala v Minister of Safety and Security*.[28] Mokgoro J stated in the *Hugo* case[29] that for a law to qualify as a law of general application, it must be accessible, precise and generally applicable. Legislative bodies are only allowed to regulate matters which fall within their sphere of competence. Furthermore, the limitation must be "reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom" which translates into the balance which must exist between the purpose of the limitation and the limitation itself. The limitation must thus be legitimate.

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[23] Devenish (1998) *A commentary on the South African Constitution* as mentioned in Swanepoel (2006) LLM thesis 72.

[24] Section 8: **Application**

1. The Bill of Rights applies to all law, and binds the legislature, the executive, the judiciary and all organs of state.
2. A provision of the Bill of Rights binds a natural or a juristic person if, and to the extent that, it is applicable, taking into account the nature of the right and the nature of any duty imposed by the right.
3. When applying a provision of the Bill of Rights to a natural or juristic person in terms of subsection (2), a court
    a. in order to give effect to a right in the Bill, must apply, or if necessary develop, the common law to the extent that legislation does not give effect to that right; and
    b. may develop rules of the common law to limit the right, provided that the limitation is in accordance with section 36(1).

A juristic person is entitled to the rights in the Bill of Rights to the extent required by the nature of the rights and the nature of that juristic person.

[25] The persons listed in section 38 are: anyone acting in their own interest; anyone acting on behalf of another person who cannot act in their own name; anyone acting as a member of, or in the interest of, a group or class of persons; anyone acting in the public interest; and an association acting in the interest of its members.

[26] Currie & De Waal (2005) 168. See in general Woolman S (2002) "Application"chapter 31 in CLoSA.

[27] See *Shabalala v Attorney- General, Transvaal* 1996 (1) SA 725 (CC), *Du Plessis and Others v De Klerk and Another* 1996 (3) SA 850 (CC) and *S v Thebus* 2003 (6) SA 505 (CC).

[28] *Khala v Minister of Safety and Security* (1994) 2 BCLR 89 (W).

[29] *President of the Republic of South Africa v Hugo* 1997 (4) SA 1(CC).

The following must be mentioned when considering the legitimacy of a limitation as stated in S v *Makwanyane and Another*:[30]

> "The limitation of constitutional rights for a purpose that is reasonable and necessary in a democratic society involves the weighing up of competing values, and ultimately an assessment based on proportionality. This is implicit in the provisions of section 33(1). The fact that different rights have different implications for democracy, and in the case of our Constitution, for "an open and democratic society based on freedom and equality", means that there is no absolute standard which can be laid down for determining reasonableness and necessity. Principles can be established, but the application of those principles to particular circumstances can only be done on a case by case basis. This is inherent in the requirement of proportionality, which calls for the balancing of different interests. In the balancing process, the relevant considerations will include the nature of the right that is limited, and its importance to an open and democratic society based on freedom and equality; the purpose for which the right is limited and the importance of that purpose to such a society; the extent of the limitation, its efficacy, and particularly where the limitation has to be necessary, whether the desired ends could reasonably be achieved through other means less damaging to the right in question. In the process regard must be had to the provisions of section 33(1), and the underlying values of the Constitution, bearing in mind that, as a Canadian Judge has said, 'the role of the Court is not to second-guess the wisdom of policy choices made by legislators.'"

The purpose, effects and importance of the legislation and the nature and effect of the infringement must be balanced. Thus, the more substantial the limitation, the more it must be justified.[31] The importance of the right is thus a factor which needs some explanation. Although the phrase "the importance of the right" is not expressly used in the Constitution, it is often seen as being suggested and this concept could thus be understood as the importance of the right in an open and democratic society based on human dignity, equality

[30] *S v Makwanyane and Another* 1995 (3) SA 391 (CC).
[31] *S v Bhulwana* 1996 (1) SA 388 (CC).

and freedom.[32] It first appeared in the *Makwanyane*[33] judgement and then in the *National Coalition* case.[34] Here it was held by Ackerman J that even though the importance of the right is not expressly mentioned in section 36(1), it is a factor which must be taken into account in any proportionality enquiry on the grounds of necessity.

Courts follow a two- stage approach which entails firstly, an interpretation stage and secondly a limitation stage.[35] Section 36 states "the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom," as the relevant factor which must be considered. The following five factors must furthermore be brought into considered when determining the reasonableness and justifiability of a limitation:[36]

1. The nature of the right. The infringement of the fundamental right must be weighed against the benefits which are sought;

2. The importance of the purpose of the limitation. The purpose must be worthwhile and important in a democracy based on the Constitution and therefore a minimum reasonableness is required;

3. The nature and extent of the limitation. An assessment must be made of the manner in which the concerned right will be affected by the limitation;[37]

4. The relation between the limitation and the purpose of the limitation. The limitation must be reasonable and justifiable and thus a good reason for the infringement must exist;

5. The existence of a less restrictive means to achieve the purpose. The limitation must achieve benefits that are proportionate to the costs of the limitation to be legitimate. Where other means are available which could achieve the same ends but which will restrict rights less or not at all, this alternative method must be employed.

[32] This may be due to the fact that all rights are seen as being of equal importance. See Iles K (2007) "A fresh look at limitations: Unpacking section 36" *South African Journal on Human Rights* 23: 68 at 78.
[33] *S v Makwanyane supra*.
[34] *National Coalition for Gay and Lesbian Equality v Minster of Justice* 1999 (1) SA 6 (CC).
[35] See in general Iles K (2004) "Limiting socio- economic rights: Beyond the internal limitation clauses" *South African Journal on Human Rights* 20: 448 at 453.
[36] Section 36(1)(a)- (e). See also Currie & De Waal (2005) 163- 188.
[37] See in general Iles (2007) *SAJHR* 68: at 80- 83.

It is therefore obvious that in attempting to regulate stem cell technology or the procurement and distribution of stem cells and stem cell research as a whole, the limitation clause will have the umbrella task of qualifying the constitutional validity of any right which relates to stem cells. The specific provisions of the Constitution which are affected by this science will be discussed in the course of this dissertation and include equality;[38] human dignity;[39] life;[40] freedom and security of the person;[41] privacy;[42] freedom of religion, belief and opinion;[43] freedom of expression;[44] health care, food, water and social security;[45] and children.[46] Also, in the context of stem cell banking, freedom of trade, occupation and profession[47] will be discussed.

3 SECTION 9: EQUALITY[48]

Equality is one of the most prominent, and probably important, rights enshrined in the Bill of Rights. It is not only mentioned in section 9, but also in sections 36 and 39.[49] Equality as a right does not stand alone and is strongly linked to other rights in the Bill of Rights. In

[38] Section 9.
[39] Section 10.
[40] Section 11.
[41] Section 12.
[42] Section 14.
[43] Section 15.
[44] Section 16.
[45] Section 27.
[46] Section 28.
[47] Section 22.
[48] Section 9: **Equality**

1. Everyone is equal before the law and has the right to equal protection and benefit of the law.
2. Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons or categories of persons, disadvantaged by unfair discrimination may be taken.
3. The state may not unfairly discriminate directly or indirectly against anyone on one or more grounds, including race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.
4. No person may unfairly discriminate directly or indirectly against anyone on one or more grounds in terms of subsection (3). National legislation must be enacted to prevent or prohibit unfair discrimination.
5. Discrimination on one or more of the grounds listed in subsection (3) is unfair unless it is established that the discrimination is fair.

See in general Albertyn C & Goldblatt B (2002) "Equality" chapter 35 in CLoSA and Devenish (2005) 47- 60.
[49] Section 39(1)(a) reads as follows: **Interpretation of Bill of Rights**

4. 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.

Makwanyane[50] the link between equality and human dignity was established and the concept of *ubuntu* became a part of South African law. For this reason, it must be discussed for purposes of this dissertation due to the fact that in the absence of compliance with the equality requirement, stem cell research will never be seen as constitutional.

To invoke the equality clause, there must firstly be an investigation into whether or not a differentiation is made between people or groups of people according to *Harksen v Lane*.[51] If such a distinction does in fact exist, it must then be determined if there is a rational connection to a government purpose therefore. This may still however amount to discrimination.

The second step concerns a determination of whether or not the differentiation amounts to discrimination and this is done via a three- stage analysis:

1) It must be established whether or not the distinction made between people or groups of people amounts to discrimination. The court stated that if the grounds of differentiation were not expressly listed, an objective enquiry must be made to determine if the distinction was made on "attributes and characteristics which have the potential to impair the fundamental human dignity of persons as human beings or to affect them adversely."

2) If the differentiation does amount to discrimination, such discrimination must be found to be unfair. If the grounds of discrimination are listed in section 9(3), the courts will presume that the discrimination is unfair. Where it is not listed,[52]unfairness will be determined by an investigation into the impact of the discrimination on the individual and other people in that situation.[53]

3) Should the discrimination in fact be found unfair, it must be determined whether or not it is justifiable under section 36 of the Constitution. In the *Harksen* case[54] it was stated that this involved "a weighing of the purpose and effect of the provision in

[50] *S v Makwanyane supra*.
[51] *Harksen v Lane* 1998 (1) SA 300 (CC).
[52] For example the decision to have an abortion or to donate embryos or fetuses to stem cell research.
[53] The Promotion of Equality and the Prevention of Unfair Discrimination Act, Act 4 of 2000 also contains a general provision which states "neither the state nor any person may unfairly discriminate against any person." It is safe to assume that this provision also protects the reproductive autonomy of women.
[54] *Harksen v Lane supra.*

question and a determination as to the proportionality thereof in relation to the extent of equality."[55]

Reproductive autonomy can be seen as a prerequisite for the sexual and social equality of women and therefore the abortion issue is part of a wider one which concerns reproductive freedom and thus sexual equality.[56] Although the state has an interest in the protection of potential life, this is not an either or situation where a choice must be made in favour of the states interest and that of the woman in reproductive self- determination and fortunately a balance is possible. The states interest in potential life may be pursued by better family planning programmes, contraception facilities and more inclusive sex education. This would then be less intrusive than a prohibition on abortion and would also not overstep the fundamental equality, privacy and dignity rights of women. It could in fact result in the protection of fetal life balanced with women's equality.[57]

Pregnancy may be seen as a biological inequality which places unique burdens on the mother. To prohibit a woman from having an abortion, thus forcing motherhood upon her can therefore be described as discrimination as it can only ever affect women.[58] It is submitted that destruction of a pre- implantation embryo also falls under the woman's right to equality as it is a choice which protects the woman's health, mobility and independence. The ability to plan her life, have relationships and contribute to the world with her career and social life are further aspects which are protected by sexual equality.

Equality therefore, in context of stem cell research, focuses on the mother or woman. The fetus is not a constitutionally protected person and therefore does not enjoy the protection or right to equality provided for by section 9.

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[55] See *President of the Republic of South Africa v Hugo supra* in which Kriegler J suggested a distinction between be made between factors which constitute interference into equality under the limitation clause and factors under the equality clause. The former concerns justification, notwithstanding unfairness and the latter is concerned with only fairness.

[56] Legal structures which support male dominance and thus promote the subservience of women are fundamentally inconsistent with the constitutional ideals of an individual's self worth and equality of opportunity as well as control of reproduction, which are essential to womens capability to live as equal persons. See Law SA (1984) "Rethinking sex and the Constitution" *University of Pennsylvania Law Review* 132(5): 955 at 1028.

[57] Slabbert MN (2000) *The human embryo and foetus: Constitutional and other legal issues* (LLD thesis unpublished, UNISA) 350.

[58] Law SA (1984) *U Penn L Rev* 132(5): 955 at 1028.

3.1 GENETIC DISCRIMINATION[59]

Genetic testing may raise important social, ethical and legal questions as it opens the door to new opportunities to discriminate and stigmatise by bodies such as insurance companies and stem cell banks. The results of genetic tests could even cause shame and fear or resentment towards family members. The history of eugenics[60] is an example of this and illustrates how the genetic composition of a person could be abused as ground or as instrument of discrimination.[61] It has even lead to genocide.[62] Equality in this context is connected to confidentiality and privacy and has been identified as a top priority to be addressed by any proposed legislation on the regulation of stem cell research. The extent and scope of this issue can however only be addressed by information in order to minimise the perceived level of discrimination.[63]

4 SECTION 10: HUMAN DIGNITY[64]

Most Constitutions containing a bill of rights could be said to give preference to certain rights and these rights or such class of rights rest upon the *Grundnorm* of that constitution and is closely connected to the historical circumstances which lead to the development of the Constitution.[65] It is also interesting to note that human dignity is often the highest

[59] Regulation 7 of the Regulations Relating to Human stem Cells may constitute a reversed form of genetic discrimination as it states that stem cells for later therapeutic use may only be obtained from high risk families. See chapter 6 infra for a discussion of this Regulation.

[60] This is where persons who are considered to have desirable genetic traits are bred to form a "super race," while those who are considered inferior genetically are sterilised. There are theories that this was done during Hitler's rule of Germany in his quest for an Arian race.

[61] Nienaber AG & Van der Nest D (2004) "Genetic testing for the purpose of insurance risk assessment and the constitutional right to privacy" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 67: 446 at 447.

[62] Markel H (1992) "The stigma of disease: The implications of genetic screening" *American Journal of Medicine* 210.

[63] Lapham VE, Kozma C & Weiss JO (1996) "Genetic discrimination: Perspectives of consumers" *Science Genome Issue* October 274(5287): 621- 624. See also 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* December 317(7173): 1632- 1635. For more on the impact of screening on employment as well as insurance see also MRC "Ethics in genetic research and practice" *Guidelines on ethics for medical research: Reproductive biology and genetic research* (Book 2) paragraph 3.7.2.3 and 3.7.2.4 available at http://www.mrc.co.za/ethics/ethics.htm accessed 5/7/2009 for more on intellectual property rights.

[64] Section 10: **Human dignity**
Everyone has inherent dignity and the right to have their dignity respected and protected.
See in general Devenish (2005) 61- 64.

[65] Van Wyk JD (2005) "Menseregte en menswaardigheid" *Koers* 70(3): 455 at 462.

prevailing right. The South African Constitution is no different and states a hierarchy of rights as "human dignity, equality and freedom."[66] One of the earliest decisions by the Constitutional Court further emphasises the importance of human dignity as it was stated in *S v Williams*[67] that the court placed high value on human dignity.

Human dignity is therefore a central value of the objective normative value system.[68] In *Carmichele v Minister of Safety and Security*, [69] Chaskalson P stated that dignity informs the content of all other rights and plays a role in balancing rights and values to bring them into harmony. In *Makwanyane*,[70] O'Regan stated that the recognition of a right to dignity is the acknowledgment of human beings' intrinsic worth. Human beings are entitled to being treated with respect and concern. She further stated that dignity is "a founding value of the new Constitution."

It could be said that human dignity is the basis of various other rights which have been entrenched specifically in the Bill of Rights. This is illustrated exceptionally well by *Dawood v Minister of Home Affairs*.[71] This case is furthermore relevant in context of stem cell research as it dealt with certain abortion issues, the destruction of potential life which is an issue in the debate surrounding stem cells, and it was held by Van Heerden J that protection must be afforded to the institution of marriage and family life by the interpretation of the right to dignity. The state is obliged to regulate abortion in order to protect potential life but also has an interest in maternal health which cannot be separated from the abortion discussion. In order to give effect to both of these duties, the state is required to reconcile the duties.[72] Human dignity justifies respect for women's personal privacy and emphasises the need to rid our society of inequality between the genders.[73]

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[66] Sections 1(a), 7(1) and 36(1).
[67] *S v Williams* 1995 (2) SA 632 (CC).
[68] The objective normative value system can be understood as the *boni mores* of a community. It is the basis on which reasonable decision are made which incorporate the communities' norms and values. Over time the values of a community will change, thus the normative element, but there will still exist a consensus as to what is acceptable within such a community, the objectivity. One must note however that the objectivity of values may be doubted and the emphasis must rather fall on the pursuit of objectivity. See also Ellman S *Now without hesitation* at http://nowwithouthesitation.blogspot.com/2009/06/where-does-objective-normative-value.html accessed 25/5/2010.
[69] *Carmichele v Minister of Safety and Security* 2001 (4) SA 938 (CC).
[70] *S v Makwanyane and Another supra.*
[71] *Dawood v Minister of Home Affairs* 2000 (1) SA 997 (C) as mentioned in Currie & De Waal (2005) 278.
[72] Slabbert (2000) LLD thesis 340.
[73] Swanepoel (2006) LLM thesis 76.

Dignity however is connected to life and in *Makwanyane*, Mokgoro J very eloquently pointed out that dignity and life are the two sides of a single coin. Thus any violation of the right to life also violates the right to dignity. It is not difficult to understand the profoundness and merit of this statement when taking into regard considerations regarding quality of life and what a life without dignity would entail. It becomes clear that a life without dignity is no life at all. In context of stem cell research, one must however consider whether or not the mother's right to dignity, equality and privacy are outweighed by the rights of the fetus to life and dignity.[74] In order to do so, the question of whether or not an embryo or fetus has the right to life must be answered. This will be done in the following paragraph. When answering this question, one further answers the question of whether the embryo or fetus is entitled to the right to human dignity.

To establish whether or not the embryo is entitled to the right to dignity, it must be determined whether the embryo has legal status. Legal status denotes the level of protection the law confers upon a subject or in this case the embryo. The legal status of the embryo is thus independent of the interests of the gamete donors, prospective parents or other entity intrinsic to the embryo.[75] Jordaan states that the current law neither imposes a legal duty of care towards the embryo, nor is the pre- embryo afforded any legal protection by the law. The laws which attempt to regulate the actions surrounding embryos are rather aimed at protecting society's sense of propriety. Since the embryo has no legal status, it cannot be entitled to the right to dignity and is therefore not protected by section 10.

4.1 THE CONCEPT OF DIGNITY AND STEM CELL RESEARCH

The concern for human dignity has become an obligation in bioethical matters. It is however unfortunate that it has not been specified and is used as an umbrella term. For this reason one must understand human dignity as a legal concept before it can be applied to stem cell

[74] McGregor M & Moore R (1995) "The constitutionality of abortion on request in South Africa" *Murdoch University Electronic Journal of Law* 2(3) at www.murdoch.edu.au/elaw/issues/v2n3/moore23.html accessed 5/7/2009.
[75] Jordaan DW (2005) "The legal status of the human pre- embryo in the context of the genetic revolution" *South African Law Journal* 237 at 240.

research.[76] The South African Constitution gives two dimensions to human dignity. Firstly, as a foundational value which informs and directs all other rights in the Bill of Rights,[77] and secondly as an independent and enforceable right. Dignity may thus be regarded as the pre-eminent constitutional value.[78] The court has however admitted that dignity is "difficult to capture in precise terms"[79] and various application- based interpretations have been given to this term which makes dignity a broad and general concept. Haysom identifies three distinct elements of dignity and therefore dignity may be seen in more exact terms:[80]

1. Individual autonomy. The sphere of individual autonomy is needed for a person to be a self- actualising and responsible being;

2. Self- worth. Dignity could be used as a shield to protect a person from attacks of their sense of worth in society and the community; and

3. Universality. Dignity is applicable to all humans and thus all humans have equal worth which is not dependant of their station in life.

Now that the legal concept of dignity has been discussed, dignity and the embryo require some attention. The pre- embryo is currently not considered a legal subject or the bearer of the right to human dignity by the South African law. Jordaan states that to claim any entity but a human is entitled to human dignity would degrade this right.[81] To ascribe this right to a microscopic entity without any of the properties associated with a human being such as intellect or consciousness or emotion would "make a mockery of human dignity." Jordaan comes to the conclusion that it is absurd to claim that en embryo is entitled to human dignity.

[76] Jordaan DW (2007) "Science versus anti- science: The law on pre- embryo experimentation" *The South African Law Journal* 124:618 at 630.
[77] See *Dawood, Shalabi & Thomas v Minister of Home Affairs* 2000 (3) SA 936 (CC) in which O' Regan J stated that human dignity is a value which informs the interpretations of many, if not all other rights.
[78] *S v Makwanyane and Another supra*.
[79] *National Coalition of Gay and Lesbian Equality v Minister of Justice supra*.
[80] Haysom N (2002) "Dignity" 31 in Cheadle MH, Davis DM & Haysom NRL (eds) *South African Constitutional Law: The Bill of Rights*.
[81] Jordaan (2007) *SALJ* 618 at 631.

5 SECTION 11: LIFE[82]

The right to human life is seen as the most basic human right and is the foundation on which other rights exist and for this reason life is the most basic value which is constitutionally protected.[83] International instruments such as *The Universal Declaration of Human Rights*[84] and *The International Convention on Civil and Political Rights*[85] have also confirmed the status and importance of the right to life. Yet the right to life is not absolute and may be limited by the limitation clause.

The right to life and the right to dignity were described in *Makwanyane* as the most important rights afforded to humans and the source of all other rights in the Bill of Rights. We are thus required to value these rights above all others when committing to a society founded on human rights.

Due to the fact that stem cell research may destroy potential life, the discussion surrounding abortion and the right to life may be used as point of departure or guideline for any discussion pertaining to the right to life in context of stem cells. Also, fetal tissue obtained from abortions may serve as a source of stem cells and therefore many of the same issues are raised. One such issue is the conflict between the embryo's or fetus's right to life and the mother's rights to bodily integrity, privacy and reproductive freedom. This conflict was described by Mahomed J in *Makwanyane* as follows:

> "What does the [right to life] mean? What is a 'person'? When does 'personhood' and 'life' begin? Can there be a conflict between the "right to life" in section 9 and the right of a mother to 'personal privacy' in terms of section 13 and her possible right to the freedom and control of her body?"

The issues of abortion and embryonic stem cell research therefore both require a resolution of the conflict between the right to freedom and bodily integrity on the one hand and the

[82] Section 11: **Life**
Everyone has the right to life.
[83] For a more detailed discussion see *S v Makwanyane and Another supra* 37-1. See also Devenish (2005) 64-70. See also Pieterse M (2002) "Life" chapter 39 in CLoSA.
[84] Article 3 reads "everyone has the right to life, liberty and security of the person."
[85] Article 6(1) reads "every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."

state's duty to protect human life on the other hand. Traditionally the right to life has been favored but freedom of choice is increasingly propagated.[86]

5.1 THE FETUS AND THE RIGHT TO LIFE

The status of the early embryo must serve as the starting point in considerations regarding research on human embryos. This may be seen as a fundamental question as it is inherently bound to the question of when human life begins and of how a person is defined. Some view an embryo as a person and therefore see any destruction thereof as murder.[87] Should the embryo be considered a person, there would be far reaching consequences for stem cell research as far as embryonic stem cells are concerned.[88] Viewing an embryo as a person would necessitate constitutional protection of the embryo.[89]

The question as to whether the embryo is a bearer of Constitutional rights was raised in the *Christian Lawyers Association of South Africa* case.[90] *In casu* it was argued that section 11 of the Constitution applied to an embryo and fetus from the moment of conception and thus abortion should be unconstitutional. In his judgment, McCreath J focused on whether the fetus could be included under "everyone" as stated in section 11. The Constitution uses "everyone" and "every person" interchangeably and the Bill of Rights thus generally protects "everyone." "Everyone" is however often referred to as "people" or "persons." It is interesting to note that section 9 of the interim Constitution read "every person shall have the right to life," while section 11 of the final Constitution uses the word "everyone." McCreath J stated that this change of wording was not intended to create a new class of constitutionally protected rights bearers. The courts are also not inclined to attach different

[86] For a discussion see Currie & De Waal (2005) 278-288, Meyerson D (1999) "Abortion: The constitutional issues" *South African Law Journal* 116(1): 50 at 59 and Naude T (1999) "The value of life: a note on the *Christian Lawyers Association of SA v Minister of Health*" *South African Journal of Human Rights* 15(4): 541-562.

[87] Ford NM (1989) *Where did I begin?* 217- 221. See also Evans D (ed)(1996) *Concieving the embryo: Ethics, law and practice in human embryology* 162.

[88] Critics of embryo destruction make two statements. The first is that the embryo is a person from the moment of conception and thus destruction of an embryo is immoral and a form of homicide. And secondly, that if embryo destruction were permitted, the embryo would not be entitled to protection and therefore any form of embryo destruction would be permissible. See Evans (ed)(1996) 151.

[89] Enmon JL (2002) "Stem cell research: Is the law preventing progress?" *Utah Law Review* 3: 621 at 626.

[90] *Christian Lawyers Association of South African and Others v Minister of Health and Others* 1998 (4) SA 1113 (T).

meanings to words according to *Davenport Corner Tea Room (Pty) Ltd v Joubert.*[91] Especially where this would have "a significant bearing on the issue before the court."

Logically, the issue of whether or not the unborn child is included under "everyone" is then raised. In the *Christian Lawyers Association of South Africa* case[92] the following syllogism was used: "every human being has a right to life. A human embryo is a human being. Therefore, the human embryo has the right to life."[93] Slabbert,[94] however criticises this "A is B, B is C therefore A is C"- argument by stating that the term "human being" is equivocated. In the first premise, "human being" is a relative moral term and is normative in nature. In the second premise, it is biological in nature. This argument can therefore not stand. A second argument is that the embryo constitutes "human life."

In *Clarke v Hurst*[95] the concept of "human life" was dealt with and the court made a distinction between "biological life" and "human life." The following was stated:

> "Life in the form of certain biological functions such as the heartbeat, respiration, digestion and blood circulation but unaccompanied by any cortical and cerebral functioning of the brain, cannot be equated with living in the human or animal context."

The question is however whether the embryo or fetus should enjoy the same protection under the Constitution as born humans. Birth is therefore an important distinction and plays a pivotal role in the common law.[96] Various theories as to when human life begins exist such as the following:[97]

1. The appearance of the "primitive streak;"

2. Viability of the fetus. This is considered the stage where the fetus can survive outside of the womb, all be it via artificial life- support;

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[91] *Davenport Corner Tea Room (Pty) Ltd v Joubert* 1962 (2) SA 709 (D).
[92] *Christian Lawyers Association of South African and Others v Minister of Health and Others supra*.
[93] Singer P, Kuhse H, Buckle S, Dawson K & Kasimba P (eds) (1990) *Individuals, humans and persons: The issue of moral status, embryo experimentation, legal, ethical and social issues* 65 at 69.
[94] 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): 514 at 519.
[95] *Clarke v Hurst* 1992 (4) SA 630 (D).
[96] For a detailed discussion on the common law, personhood and the status of the embryo and fetus see Swanepoel (2006) LLM thesis 87- 104.
[97] *Idem* 97-102.

3. Brain birth. This is the stage where humans and animals are distinguished as it is the development of higher intelligence;

4. Conception as the moment of "ensoulment;"[98] and

5. Since the human embryo and fetus are not "things," they are persons.

According to common law, a natural person's legal personality begins when the birth is complete.[99] An example of the common laws occupation with live birth as marker of personhood is the *nasciturus* fiction.[100] Before birth the fetus is a part of the mother[101] and the following requirements must be met before acquisition of legal personality:

1. The birth must be completed to the fullest extent. There must be complete separation between the mother and fetus. The umbilical cord however need not be severed; and

2. The child must be alive, even if only for a short time, after the separation.

Legal personality means that the bearer thereof has legal competencies, rights and obligations.[102] Legal personality is what makes a person, a person in the eyes of the law. Should the embryo or fetus be considered a legal person or the bearer of legal personality, the embryo or fetus would be entitled to the rights in the Bill of Rights. As illustrated by die above discussion, it is clear that legal personality only establishes at birth and thus the embryo or fetus does not possess legal personality and will never be regarded as a person in terms of the law. In the *Christian Lawyers Association of South Africa* case,[103] McCreath J further held that the Constitution does not change the common law position and thus the fetus is not a legal person.

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[98] See chapter 4 paragraph 2.1 for more on the concept of "ensoulment" and how it is applied in ethical debates.
[99] See in general Davel CJ & Jordaan RA (2004) *Personereg student handbook* (3de uitgawe) 11- 26.
[100] It has however been argued convincingly, that this fiction should not be applied outside of the law of succession and for the purpose of this dissertation it will therefore not be discussed is further detail. See in general Joubert WA (1963) "*Pinchin & Another NO v Santam* 1963 (2) SA 254 (W)" *Tydskrif vir Hedendaagse Romeins- Hollandes Reg* 26: 295.
[101] *S v Mashumpa and Another* 2008 (1) SACR 126 (ECD).
[102] Davel & Jordaan (2004) 3.
[103] *Christian lawyers Association of South Africa and Others v Minister of Health and Others supra*.

In conclusion and with reference to the above it is thus obvious that the embryo and fetus are not seen as persons and therefore not included under the right to life which is afforded to everyone under section 11 of the Constitution.

5.2 THE EMBRYO AND THE RIGHT TO LIFE

To assess the question of whether or not the embryo is a bearer of the right to life, a different form of argumentation will now be followed. Certain arguments based on the notion that the embryo is protection worthy and is in fact entitled to this right will be rebutted in order to illustrate that the embryo is not a bearer of the right to life as provided for in section 11 of the Constitution.

5.2.1 The Pre- Embryo Is Human Life and Must Therefore Be Protected

The argument which is used in favour of embryo protection is that the embryo constitutes human life. An analysis of "human life" is therefore necessary. Silver states that there are two different meanings to the word life as used in connection to humanness.[104] The first is connected to the utilisation of energy, maintenance of structure and information, reproduction and evolution which all living entities share. Life is thus rooted in the individual cell. The second meaning however is rooted in the cerebral functioning which leads to consciousness and this lies beyond an individual cell in humans. Jordaan thus states that based on Silver's distinction the following may be concluded. Firstly, the pre- embryo is alive and secondly, it is human. Thirdly however, the embryo is not human life as it possesses no neurological attributes associated with specific human life. It may be seen as human life in a general sense.[105]

This distinction between special and general human life is also found in the South African case of *Clarke v Hurst*,[106] in which it was held that biological life, human life in general, referred to the continued function of certain bodily organs and human life, special human

[104] Silver LM (1999) *Remaking Eden: Cloning and beyond in a brave new world* 25.
[105] Jordaan (2005) *SALJ* 237 at 241.
[106] *Clarke v Hurst supra*. See also paragraph 5 *supra* regarding the fetus and the right to life.

life, referred to cortical functioning. Other elements of human life which were mentioned include self- awareness, awareness of surroundings, registration of sensations and social interaction. The embryo does therefore not qualify as being human life. Some then fall back onto the next argument.

5.2.2 The Pre- Embryo Is Potential Human Life and Must Therefore Be Protected

The human species has the intellectual capacity to conceptualise the future and thus recognise the value of potential. "Potential" is the inherent capacity of coming into being. The future is however not the present and potential is not actual. Potential can therefore not be given the same status as the actual. Potential is also not absolute.[107]

Potential does have some value and does deserve some protection. The argument can however be made that protection must increase according to the level of progress to actualisation the potential makes. In other words, should a certain stage of the reproductive process be afforded more protection, there should be a morally differentiating element to the specific stage of reproduction. Gametes as such are not protection worthy and thus for an embryo to be, the following arguments have been made:[108]

1. The pre- embryo is potential human life and unlike gametes, has a complete genotype and must therefore be protected;
2. The pre- embryo is potential human life and unlike gametes, has a unique genotype and must therefore be protected;
3. The pre- embryo is potential human life and unlike gametes, is a self- growing entity and must therefore be protected; and
4. The pre- embryo is potential human life and unlike gametes, has symbolic value and must therefore be protected.

The above arguments can however be rebutted as complete genotype and self- growth cannot be applied consistently without leading to absurd consequences, unique genotype and self- growth lack general applicability and symbolic value has no moral significance from

[107] Jordaan (2005) *SALJ* 237 at 243.
[108] *Idem* 245- 248. For a detailed discussion of these arguments see Jordaan (2005) *SALJ* 237.

an open society perspective.[109] In the absence of a morally differentiating element is must thus be concluded that the pre- embryo is no more protection worthy than a gamete and should be afforded no legal protection.

It is however important to note that the entire debate surrounding the right to life may be eliminated by the use of induced pluripotent stem cells or, iPS cells.[110] No embryos are destroyed in this process and the process of stem cell research is being revolutionized by the discovery of iPS cells and protein induced pluripotent stem cells, thus minimizing if not completely mitigating the controversy which shrouds this science.[111] For this reason iPS cells have been dubbed the "Holy Grail" of stem cell research as they are patient specific and can benefit humanity without the ethical controversy from the loss of life. iPS cells are a obvious example of how the treatment of one person does not have to mean the sacrifice of another. It is submitted that the argument may even be made that since stem cell research and therapy holds the potential to greatly improve the lives of human beings, it increases the quality of life. It may then be argued that it even enables life and should be protected under section 11 of the Constitution.

6 SECTION 12: FREEDOM AND SECURITY OF THE PERSON[112]

Section 12 of the Constitution is relevant in context of this dissertation for two reasons. Firstly, it guarantees the right to freedom and security of the person[113] and secondly it

[109] *Idem* 248- 249.
[110] Chapter 2 paragraph 3.6.3 *supra.*
[111] "iPS cell research: The discovery of iPS cells should end the stem cell debate" at http://www.wrtl.org/stemcell/iPScellresearch.aspx accessed 21/6/2010.
[112] Section 12: **Freedom and security of the person**

1. Everyone has the right to freedom and security of the person, which includes the right
    a. not to be deprived of freedom arbitrarily or without just cause;
    b. not to be detained without trial;
    c. to be free from all forms of violence from either public or private sources;
    d. not to be tortured in any way; and
    e. not to be treated or punished in a cruel, inhuman or degrading way.
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.

[113] Section 12(1). See in general Devenish (2005) 70- 71. See also Bishop M & Woolman S (2002) "Freedom and security of the person" chapter 40 in CLoSA.

provides for the right to bodily and psychological integrity.[114] Section 12 therefore contains a combination of the rights. In *Ferreira v Levin*[115] Chaskalson P held that the aim of this section is the protection of an individual's integrity.[116] For the purpose of this dissertation the provisions of section 12 will be discussed according to sub-section (1) and (2).

6.1 SECTION 12(1): FREEDOM AND SECURITY OF THE PERSON

The South African courts are often required to harmonise health and the fundamental rights contained in the Constitution. As the state is required to "respect, protect, promote and fulfil" the rights contained in the Bill of Rights, judges must then be committed to uphold the rights of an individual in circumstances where laws and policies which have the advancement of public health at heart, could possibly violate or limit the rights of an individual.[117] According to Ackerman J, the right to freedom and security of the person consists of substantive as well as procedural components in that any deprivation of freedom would violate section 12(1) unless it were substantially and procedurally fair.[118] Also, the requirements as set out in the limitation clause must be met. One such requirement is that the limitation must be justifiable. In other words a good reason must exist before a right enshrined in the Bill of Rights may be limited. In context of section 12(1), freedom may be deprived for a good reason which includes public health.[119]

Chaskalson P stated in the *Ferreira* case[120] that although the primary concern of this section, then section 11(1) of the interim Constitution, was the protection of physical integrity it could residually protect any other freedoms that were not specifically mention or protected

[114] Section 12(2). See Devenish (2005) 75.
[115] *Ferreira v Levin NO* 1996 (1) SA 984 (CC).
[116] It should be noted that this statement was made regarding section 11(1) 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." The right protects physical liberty and security and Chaskalson P further stated that it must not however be limited to physical integrity only. The new section 12(1) is formulated much more specifically. See Swanepoel (2006) LLM thesis 107.
[117] 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 at 232. See also Carstens P (2009) "The involuntary detention and isolation of patients infected with extreme resistant Tuberculosis (XDR-TB): Implications for public health, human rights and informed consent: *Minister of Health, Western Cape v Goliath* 2009 2 SA 248 (C)" *Obiter* 30(2): 420- 429.
[118] *De Lange v Smuts* 1998 (3) SA 785 (CC).
[119] *Minister of Health, Western Cape v Goliath & Others* 2009 (2) SA 248 (C).
[120] *Ferreira v Levin NO supra*.

in the Bill of Rights. Thus where a freedom could be identified but was not adequately protected, it could fall under the ambit of this section.[121] The requirements for this were that the freedom must be of a fundamental nature and furthermore of an appropriate character which would stand against the scrutiny which limitations to this section were subjected to.[122]

For the purpose of this dissertation however, section 12(2) is of more importance as it expands the freedom protected in section 12(1) by protecting aspects of self-determination[123] such as reproduction, bodily integrity and consent which are relevant issues in context of stem cell research. Section 12(1) is helpful in an interpretive manner as it is clear that the fetus and embryo are not intended to be included under "everyone" and thus the protection provided for by this section.[124]

6.2 SECTION 12(2): BODILY AND PSYCHOLOGICAL INTEGRITY

Section 12(2) contains three important rights which are included under integrity namely:[125]

(a) The right to make decisions regarding reproduction;

(b) The right to security in and control over the body; and

(c) The right to give informed consent to any medical or scientific experimentation.

6.2.1 Section 12(2)(a): Decisions Concerning Reproduction

The right to procreate and to contraceptives are internationally recognised and it may thus be inferred that this includes the woman's right to control her fertility by being able to

[121] Most freedoms are however specifically protected. Examples of this are the right to privacy and the freedom of conscience, thought and religion.
[122] Currie & De Waal (2005) 292. See also section 11(1) of the Interim Constitution.
[123] *Idem* 293.
[124] The nature of the fetus or embryo precludes it from being able to be deprived of its freedom, to be detained, to be tortured or punished. An attempt to include the fetus under these provisions would surely lead to absurd results.
[125] Section 12(2)(a)- (c).

decide to terminate her pregnancy by way of abortion.[126] The focussed inclusion of the right to make reproductive decisions may be seen as an essential element of control over the body. In context of this dissertation, the recognition of this right confirms that a person has the power to decide the fate of their own "reproductive material" which includes gametes and embryos.

Returning to the question of whether a fetus enjoys the right to life it must be mentioned that should the fetus be awarded the right to life it would have far reaching consequences for section 12(2)(a)'s interpretation. The mother and fetus would then be protected equally and abortion would have to be declared unconstitutional. Although the "abortion issue" is by now a tired subject of debate, it must be discussed briefly as many principles and arguments surrounding stem cell research and abortion are similar. An example of this would be the decision to not let a fertilised embryo develop to term and be born. Thus both stem cell research and abortion deal with the destruction of potential life.

When discussing abortion, one must consider the person or potential person, the mother and the fetus, whose rights will be affected as the starting point of such discussion. Swanepoel that the issue of abortion is not based on the justification thereof, but involves the greater issue of a woman's right to make decisions regarding procreation and to do so autonomously.[127] The focus is often shifted from this pivotal point by loaded language and care must be taken to remind oneself that the true question involved in the abortion issue is whether or not the state may force a woman to bear a child and then support such a child against her will.[128] It is seen as forcing the woman to make a sacrifice and it denies her the freedom to make decisions regarding her body. Furthermore, it infringes on her right to psychological integrity which is protected under section 12(2)(a) and (b). The consequences of forcing a woman to carry a child range from possible illegal abortion, which involves legal risks[129] and medical danger, to possible suicide. This is clearly a violation which physically

[126] Davis D, Cheadle H & Hayson N (1997) *Fundamental rights in the Constitution: Commentary and cases* 87.
[127] Swanepoel (2006) LLM thesis 109.
[128] Tribe as mentioned in Swanepoel (2006) LLM thesis 110.
[129] Section 10 of The Choice on Termination of Pregnancy Act states that any person who is not a medical practitioner or registered midwife who performs the termination of a pregnancy or anyone who prevents the lawful termination of a pregnancy or obstructs access to a facility therefore, is guilty of an offence and liable on conviction to a fine or to imprisonment for a period no longer than 10 years.

manifests itself. According to Slabbert[130] the Choice on Termination of Pregnancy Act[131] suggests that women are entitled to abortion. This is substantiated when taking into consideration the preamble of the Choice on Termination of Pregnancy Act which reads as follows:

> "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***

[130] Slabbert (2000) LLD thesis 372 & 373. See also Swanepoel (2006) LLM thesis 110.
[131] The Choice on Termination of Pregnancy Act, Act 92 of 1996.

> the right to choose whether to have an early, safe and legal termination of pregnancy according to her individual beliefs."[132]

It is thus submitted that the right of a woman to make decisions regarding reproduction autonomously, which includes the right to terminate a pregnancy weighs heavier than the right of a fetus to be protected under the Constitution. This can be said to apply equally to an embryo in context of stem cell research.

6.2.2 Section 12(2)(b): Security In And Control Over The Body

The essence of the right to freedom and security of the person is the right to be left alone and this creates inviolability on an individual level. There are two elements with differing meanings, to section 12(2)(b) namely "security in" and "control over" the body. "Security in" indicates that bodily integrity is protected from outside violation by the state or others. "Control over" indicates that bodily autonomy and self- determination are protected.[133] It is important to now discuss the importance of section 12(2)(b) in context of stem cell research and the purpose of this dissertation.

Section 12(2)(b) is a confirmation of the right to have security in and control over one's body. In the context of stem cell research it is therefore relevant in determining whether or not a woman may terminate her pregnancy and then donate the aborted fetus to stem cell research. This question also concerns whether or not a fertilised embryo may be donated to stem cell research.

Some might argue that an embryo is not a fetus and therefore the arguments equating the embryo to a fetus are of little use. It is true that there does exist a biological and developmental difference and thus the following rebuttal to such arguments is submitted. In cases where abortion is impermissible, potential life is protected in spite of the privacy

[132] Own emphasis.

[133] "Security in" may be seen as the right to not be harassed by others and to be left in peace. "Control over" may be seen as being able to live the life or ones choosing. See Currie & De Waal (2005) 308. See also *Phillips v De Klerk* 1983 TPD (unreported) as quoted by Strauss SA (1991) "Voluntary sterilization for convenience: The case of the unwanted child" *Consult* 3(2): 93-97 in which it was held that a competent persons right to control his own destiny according to his values must be rated higher than his health and life. This was held regarding an individual's right to dispose of his own body.

interests in the body of the mother. An example of such circumstances is where the fetus is viable.[134] The woman's body is however not involved in *in vitro* fertilisation and as there are no bodily privacy interests, it may be argued that no right to destroy an embryo is provided for. This argument however fails when it is considered that before implantation and outside of the womb an embryo is never viable. According to the *Roe*[135] decision a pre- implantation embryo, which is obviously then intended for *in vitro* fertilisation, is not viable and it would be impossible to save the embryo in the case where it is decided to not implant such an embryo. During the process of abortion the woman chooses to not carry and bear the child before the fetus becomes viable. Therefore it should be allowed to destroy a frozen pre-implantation embryo as it is not yet viable.[136]

Regarding the donor or recipient of cells in the application of stem cell therapy, it is submitted that section 12(2) could be used to protect the decision to undergo such procedures or treatments. Should a person thus choose to make use of stem cell therapy or to donate to stem cell research, section 12 may be invoked in order to protect this decision from any state, or other intervention. This argument is substantiated by *Castell v De Greef*[137] in which it was held that a person is entitled to make decisions regarding the form of medical treatment or intervention in the same way as they are entitled to refuse medical treatment on the grounds of bodily integrity. Stem cell therapy, utilising embryonic stem cells or iPS cells, as a form of medical treatment may therefore be protected under section 12(2).

[134] Section 2 of the Choice on Termination of Pregnancy Act states the circumstances in which pregnancy may be terminated. According to section 2(1)(a) "a pregnancy may be terminated upon request of a woman during the first 12 weeks of the gestation period of her pregnancy." From this one can then assume that before the 12th week of pregnancy the fetus is not seen as viable and can be terminated without any other compelling circumstances as those listed in the rest of section 2.
[135] *Roe v Wade* 410 US 113, 152 (1973). See Swanepoel (2006) LLM thesis 112.
[136] Schaefer K (1990) "In vitro fertilisation, frozen embryos and the right to privacy: Are mandatory donation laws constitutional?"*Pacific Law Journal* 22(1): 87 at 96-96.
[137] *Castell v De Greef* 1994 (4) SA 408 (C).

6.3 CONSENT[138]

The *Nuremberg Code* of 1974 first articulated the principle of informed consent and since then it has been accepted as an essential requirement for all research and experimentation, especially in clinical trials or medical procedure involving humans. Informed consent may be seen as both a legal and moral term. The legal notion finds concrete form in a formal, signed contract between the medical practitioner or scientist and the patient or research participant. Morally, informed consent is the realisation of optimal decision making by the patient or participant about if and how, they would take part in the proposed process.[139]

Since the subject of stem cell research is highly contentious, many different views exist as to how consent should be regulated. The Constitution provides for a framework to a certain extent.[140] Section 12(2)(c) explicitly states that no person may be subjected to medical or scientific experimentation without their informed consent. The use of the word "their" implies that proxy consent may not be given and that the research subject only may consent to the experimentation.[141] Van Oosten is however of the opinion that this is unrealistic and not "up- to- date" with national and international trends in this regard. In the context of stem cell research, this is impossible due to the very nature of the research subject.

Two issues however still remain in context of this dissertation. Firstly, does the use of the word "their" mean that research may therefore not be done on embryos, as naturally they cannot give their consent and secondly, when and to what extent can the societal benefits arising from medical and scientific research outweigh considerations of the individual's dignity and autonomy. The concept of informed consent must briefly be discussed before any further discussion surrounding this subject can take place.

The doctrine of informed consent usually requires a physician or the particular health care provider to give the patient sufficient information to enable that patient to make an

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[138] This section of this dissertation must be read in conjunction with chapter 5 *infra* which offers a more detailed discussion on consent. See in genral Van Wyk C (2001) "Guidelines on medical research ethics, medical 'experimentation' and the Constitution" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 64:4- 22.

[139] 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.

[140] Consent in context of stem cell technology may be seen as possessing over a constitutional layer, an ethical layer, a common law layer and a statutory layer as provided for by the National Health Act of 2003.

[141] Van Oosten FFW (2000) "The law and ethics of information and consent in medical research" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 63(1):5 at 17.

intelligent, informed decision regarding giving consent to a proposed medical treatment or procedure.[142] Consent may be regarded as the moral, ethical and legal expression of a person's right to respect for autonomy and self- determination. Therefore, any failure of a physician in obtaining consent from the patient could result in legal liability.[143] Consent is thus a prerequisite in any medical or scientific procedure.

Consent, in the context of medical interventions may be understood as a voluntary decision made by a competent person on the basis of adequate information.[144] This was reiterated in *Stoffberg v Elliott*[145] wherein it was held by Watermeyer J that any procedure undertaken on a person without consent is "an unlawful interference with his right to security and control of [the] body." For consent to be valid, the following components are thus required:[146]

1. Disclosure of all relevant information regarding the research or procedure;
2. Ensuring the proposed participant or patient understands the information that has been provided;
3. The patient or participant must be mentally and legally competent;
4. The consent must be given freely and voluntarily; and
5. Formal consent in the form of a written and signed contract or an acceptable alternative.

The relationship between a physician and patient, which is based on trust, gives rise to the physicians' obligation to obtain the patients informed consent. For consent to be informed however, it is required that the physician offers the patient a reasonable explanation of the contemplated treatment or procedure. This is referred to as the duty of disclosure.[147] The duty to disclose has been a part of the South African law for a long time and the doctrine of

[142] Currie & De Waal (2005) 311. See also Carstens & Pearmain (2007) 875- 876.
[143] Van Oosten FFW (1989) *The Doctrine of informed consent in medical law* (LLD thesis unpublished, UNISA) 31.
[144] Earle M (1995) "Informed consent: Is there room for the reasonable patient?" *South African Law Journal* 112(4): 629 at 629.
[145] *Stoffberg v Elliott* 1923 CPD 148.
[146] Van Loon & Lindegger (2009) *Health SA Gesondheid* 14(1): 1.
[147] See in general *Lymberg v Jefferies* 1925 AD 236. See also the discussion regarding the standard of disclosure in chapter 5 parahraph 2.4.1 *infra*.

informed consent was pertinently accepted in the case of *Castell v De Greef*.[148] The case stated the following which is relevant to this particular discussion of consent:

1. There is a definite need for the patient- orientated approach and thus informed consent;

2. The duty to disclose is seen in a contractual light;

3. The doctor must warn the patient of any material risks and a risk is material where a reasonable person in the patients shoes, if warned of the risks, would be likely to attach significance thereto, or the doctor is or should reasonably be aware that the specific patient, if warned of the risks, would be likely to attach significance to the risks; and

4. Expert evidence must be used in determining what risks are inherent in particular treatments.

The duty to disclose may in some instances however be limited by therapeutic privilege. This case further established the basis for further developments in this field of law.

Finally, the last important aspect of informed consent is the scope of information which must be given to the patient before consent can be sufficiently given. In *Rompel v Botha*[149] it was stated that consent was not given if the full scope of the proposed procedure is not explained to the patient. In context of stem cell research, the scope can however never fully be explained. It is submitted that this is an issue which will need to be clarified and perhaps a minimum scope must be established by any proposed legislation.[150]

It is thus clear that consent is required for any lawful medical or scientific intervention. Any scientific or medical procedure, experimentation or intervention is the absence of informed consent will be an infringement of a person's right to physical integrity. Regarding the issues as stated above,[151] it is submitted that the donor of research material will have to give

[148] *Castell v De Greef supra*.
[149] *Rompel v Botha* 1953 (T) (unreported) as mentioned by Van Oosten (1989) 47.
[150] See chapter 5 paragraph 7.1 for recommendations regarding such a minimum scope.
[151] Does the use of the word "their" mean that no research may be done on embryos, as an embryo cannot consent thereto and when and to what extent can the societal benefits acquired by medical and scientific research outweigh considerations of the individual's dignity and autonomy?

consent to any experimentation after the required information has been provided. Section 12(2)(c) states that everyone has the right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent. Since the embryo, or the donated cells in the case of iPS cells, cannot consent, it is a moot point to argue whether or not the donors consent is sufficient. It is submitted that the embryo or donated cells should thus be regarded as the product of the donor's body and thus the donor has control there over. This also applies to a person undergoing stem cell treatment and a participant in research. This issue however needs to be directly addressed by any legislation or regulations hoping to regulate stem cell research in South Africa.

Section 36 requires that a fundamental right may only be limited by a law of general application and that this must be done in a manner which is reasonable and justifiable in an open and democratic society. The importance of the community is thus emphasised. However, the proportionality inquiry requires a legitimate governmental purpose which is not overly restrictive of fundamental rights. It has been argued by public health scholars in South Africa,[152] that individual rights should only be limited in the interest of public health, thus societal benefit, when it is the least invasive option which is available to the state. In that case the public health measures must be clearly conceptualised, effective, well-targeted, linked to realistic risk assessments and be administered in a transparent and fair manner.[153] Section 36 of the Constitution will have to be employed in order to find a balance between the competing rights and interests of autonomy and the benefits to society and the courts will have to clarify this situation when the time comes.

[152] See in general Mann JM, Gruskin S, Gordin MA & Annas GJ (eds) (1999) *Health and Human Rights: A reader* 54- 71.
[153] Pieterse & Hassim (2009) *SALJ* 232. See also Carstens P (2009) *Obiter* 420- 429.

7 SECTION 14: PRIVACY[154]

The privacy debate is an emotional and complicated one as it has implications for bodily privacy, communication and personal information and the right to privacy as enshrined in section 14 of the Constitution is not absolute and can therefore be limited in terms of section 36. This means that competing interests must be balanced.[155]

Privacy finds its roots in the common law wherein every person has personality rights which further include the right to physical integrity, reputation, freedom and dignity. Privacy is special in that both juristic and natural persons are entitled thereto. Also, the concept of *boni mores*[156] is relevant to privacy as it sets the standard of measurement of the wrongfulness of any privacy violation. The facts of each individual case and the community's sense of justice are other factors that will play a role in determining whether or not an infringement, or alleged infringement, on privacy may be justified.

McGregor and Moore[157] state that an inviolable sphere of privacy which is beyond the reach of public authority is constitutionally recognized. Thus certain matters pertaining to privacy are of such a nature that it cannot be regulated by the state. This includes choices regarding marriage, family size, contraception and child rearing as they are matters concerning an individual's values, morality and conscience.

The protection of human dignity is also linked to the protection of privacy as it guarantees a person's right to have control over the use of their private information. In *Jansen van Vuuren v Kruger*[158] it was remarked by Harms J that even in the case of serious disease, *in casu* AIDS, the right to privacy is not detracted from, especially where it stems from practitioner- patient relations. In this case the HIV status of the plaintiff was disclosed by the

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[154] Section 14: **Privacy**
Everyone has the right to privacy, which includes the right not to have
a. their person or home searched;
b. their property searched;
c. their possessions seized; or
d. the privacy of their communications infringed.

[155] See Slabbert (2000) LLD thesis 374- 377 for a discussion on the right to privacy. See also Carstens & Pearmain (2007) 32- 33, Devenish (2005) 78- 86 and McQuiod- Mason D (2002) "Privacy" chapter 38 in CLoSA.

[156] For a discussion on the concept of *boni mores* see in general Carstens & Pearmain (2007) 297- 302. See also Devenish (2005) 23.

[157] As mentioned by Swanepoel (2006) LLM thesis 115.

[158] *Jansen van Vuuren v Kruger* 1993 (4) SA 842 (A).

first defendant to two of his colleagues during a game of golf after he had expressly promised to keep the information confidential. Privacy and human dignity are therefore closely connected as any information which has a negative impact on a person's image, damages that person's dignity.[159] Information, private and personal, is required in the realisation reproductive health.

The following question thus arises: do parents have the fundamental right to decide the fate of the embryo? This includes the right to decide to destroy the embryo should the parents decide not to have children. The right to procreate, the right to have an abortion, the right to contraception and the privacy interests involved in marital relationships are included in the right to privacy. Thus, the issue is whether or not parents are entitled to destroy an embryo under the provisions of section 14. As the creators of the embryo, most would agree that the parents have authority to make decisions regarding the embryo but the scope of the parents' rights over the embryo is still unclear and undefined.

Narrowly seen, the destruction of a pre- implantation embryo has not traditionally been protected by society. When seen with a wider perspective one can however argue that although this method of embryo destruction is new, the concept thereof has been protected by courts. *Roe v Wade*[160] is an illustration of this. Contraceptive methods such as the intra-uterine device, which destroys embryos, have also been legally protected as falling under the right to privacy.[161] It thus becomes obvious that courts have consistently found that reproductive decisions[162] are inherently private and protected from state interference.[163] For this reason it is important to discuss abortion and contraception as guidelines in overcoming the issues surrounding embryo destruction.

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[159] It is therefore obvious that freedom of information must be kept in consideration when dealing with privacy matters. See section 32 of the Constitution: **Access to information**

1. Everyone has the right of access to
    a. any information held by the state; and
    b. any information that is held by another person and that is required for the exercise or protection of any rights.
2. National legislation must be enacted to give effect to this right, and may provide for reasonable measures to alleviate the administrative and financial burden on the state.

See also section 9 and 34 of the Promotion of Access to Information Act, Act 2 of 2000.

[160] *Roe v Wade supra.*

[161] Swanepoel (2006) LLM thesis 118.

[162] This includes contraceptives, abortion and embryo destruction.

[163] It is submitted that for the state to be permitted to interfere, it must be justified by a compelling state interest. See Schaefer (1990) *Pac LJ* 22(1): 87 at 100- 105.

7.1 ABORTION AND EMBRYO DESTRUCTION

As the same privacy interests are involved in abortion and embryo destruction, arguments surrounding abortion may offer insight into the issues surrounding embryo destruction. One such issue is the conflict between the right to privacy and the right to life. The state has an interest in protecting potential life. Therefore, it is submitted that to be able to find that parents have the right to destroy a pre- implantation embryo, courts will have to find that destruction of an embryo is similar to previously protected privacy interest such as abortion and contraception.[164] Some of the similarities that should be considered may be taken from the *Roe* case:

1. The psychological impact of an unwanted child on the mother and the possible distress. This could be caused by the stigmatisation of single mothers;
2. The emotional attachment between the parents and the child;
3. The fear and concern of having another couple raise one's biological child should adoption or embryo donation be considered as alternative.

A further consideration which is of importance is the violation of a woman's bodily privacy if she were to be forced to bear a child. This stands even in cases where the woman's body is not involved, such as during *in vitro* fertilisation, as it remains a privacy interest to decide to not have children. Therefore, parents should be permitted to destroy the embryo before implantation on the grounds of previous decisions to protect abortion and reproductive choices.[165]

7.2 CONTRACEPTION AND EMBRYO DESTRUCTION

The privacy interests in a person's use of contraceptives are similar to the interests in destroying an embryo. The intra- uterine device prevents the implantation of the embryo inside the body of the woman after her decision to use that particular contraceptive

[164] For a general discussion see *Carey v Population Services International* 431 U.S. 678 (1977) and Robertson JA (1987) "Gestational burdens and fetal status: Justifying Roe v Wade" *American Journal of Law & Medicine* 13(2): 189- 212.
[165] Schaefer (1990) *Pac LJ* 87 at 115- 117.

method. The destruction of an embryo intended for *in vitro* fertilisation is also done by choice. Therefore the only difference is the context in which the embryo is destroyed.

Policy considerations are of further assistance. Where a couple is capable of natural conception, they could later decide to undergo an abortion. A couple making use of *in virto* fertilisation should thus have the same freedom as even after implantation a decision could be made to abort. Destruction of the embryo at the pre- implantation phase can therefore be seen as avoiding the trauma of abortion at a later stage.[166]

Although slight differences do exist between *in vitro* fertilisation, abortion and contraception and keeping the states interests in mind, it is safe to say that the same privacy interests are applicable. The courts should thus be able to pronounce the destruction of an embryo as included in the fundamental right to privacy.

It is however also important to examine the privacy interests which could be affected in the process of somatic cell nuclear transfer and more specifically induced pluripotent stem cells. The reason for this is the fact that in the course of these procedures, certain tests might be performed on the donated material and information may be acquired about the donor such as a predisposition to cancer or genetic diseases. The right to privacy is considered relevant due to the fact that genetic information is very personal in nature.[167] Section 14 may be used to protect the donor against a request to undergo genetic testing[168] and may be used to protect the communication[169] between the donor and the scientist or medical practitioner. Privacy may further become relevant when a person attempts to bank stem cells. Stem cell banks must adhere to strict quality standards which include testing the safety of prospective cells.[170] Should information surface which renders the cells undesirable, stem cell banks may refuse storage thereof. This could likely amount to discrimination or even an infringement on a person's right to access to health care services. It must further be mentioned that in the context of genetic information, privacy is linked to the right to human dignity as the information which could be accrued by genetic testing

[166] Swanepoel (2006) LLM thesis 120.
[167] Nienaber & Van der Nest (2004) *THRHR* 67:446 at 455.
[168] Section 14(a) prohibits searches of the person.
[169] Section 14(d) prohibits the infringement of private communications.
[170] See chapter 4 paragraph *infra* 4.4 for more on this.

could have implications on a person's view of themself and the way in which society perceived them.

In *Bernstein v Bester*,[171] Langa J stated:

> "Privacy is a right which becomes more intense the closer it moves to the intimate personal sphere of the life of human beings, and less intense as it moves away from the core."

It is submitted that this confirms the inherent privacy in a person's genetic composition as it is most probably the most personal element of a human being. Nienaber and Van der Nest[172] state that the "truly personal realm" of a person is threatened when a person is compelled to reveal or undergo genetic testing and few intrusions on the self could be more sever. It thus becomes obvious that genetic information is uniquely personal and deserves special protection. It must however be mentioned that the right to privacy may be limited by the communities' interests.[173] The issue is thus raised on whether or not information regarding a donor's genetic composition or predisposition towards certain conditions or diseases should be kept on record by stem cell banks and if so, if this information should be made available to the prospective recipient of the donated material. The community does have an interest in receiving safe donated material. This issue is however addressed in the course of this dissertation.

[171] *Bernstein v Bester* 1996 (2) SA 751 (CC).
[172] Nienaber & Van der Nest (2004) *THRHR* 67: 446 at 458.
[173] *Idem* 460.

8 SECTION 15: CONSCIENCE, RELIGION, THOUGHT, BELIEF AND OPINION[174]

The right to freedom of conscience compromises of more than religious beliefs and is all encompassing in that it also protects the political, ethical and moral beliefs and practices which are genuine and which are held in spite of whether or not they fall outside of conventional religious doctrines or practices.[175] It is thus submitted that section 15 consists of two separate elements and a distinction is made between religious freedom and the freedom of conscience, thought, belief and opinion. For the purpose of this dissertation freedom of conscience, though, belief and opinion may be seen as falling under the umbrella of peace of mind. The distinction is due to the fact that religion is connected to a higher power and is often substantiated by scripture whereas peace of mind is based on more abstract notions, ideas, values or even tradition and culture which are seldom linked to an organised lifestyle.

8.1 FREEDOM OF RELIGION

In *S v Lawrence*,[176] the essence of religious freedom was described as:

> "The right to entertain such religious beliefs as a person chooses, the right to declare religious beliefs openly and without fear or hindrance or reprisal, and

[174] Section 15: **Freedom of religion, belief and opinion**
1. Everyone has the right to freedom of conscience, religion, thought, belief and opinion.
2. Religious observances may be conducted at state or state-aided institutions, provided that
   a. those observances follow rules made by the appropriate public authorities;
   b. they are conducted on an equitable basis; and
   c. attendance at them is free and voluntary.
3. This section does not prevent legislation recognising
   i. marriages concluded under any tradition, or a system of religious, personal or family law; or
   ii. systems of personal and family law under any tradition, or adhered to by persons professing a particular religion.
   b. Recognition in terms of paragraph (a) must be consistent with this section and the other provisions of the Constitution.

[175] Devenish GE (1999) *A commentary on the South African Bill of Rights* 183. See also Devenish (2005) 87- 94 and Farlam P (2002) "Freedom of religion, belief and opinion" chapter 41 in CLoSA.

[176] *S v Lawrence* 1997 (4) SA 1176 (CC).

> the right to manifest religious belief by worship and practice or by teaching and dissemination."[177]

The limitation clause will play a pivotal role in the resolution of disputes which concern an individual's right to religious freedom due to the fact that the broad ambit of this right opens it to violation. It is not a case of commitment to conviction, it must be taken as a given and the effect or even purpose of legislation could infringe upon this right. The National Health Act, the Human Tissue Act and the Choice on Termination of Pregnancy Act violate certain religious groups' freedom of religion in the context of stem cell research.[178]

Liebenberg J explained this in *Christian Education SA v Minister of Education*:[179]

> "In cases of this nature a court will in the first place consider whether the belief relied upon is fact forms part of the religious doctrine of the religion practiced by the person concerned. Once it is found that the belief does form part of the doctrine, the court will not embark upon an evaluation of the acceptability, logic, consistency, or comprehensibility of the belief. But, the court will then inquire into the sincerity of the person's claim that a conflict exists between the legislation and the belief which is indeed burdensome to the person."

Most human rights treaties contain the right to religious freedom, but members of religious communities often misuse this right to justify unconstitutional aspects of religious behaviour.[180] In the context of stem cell research, the focus thus falls on the right to religious expression and philosophical or social convictions regarding reproductive self-determination. This means that on the one hand persons may enjoy human rights concerning reproductive choice, and on the other that those who provide certain health care services are not forced to participate in practices that they might find offensive

[177] *R v Big Drug Mart* [1985] 1 SCR 295 at 336 as mentioned by Chaskalson P in *S v Lawrence supra*.
[178] The National Health Act, Act 61 of 2003; the Human Tissue Act, Act 65 of 1983 which is soon to be repealed by the National Health Act and the Choice on Termination of Pregnancy Act, Act 92 of 1996. See also Currie & De Waal (2005) 341.
[179] *Christian Education SA V Minister of Education* 2000 (4) SA 757 (CC).
[180] *Ibid.*

according to their beliefs. This belief may however not be used as justification for refusal to partake in life- saving procedures.[181]

8.2 PEACE OF MIND

Freedom of conscience has universal appeal and has been entrenched in numerous international instruments of human rights. These include the *Universal Declaration of Human Rights*[182] and the *International Covenant on Civil and Political Rights*.[183] Regional instruments such as the *European Convention on Human Rights*[184] and the *African Charter on Human and Peoples Rights*[185] also protect this right. This right may be described as an affirmation of moral diversity and is an acknowledgement that people do not always share the same outlook.[186] The practice of freedom of conscience, belief thought and opinion must also be protected as it serves no purpose in protecting the right, but not the manifestation thereof.[187] The belief would be undermined or nullified in the absence of protection of the practice.

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[181] Slabbert (2000) LLD thesis 363 & 364.

[182] Article 18 states "Everyone has the right to freedom of thought, conscience and religion; this right includes freedom to change his religion or belief, and freedom, either alone or in community with others and in public or private, to manifest his religion or belief in teaching, practice, worship and observance."

[183] Article 18 states the following: (1) Everyone shall have the right to freedom of thought, conscience and religion. This right shall include freedom to have or to adopt a religion or belief of his choice, and freedom, either individually or in community with others and in public or private, to manifest his religion or belief in worship, observance, practice and teaching. (2) No one shall be subject to coercion which would impair his freedom to have or to adopt a religion or belief of his choice. (3) Freedom to manifest one's religion or beliefs may be subject only to such limitations as are prescribed by law and are necessary to protect public safety, order, health, or morals or the fundamental rights and freedoms of others. (4) The States Parties to the present Covenant undertake to have respect for the liberty of parents and, when applicable, legal guardians to ensure the religious and moral education of their children in conformity with their own convictions.

[184] Article 9 states the following: (1) Freedom of conscience, the profession and free practice of religion shall be guaranteed. No one may, subject to law and order, be submitted to measures restricting the exercise of these freedoms. (2)Freedom to manifest one's religion or beliefs shall be subject only to such limitations as are prescribed by law and are necessary in a democratic society in the interests of public safety, for the protection of public order, health or morals, or the protection of the rights and freedoms of others.
2.Freedom to manifest one's religion or beliefs shall be subject only to such limitations as are prescribed by law and are necessary in a democratic society in the interests of public safety, for the protection of public order, health or morals, or the protection of the rights and freedoms of others

[185] Article 8: "Freedom of conscience, the profession and free practice of religion shall be guaranteed. No one may, subject to law and order, be submitted to measures restricting the exercise of these freedoms."

[186] Ngwena C (2003) "Conscientious objection and legal abortion in South Africa: Delineating the parameters" *Journal for Juridical Science* 28(1): 1 at 5.

[187] Hammer L (1999) "Abortion objection in the United Kingdom within the framework of the European Convention of Human Rights and Fundamental Freedoms" *European Human Rights Law Review* 6: 564 at 572.

An assessment of the right to freedom of conscience, though, belief and opinion in context of the Choice on Termination of Pregnancy Act is useful in examining the impact this fundamental right will have in the debate regarding stem cell research. Access to an abortion is seen as a constitutional right according to the preamble of the Constitution and while the Choice on Termination of Pregnancy Act has made a huge impact in the realisation of the reproductive rights of women as well as meeting the health needs of women, abortion is not supported by everyone and is underpinned by moral dichotonomy.[188] Many health care providers refuse to partake in abortions based on conscientious of religious grounds and the question arises whether this right may be limited in terms of section 36. In the context of stem cell technology, the same problem may occur as stem cell research is highly contentious and may offend the beliefs of the health care provider. This right is thus examined in a different light than the other provisions which have been, and will be discussed in this dissertation. Here, the focus falls on a third party, namely the health care practitioner and not on the donor of embryos, a fetus or adult cells nor the embryo itself or the recipient of the stem cell therapy.

No political ideology, religion, science or law is capable of masking the rift between differing attitudes towards stem cell research. It is thus necessary to respect individual autonomy. For many health care practitioners, their services are a moral enterprise and not simply a technical of indifferent exercise.[189] Stem cell research and therapy is morally controversial and thus have an impact on the health care providers who are expected to participate therein. This could be, seen from the health care practitioners' point of view, experienced as self- betrayal or participation in the destruction of innocent life.[190] This obligation is excessively utilitarian and does not regard the medical personnel as a person with equal moral worth. Ethically seen the protection of freedom of conscience protects moral integrity and human dignity. Respect for human dignity implies respect for moral diversity, individual

[188] Ngwena (2003) *Journal for Juridical Sciences* 1 at 4.
[189] Wicclair MR (2000) "Conscientious objection in medicine" *Bioethics* 14(3) 205 at 215.
[190] Hammer L (1999) "Abortion objection in the United Kingdom within the framework of the European Convention of Human Rights and Fundamental Freedoms" *European Human Rights Law Review* 6: 564 at 572-574. See also Dickens BM (2000) "Reproductive health services and the law and ethics on conscientious object" Proceedings to the 13th Congress on Medical Law, Helsinki 266 at 227.

autonomy and moral integrity as values which guide the manner in which health care practitioners interpret and practice their duties.[191]

As illustrated by the above, freedom of conscience is connected to other constitutional rights. Section 10 protects human dignity and it could be argued that the suggested respect for dignity is the source and origin of conscientious objection.[192] The concept of human dignity is not only found in Western though but also in African moral thought and is embodies in the value of *ubuntu*. Here, it is important to explain that *ubuntu* is the belief that all persons are connected and are only human, by the humanness of others. It is therefore submitted that freedom of conscience is perhaps, on a philosophical level what makes and human an individual and it is therefore applicable to the current discussion. In *Makwanyane*,[193] Mokgoro J stated that ubuntu is ultimately about humanity and morality. Section 9 of the Constitution is of some importance as no person may be unfairly discriminated against on religious or related grounds.

The limitation of this right is thus of great importance as the rights protected in section 15 of the Constitution are not absolute. The Constitution must be called upon to address the situation of conscientious object as the Choice on Termination of Pregnancy Act omits to do so. Section 36 may be used to limit this right in two cases. Firstly where maternal life or health is at risk and secondly, where a medical emergency exists. It is further stated that given the current position of the South African health system, shortage of skilled medical personnel for instance, section 36 could be used to impose a duty on health care practitioners and thus limit this right.[194] It is submitted that in the context of abortion, the Constitution is the only available yardstick to determine if the right to freedom of conscience may be limited.[195]

[191] Wicclair MR (2000) "Conscientious objection in medicine" *Bioethics* 14(3): 205 at 210- 217. See also Beauchamp TL & Childress JF (1994) *Principles of biomedical ethics* 478- 483.
[192] Chaskalson A (2000) "Human dignity as a foundational value under our constitutional order" *South African Journal on Human Rights* 16:193 at 197- 198.
[193] *S v Makwanyane and Another supra.*
[194] Ngwena (2003) *Journal for Juridical Science* 1 at 5.
[195] For a detailed discussion hereof see Ngwena C (2003) *Journal for Juridical Science* 1 at 11- 16.

9 SECTION 16: FREEDOM OF EXPRESSION[196]

Freedom of expression includes academic freedom and freedom of scientific research.[197] Generously interpreted,[198] the process of scientific research is thus protected and encouraged. Stem cell research may therefore fall into this category.[199] Freedom of expression which includes and more specifically for the purpose of this dissertation, freedom of scientific research is fundamentally connected to human dignity.[200] Freedom of scientific research could be described as a part of individual autonomy and self-actualisation on two levels. Firstly on the level of the scientist as the exercise of his freedom and secondly, at a societal level as it constitutes the beneficiaries of this science which constitutes the exercise of such freedom. On contemplation, science has offered humanity various gifts. Surely not all of these gifts have improved human life, the atom bomb is an example of ways in which science has enabled humans to more effectively destroy each other, but when considering the positive contributions of science, one must admit humanity has undoubtedly benefitted enormously. Examples of this include new career choices which allow for the realisation of talent[201] and embryo research which has made it possible for barren couples to have children.[202] It is submitted that the relationship between society and science is based on freedom of scientific research as scientific advancement is a *condition sine qua non* for improvement of human lives.

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[196] Section 16:**Freedom of expression**

1. Everyone has the right to freedom of expression, which includes
    a. freedom of the press and other media;
    b. freedom to receive or impart information or ideas;
    c. freedom of artistic creativity; and
    d. academic freedom and freedom of scientific research.
2. The right in subsection (1) does not extend to
    a. propaganda for war;
    b. incitement of imminent violence; or
    c. advocacy of hatred that is based on race, ethnicity, gender or religion, and that constitutes incitement to cause harm.

See in general Milo D, Penford G & Stein A (2002) "Freedom of expression" chapter 42 in CLoSA. See also Devenish (2005) 95- 97.

[197] Section 16(1)(c).

[198] Kentridge AJ in *S v Zuma* 1995 (2) SA 642 (CC) stated that constitutional rights must be generously interpreted.

[199] Slabbert MN (2001) "Are the human embryo and foetus *extra uterum* sufficiently protected in terms of South African law?" *Tydskrif vir die Suid- Afrikaanse Reg* (3): 495 at 504

[200] See parapaph 4 *supra* regarding dignity.

[201] See also pararagraph12.5 *infra* regarding freedom of trade, occupation and profession.

[202] Jordaan DW (2007) *SALJ* 618 at 632.

Medicine is a field that is in constant need of progress and therefore research and experimentation is necessary. "Experimentation" could be understood as nothing more than research.[203] Medical or scientific experimentation however still confronts society with complex ethical dilemmas.[204] For the purpose of this dissertation, medical and scientific experimentation concerns stem cells and therefore the human embryo and other cells of the human body. Clearly, this is a contentious subject and has caused many ethical debates. Ethics as regulatory framework is discussed in the course of this dissertation.[205] The Constitution however attempts to overcome some of the difficulties concerning experimentation on human subjects and a discussion thereof follows.

Firstly, mention should be made of section 12(2)(c) of the Constitution which states that "everyone has the right to bodily and psychological integrity, which includes the right to not be subjected to medical or scientific experiments without their informed consent." This right can thus be divided into two components. The first leads to the question of what medical or scientific experimentation comprises of and the second concerns informed consent. Consent has been discussed previously in this dissertation.[206]

To determine the meaning of medical or scientific experimentation is however a much more complicated process than one would imagine. This is due to the fact the "normal" everyday medical treatments are seen as experimentation, all be it a different kind. For example, no two patients react in exactly the same manner when identical medication is prescribed or procedure is done.[207] Medical knowledge is therefore not absolute and it is submitted that medicine is the profession in the greatest need of continuous development.[208]

Development is however dependant on research and experimentation and two opposing interests are present and must be balanced in an experimental situation:

1. The interests of the patient not to be subjected to any abuse that may result from an uncontrolled experiment; and

[203] Van Wyk (2004) *THRHR* 1 at 8.
[204] Van Wyk (2001) *THRHR* 3 at 6.
[205] See chapter 4 *infra*.
[206] See paragraph 6.3 *supra* regarding consent.
[207] Currie & de Waal (2005) 310.
[208] Claassen NJB & Verschoor T (1992) *Medical negligence in South Africa* 54.

2. The interests of the physician and of society in furthering knowledge of treatment of disease.[209]

Section 16(1)(d) of the Constitution reads that everyone has the right to freedom of expression, which includes academic freedom and freedom of scientific research. The right to do research may be seen as the core of the right to academic freedom. This right does not only vest in universities but also in individual academics.[210] Human genetics and state regulation is currently one of the areas in which the most contradictions are found. Section 16 suggests that the state has a positive duty to promote research and teaching via functional academic and scientific institutions. At the very least, the state must provide the necessary financial and organisational backup required to exercise the right to academic freedom and scientific research.[211]

The most important question is whether embryo research should be constitutionally permitted. Issues in embryo research include:

1. To what point in embryonic development research is possible;
2. Whether it is admissible to create embryos for the sole purpose of research; and
3. What can embryonic stem cells or fetal tissues be used for.

The significance lays in whether or not it is permissible to destroy embryos for research purposes and if so, up until what point in the development of the embryo it would be permissible. As previously stated, arguments for and against embryo research do exist but benefits of stem cell research which could not be attained in any other way and falls into four categories:

1. Improving infertility treatment;
2. Gaining further knowledge about the cause of congenial diseases;
3. Developing more effective contraceptive methods; and

[209] *Ibid*.
[210] Currie & De Waal(2005) 370. See in general Alston K (2007) "The right to academic freedom in South African schools" *Acta Academica* August 39(2): 158-179.
[211] Currie & De Waal (2005) 371.

4. Detecting abnormalities in genes or chromosome before implantation of an embryo.[212]

The main conflict and also an important question in context of stem cell research concerns whether or not embryos can be created for the specific purpose of research. Some justify using created embryos by stating that it is better that some good come from using these embryos than simply destroying them as most research embryos are by- products which were created for *in vitro* fertilisation but were never used.[213] The intention however to create an embryo for research or for creating a child differs greatly. This argument is correct but still offers no solution to the moral or ethical issues surrounding this research. The following arguments can be made to support the use of "spare embryos" for research purposes:

1. "Spare embryos" are created as unavoidable consequence even if the intention of creation was originally for reproductive purposes. This means the line between creating embryos for reproduction and research is blurred;

2. When looking at this situation form a Kantian point of view,[214] the intention to "use" these embryos as a "means" to other ends can only be used if it is established that these embryos are persons, which most would now agree on is not the case;[215] and

3. Although the motives behind such intentions are not altruistic,[216] it cannot be inferred that embryo experimentation is wrong.[217]

[212] Lupton (1992) *TSAR* 466 at 467 & 468. See also Carstens & Pearmain (2007) 198.
[213] Blackbeard M (2002) "Therapeutic cloning-OK?" *De Jure* 35(2) 318.
[214] According to Deontological ethics the "end" never justifies the "means," the means must be ethical in their own right. See in general Stanford Encyclopaedia of Philosophy "Deontological ethics" at http://plato.stanford.edu/ethics/entries/ethics-deontological/ accessed 20/6/2010. For a discussion of Deontology versus utilitarianism in context of medicine see Steinberg A "Medical ethics" available at http://www.medethics.org.il/articles/JME/JMEB1/JMEB1.1.asp accessed 3/6/2010.
[215] The Kantian model which requires one to treat a person as an end and not as a means [to an end] is often applied, incorrectly, to experimentation on embryos. Neither the law nor Deontology considers an embryo a person. Kantian ethics regard the embryo as a means to an end as it is not an autonomous moral agent. See Jordaan (2007) *SALJ* 618 at 631.
[216] Altruism is the unselfish concern for other people. See in general Stanford Encyclopaedia of Philosophy "Biological altruism" at http://plato.stanford.edu/entries/altruism-biological/ accessed 20/ 6/ 2010.
[217] Schüklenk U & Ashcroft R (2000) "The ethics of reproductive and therapeutic cloning" *Monash Bioethics Review* 19(2):34 at 42- 44. See also Swanepoel (2006) LLM thesis 132.

A further concern is related to the question of what happens should it one day, become routine to use stem cells in treatment. Where will all these embryos come from? The concern here is that embryos will be mass- produced in order for stem cells to be harvested and thus destroyed in the process. Furthermore, other concerns include firstly, that women could possibly be exploited.[218] Secondly, that this is the start of the slippery slope to reproductive cloning and thirdly, that false hope could be given to patients by promises made to early.[219] Also questions as to [intellectual] property rights in cell lines and the techniques used are raised.[220]

The right to scientific freedom must be acknowledges and its position in the debate surrounding stem cell research cannot be downsized. Not only does this right have implications for the procurement of stem cells but also for the process of distribution or banking thereof. In conclusion it is submitted that the scientific community should be given the right to research and explore the possibilities of stem cell research but under governmental supervision and also under guidance of an independent regulatory body following strict ethical guidelines.[221]

[218] For more see chapter 4 paragraph 2.4.1 *infra* regarding exploitation of women and justice concerns.

[219] See Dhai A (2004) "Ethical and legal controversies in cloning for biomedical research: A South African perspective" *SAMJ* 94(11): 906 at 906 & 907 in this regard.

[220] Issues surrounding the procurement and use of stem cells lead to questions regarding the commercialisation and patenting of biological material. Patents on stem cells could be seen as invalid for two reasons. Firstly, stem cells are found in nature and secondly, stem cells are a human life form. Therefore, human stem cells are not a patentable subject matter. See Miller J (2003) "A call to legal arms: Bringing embryonic stem cell therapies to market" *Albany Law Journal of Science & Technology* 13(2):555. Schüklenk & Ashcroft further argue that the issue surrounding stem cell lines patents require the technology to be regulated and should not place prohibitions based on moral grounds on stem cell research. See also Laurie G (2004) "Patenting stem cells of human origin" *European Intellectual Property Review* 26(2): 59 at 60- 66, Enmon (2002) *Utah L Rev* 621 at 621- 648 and Miller (2003) *Alb LJ Sci & Tech* 555 at 592 for more on stem cell lines.

[221] It is submitted that such an independent regulatory body should be based on the United Kingdom model of the Human Tissue Authority and Human Fertilisation and Embryology Authority. For more see chapter 6 paragraph 4.1.

10 SECTION 27: HEALTH CARE, FOOD, WATER AND SOCIAL SECURITY[222]

The 1996 Constitution is the first constitution in the world to entrench socio- economic rights[223] and post- 1996, South African courts are constitutionally obligated to give meaning to socio- economic rights by interpretation, to evaluate the governments' compliance with imposed duties, pronounce on the validity of legislation and policy concerning socio-economic rights and to remedy non- compliance with socio- economic obligations.[224] The Constitution provides wide recognition of socio- economic rights and there is no distinction[225] between first, second and third generation rights in the Bill of Rights.[226] Although some argue that socio- economic rights are not enforceable,[227] the court has stated that socio- economic rights are "justifiable" to an extent.[228] Yacoob J held in *Grootboom*[229] that socio- economic rights are expressly included in the Bill of Rights and can

[222] Section 27: **Health care, food, water and social security**

1. Everyone has the right to have access to
    a. health care services, including reproductive health care;
    b. sufficient food and water; and
    c. social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
2. The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
3. No one may be refused emergency medical treatment.

[223] Iles (2004) *SAJHR* 448 at 449.

[224] Pieters M (2004) "Coming to term with judicial enforcement of socio- economic rights" *South African Journal on Human Rights* 20(3): 383 at 383.

[225] Socio- economic rights have been said to differ from civil and political rights on the basis that they are positive in nature and thus not suitable for judicial deliberation, ideologically loaded, vague and indeterminate, expensive to realise and achievable only progressively. Civil and political rights on the other hand are said to be negative in nature, ideologically neutral, precise in their content and imposed obligations, cheap[er] to realise and can be immediately realised. See Pieters (2004) *SAJHR* 383 at 389. I was however held in during the certification proceedings of the Constitution that civil and political rights could also have cost implications and it is thus submitted that socio- economic rights are no less justiciable on these grounds. See also *Ex parte Chairperson of the Constitutional Assembly: In re Certification of the Constitution of the Republic of South Africa, 1996* 1996 (4) SA 744 (CC). See in general Devenish (2005) 145- 151.

[226] Socio- economic rights are therefore equal in status to political and civil rights. In 1689, John Lock published the first model of human rights, thus the first generation of human rights, in *Two treaties of civil government*. Locks main focus fell on civil rights. This included *inter alia* the right to exist, personal freedom and self fulfilment. These rights may thus be described as the rights which make human existence possible. The South African Constitution has entrenched the spirit of this in the rights to equality, dignity and life. In 1762, Jean-Jacques Rousseau expanded the concept of human rights to include political rights such as the right to choose ones leaders. This principle is illustrated by the principle of democracy. Rousseau is therefore responsible for the second generation of human rights. Socio- economic rights as the third generation of rights surfaced in the early decades of the 20th century. See in general Van Wyk (2005) *Koers* 455- 471.

[227] Van Wyk J (1999) *Planning Law in South Africa* 34.

[228] *Ex parte Chairperson of the Constitutional Assembly: In re: certification of the Constitution of South Africa supra*.

[229] *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC).

therefore not be said to exist only on paper. It is however difficult to enforce such rights and this will have to be examined on a case- by- case basis.

Section 7(2) of the Constitution reads that the state must "respect, protect, promote and fulfil the rights in the Bill of Rights" and therefore places a duty, positive or negative, on the state to act in a certain manner. This duty is further emphasized by section 27(2) which requires reasonable legislative measures to progressively realise access to health care and section 24(a) which entitles citizens to a healthy environment. The term "reasonable," as used in the internal limitations of section 27(2) has not been defined by the Constitutional Court and as it is context- sensitive, it may only be defined on a case- by- case basis.[230] To determine the exact scope and nature of this duty the wording of the right and its relationship to other fundamental rights must be examined.[231] "Respect" suggests a negative duty in that the state may not interfere unjustly with an individual's rights. The state may therefore, in no way, impair a woman's right to reproductive health care in the context of reproductive health care. This includes a woman's right to terminate pregnancy. "Promote" places a positive duty on the state to ensure that executive and legislative frameworks exist to ensure the protection of citizens. "Fulfil" suggests a positive duty to ensure the realization of a right by providing therefore. This could mean the state must provide for the resources necessary to realize the right.[232] Socio- economic rights may however be qualified by the availability of resources.[233] The state is not under an

[230] Iles (2004) *SAJHR* 448 at 455- 463. See in general Stewart L (2008) "Interpreting and limiting basic socio-economic rights of children in cases where they overlap with the socio- economic rights of others" *South African Journal on Human Rights* 24(3): 472 at 485- 493.

[231] Regarding the duties of the state and the enforcement of socio- economic rights see Pieters (2004) *SAJHR* 383 at 403- 416.

[232] See in general *Governemnt of the Republic of South Africa and Others v Grootboom and Others supra.*

[233] The argument could be made that stem cells are a scarce resource and that this will play a role in any matter wherein stem cell therapy is see as falling within the right to access to health services. The use of scarce resources in context of cloning has also been the subject of critique as the extension of primary health care to all South Africans must be regarded as the first priority in the field of medical care. Questions are thus raised as to whether research into and the practice of stem cell technology justifies the use of state resources. Stem cells are scarce and therefore care should be taken in the use thereof. Health researchers should deal responsibly with scarce health care resources and refrain from research that duplicates other research and from any form of resource wastage which might occur in the process of carrying out research. Research must be designed and conducted to include or provide the use of appropriate facilities, so as to manage any contingencies while avoiding research which has an adverse impact on public health facilities. See MRC (Book 2) paragraph 3.4.4.2 and HPCSA "General ethical guidelines for health researchers" Guidelines for good practice in the health care professions, Booklet 6: 9 available at http://www.hpcsa.co.za/hpcsa.default.aspx?id+152 accessed 8/7/2009.

unqualified obligation to meet the needs for the people of the state.[234] A balance is therefore necessary between the constitutional objectives and the available means by which to achieve these objectives. An attempt must be made to achieve these goals effectively and expeditiously but in determining what is reasonable, the amount of available resources will play an important role. Reasonableness must thus be understood in context of the Bill of Rights.[235]

According to the *International Covenant on Economic, Social and Cultural Rights* (ICESCR),[236] the state has a "minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels" of socio- economic rights. South Africa is not a party to the covenant, but must consider international law when interpreting the Bill of Right according to section 39(2) of the Constitution. The state must thus only discharge a core obligation when there are insufficient resources and the state can show that every effort was made to meet the minimum level of the right.

10.1 ACCESS TO HEALTH CARE SERVICES[237]

The South African Constitution states that everyone has the right of access to health care and the realisation of woman's right to access to health care is a pivotal aspect which is included therein. The courts are bound to consider international law according to section 39(1) of the Constitution when rights are interpreted and thus the highest attainable standard of health care is provided for by the ICESCR.[238] The Committee on Economic and Social Cultural Rights (CESCR) and also the Committee on the Elimination of Discrimination Against Women (CEDAW) have interpreted this right and concluded that the importance thereof lies in the realisation of women's health.[239] CESCR General Comment No 14[240] on

[234] *Soobramoney v The Minister of Health, KwaZulu- Natal* 1997 12 BCLR 1696 (CC).
[235] *Governemnt of the Republic of South Africa and Others v Grootboom and Others supra.* See also Liebenberg S (2001) "The right to social assistance: The implications of *Grootboom* for policy reform in South Africa" *South African Journal on Human Rights* 17(2): 232- 257.
[236] *International Covenant on Economic, Social and Cultural Rights* section 41(6)(d).
[237] See in general Pearmain D (2004) *A critical analysis of the law on health service delivery in South Africa* (LLD thesis unpublished, University of Pretoria).
[238] *International Covenant on Economic, Social and Cultural Rights* article 12.
[239] Amollo R (2009) "Advancing women's access to health services in South Africa: Legal and policy responses to HIV/AIDS" *ESR Review* 10(1): 3.

the right to the highest attainable standard of health and CEDAW General Recommendation No 24[241] on women and health are examples of the commitment to woman's health. General Comment No 14 contains important provisions for the availability, accessibility, acceptability and quality for evaluating health care standards. Accessibility has elements of non- discrimination, physical accessibility, affordability and access to information. This right is thus not viewed narrowly as relating only to medicines and clinics.[242]

Health care is a basic need and according to section 27(1)(a) of the Constitution everyone has the right to access to health care and this includes reproductive health care. The Bill of Rights may be limited in two ways, one being by the limitation clause and the other by internal limitations.[243] Section 27 is internally limited by subsection (2) which states that the state must take the reasonable legislative and other steps to achieve the realisation of rights "within its available resources." Section 27(1) and (2) must be read together and define the scope of the positive rights of everyone. It further defines the ambit of the corresponding duty on the state to respect, protect, promote and fulfil such rights.[244]

The court interpreted the ambit of the right to access to health care in the *Soobramoney* case.[245] *In casu* the appellant relied on sections 27(3) and 11[246] of the Constitution in an attempt to direct a hospital to provide him with dialysis treatment. The court held, *inter alia*, the following:

1. Obligations which were imposed on the state by section 27 are dependent on the resources available for that purpose and thus the rights themselves can be limited by a lack of the necessary resources;[247] and

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[240] UN document E/C.12/2000/4 (2000).
[241] UN document A/54/38/Rev.1, chapter i.
[242] Hassim A, Heywood M & Berger J (eds) (2007) *Health and democracy: A guide to human rights, health law and policy in post apartheid South Africa* 4.
[243] Section 7(3) of the Constitution states "the rights in the Bill of Rights are subject to the limitations contained or referred to in section 36, or elsewhere in the Bill."
[244] *Treatment Action Campaign v Minister of Health* 2002 (5) SA 721 (CC). This judgement illustrates that the state is subservient to the Constitution and that the Constitutional Court will hold the state responsible in the exercise of its duties.
[245] *Soobramoney v The Minister of Health, KwaZulu- Natal supra.*
[246] See paragraph 5 *supra* regarding section 11 and the right to life.
[247] The availability of resources is a repeating issue in socio- economic rights disputes. Due to the finite nature of a national budgets and the fact that a vast variety of valid ways to distribute national funds exist, decisions regarding socio- economic rights regarded as "preponderantly polycentric." This is attributed to the society-

2. The case must be seen in context of the needs which must be met by health services.

Due to the fact that access to health care services is recognised in the Constitution, it is submitted that this also applies to certain elements of stem cell therapy. Even more so where no alternative to the proposed stem cell treatment exists.

10.2 REPRODUCTIVE HEALTH CARE

The right to access to reproductive health care is an aspect of reproductive equality.[248] A lack of reproductive health care may have a negative effect on a woman's ability to freely exercise other fundamental human rights. This includes the right to reproductive information which enables a woman to make decisions regarding reproduction and ultimately limits control over the body. It is interesting to note that the Choice on Termination of Pregnancy Act[249] was enacted as a means of giving effect to the right to access to reproductive health care.[250]

In context of this dissertation the question arises as to whether reproduction with the intent of creating a baby from which to derive stem cells in order to treat other children, should be allowed. This is a controversial topic and has been the subject of fictional literary works.[251] A

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wide impact and inevitable budgetary implications of the realisation of socio- economic rights. In fact, during the certification proceedings, arguments were made against the inclusion of socio- economic rights in the Bill of Rights as it was thought that socio- economic rights are not justiciable due to their budgetary implications. It was feared that this would lead to the court overstepping the separation of powers and encroaching on the legislative and executive authority. See Pieters (2004) *SAJHR* 383 at 393 & 399. In the *Soobramoney* case it was stated that the scarcity of resources exist as a limitation on the ability of the government to fulfil its obligations on not a limitation on what defines the content of the right. The available resources will thus qualify the content of the right only by way of the rate at which the realisation is achieved and the reasonable measures employed to achieve it. Resource availability must therefore be viewed as a factor which indicates how much of a socio- economic right may be claimed at a certain point in time. See also Iles (2004) *SAJHR* 448 at 464.

[248] Slabbert (2000) 383 & 384. See also article 12 the Convention on the Elimination of All Forms of Discrimination Against Women which reads (1) States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning. (2) Notwithstanding the provisions of paragraph I of this article, State Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.

[249] The Choice of Termination of Pregnancy Act, Act 92 of 1996.

[250] Amollo (2009) *ESR Review* 3 at 6.

[251] An example of this is Picoult J (2004) *My sisters keeper*. In this novel Kate Fitzgerald has leukaemia. In order to treat her, she needs the cord blood of a genetically perfect donor. Her parents find a geneticist to help them select the embryo from which they can create a second daughter and thus create a donor for Kate. Anna is born from this embryo and for 13 years she donates platelets, bone marrow, and cells to her sister, helping her

balance between section 27 and section 28[252] must be reached. It is however submitted that this should be permissible in cases where no alternative treatment exists. It would however still be subject to section 36.

11 SECTION 28: CHILDREN[253]

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to fight the disease. However, she is then asked to donate a kidney and sues her parents for medical emancipation, wanting to control the decisions over her body. This is then also related to the issues regarding cloning for the purpose of donation. In some instances, cloning is used to create an embryo which is intended to be implanted in order to develop and eventually be born so as to harvest tissue from that child to help its sibling. Often pre- implantation genetic diagnosis (PGD) is used to choose the "best" embryo. This raises further ethical questions which will not be discussed here. It would seem as though conceiving a second child in order to harvest stem cells from them, such as bone marrow stem cells known as Hematopoietic stem cells, to treat a previously born child may be justifiable as long as the second child is not abused or harmed. Where the second child is however conceived merely as a source of stem cells, ethical issues arise which are much more complicated and it is widely agreed that such practices should be discouraged. The question may also be asked whether parents are not morally obligated to conceive a second child in order to help and perhaps save another child's life. This question does however have an answer and it is stated that parents have no legal obligation to provide blood, tissue or organs and parents are further not obligated morally to subject themselves to the burdens involved in conception and child rearing. See in general King D (2003) "Why we should not permit embryos to be selected as tissue donors" *The Bulletin for Medical Ethics* August 190: 13-16. See also Robertson JA, Kahn JP & Wagner JE (2002) "Conception to obtain Hematopoietic stem cells" in Huhse H & Singer P (eds) (2006) *Bioethics: An anthology* 2nd edition 150 at151- 152.

[252] See paragraph 11 *infra* for a discussion on section 28 and the rights of children.

[253] Section 28: **Children**

1. Every child has the right
    a. to a name and a nationality from birth;
    b. to family care or parental care, or to appropriate alternative care when removed from the family environment;
    c. to basic nutrition, shelter, basic health care services and social services;
    d. to be protected from maltreatment, neglect, abuse or degradation;
    e. to be protected from exploitative labour practices;
    f. not to be required or permitted to perform work or provide services that
        i. are inappropriate for a person of that child's age; or
        ii. place at risk the child's well-being, education, physical or mental health or spiritual, moral or social development;
    g. not to be detained except as a measure of last resort, in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the shortest appropriate period of time, and has the right to be
        i. kept separately from detained persons over the age of 18 years; and
        ii. treated in a manner, and kept in conditions, that take account of the child's age;
    h. to have a legal practitioner assigned to the child by the state, and at state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and
    i. not to be used directly in armed conflict, and to be protected in times of armed conflict.
2. A child's best interests are of paramount importance in every matter concerning the child.
3. In this section "child" means a person under the age of 18 years.

See in general Boezaart T (ed) (2009) *Child law in South Africa*. See also Mahery P, Proudlock P & Jamieson L (2010) *A guide to the Children's Act for health professionals*. See in general *S v M (Center for Child law as amicus curiae)* 2008 (3) SA 232 (CC).

Section 28 provides the spectrum of rights intended to protect children. These rights are then supplementary to the rights provided for by the other provisions in the Bill of Rights. Had the drafters of the Constitution intended to enshrine the rights of an unborn child, express provision would have been made therefore[254] and section 28 would have been the ideal place to do so. As stated above, the rights in section 28 are subsidiary to the other rights in the Bill of Rights but do not have any special status. In the case of *De Reuck v Director of Public Prosecutions*,[255] it was held by Epstein AJ that a child's best interests is the "single most important factor" in the consideration and weighing of competing interests concerning children. All competing rights must defer to children's rights unless it is unjustifiable. This is in line with and relating to section 28(2). When overruled in 2004 it was however stated that to consider the rights in section 28 as higher rights, which trump the other rights in the Bill of Rights, would be a foreign approach and contrary to the approach that constitutional rights are dependant and related to one another and form a single value system.[256] The best interests of the child is however of "paramount importance" in all matters relating to children.[257] This sentiment is also reflected in the *Convention on the Rights of the Child*[258] and the *African Charter on the Rights and Welfare of Children*,[259] which places even greater emphasis on the importance of the child's best interests.

The question arises whether the fetus, or the embryo, is protected under section 28 and herein lays one aspect of the importance of section 28 in context of this dissertation. Should the fetus be protected under section 28, it would be entitled to the following:[260]

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[254] See McCreath J in *Christian Lawyer Association of South Africa and Others v Minister of Health and Others supra*.

[255] *De Reuck v Director of Public Prosecution*, Witwatersrand Local Division 2003 (3) SA 389 (W). This case was overruled in 2004 in *De Reuck v Director of Public Prosecution*, Witwatersrand Local Division 2004 (1) SA 406 (CC). See also Currie & De Waal (2005) 600.

[256] Currie & De Waal (2005) 600. See also Carstens & Pearmain (2007) 115.

[257] Section 28(2).

[258] Article 3(1) states that "in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be primary consideration."

[259] Article 4 states (1) In all actions concerning the child undertaken by any person or authority the best interests of the child shall be the primary consideration. (2) In all judicial or administrative proceedings affecting a child who is capable of communicating his/her own views, and opportunity shall be provided for the views of the child to be heard either directly or through an impartial representative as a party to the proceedings, and those views shall be taken into consideration by the relevant authority in accordance with the provisions of appropriate law.

[260] Section 28(1).

(a) A name and a nationality;

(b) Family or parental care, or an appropriate alternative thereto;[261]

(c) Basic nutrition, shelter, health care services and social services;[262]

(d) Protection from maltreatment, neglect, abuse or degradation;[263]

(e) Protection from exploitative labour practices;

(f) Not to be required or permitted to perform work or provide age inappropriate services which place the child at risk;

(g) not to be detained except as a measure of last resort but when detention is the last resort, to be detained for the shortest possible period;

(h) legal representation;[264] and

(i) to not be used directly in armed conflict but to rather be protected.

Section 28(2) would then further protect the fetus as it states that the best interests of the [unborn] child are of paramount importance and is the deciding factor in decisions regarding children. The "child's best interests" have however not steadfastly provided a true and reliable standard and is therefore controversial and will have to be determined at the hand of each set of facts it is applied to.[265]

It is however clear that the protection provided by section 28 does not apply to the unborn child: the fetus or the embryo. The reason for this is that section 28 is aimed at protecting children. A "child" according to section 28(3) is a person below the age of eighteen. Section 28- protection is therefore qualified by age and age commences only at birth. Since the fetus has not yet been born it is not a child of any age[266] and thus the fetus and embryo are excluded from the protection afforded by section 28.

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[261] Currie and De Waal state that the right to family life is indirectly protected under the right to dignity as enshrined in section 10 of the Constitution. See Currie & De Waal (2005) 605.

[262] Where the parents of a child do not fulfil their parental duties the State is obligated to do so. See *Grootboom v Oostenberg Municipality* 2000 (3) BCLR 227 (C) and *Government of the Republic of South Africa v Grootboom supra*.

[263] An example of this is the abolishment of corporal punishment as it is "cruel, inhuman and degrading." See *S v Williams supra.*

[264] Children and adults are equally entitled to legal representation in both criminal and civil litigation. This is done in order to prevent gross injustice. See *Du Toit v Minister of Welfare and Population Development* 2003 (2) SA 198 (CC) for a discussion.

[265] *Smith v Smith* 2001 (3) SA 845 (SCA).

[266] *Christian Lawyer Association of South Africa and Others v Minister of Health and Others supra.*

Echoing the logic of McCreath J,[267] the fetus can therefore not be included under any provisions of the Bill of Rights. In *Christian Lawyer Association of South Africa and Others v Minister of Health and Others*[268] it was held that if section 28 of the Constitution does not include the fetus within its ambit, it cannot be said that the other Bill of Rights provisions were intended to include the fetus.[269] Furthermore, the rights in the Bill of Rights are conferred on "everyone," except where a different class of rights bearer is specified and it is clear that "everyone" does not include the fetus. Including the fetus would have the implication of ascribing a meaning to the word which was not intended and thereby change the ambit of the right and all other rights in the Bill of Rights.[270]

The relevant constitutional provisions in context of the procurement of stem cells have now been examined and discussed. Stem cell banking is however an important aspect of the future of stem cell research and in context of this dissertation, qualifies as distribution of stem cells. For this reason it is essential to now discuss certain constitutional aspects of stem cell banking.

12 CONSTITUTIONAL ASPECTS OF STEM CELL BANKING

12.1 PRIVACY

Questions regarding the right to privacy must be clarified in context of stem cell banking. Confidentiality is an integral part of any medical practice and is protected by the section 14 of the Constitution,[271] section 14 of the National Health Act[272] and the common law. Any

[267] *Ibid.*
[268] *Ibid.*
[269] Section 11 which is designed to protect everyone's right to life is included in this statement.
[270] Reference must also be made to section 12(2) which states that everyone has the right to security in and control over their body which includes making decisions regarding reproduction. The woman's right is not qualified in any manner to protect the fetus. *S*ection 36 may however be invoked to limit this right in cases where it is reasonable and justifiable to do so in an open and democratic society based on human dignity, equality and freedom.
[271] See paragraph 7 *supra* concerning section 14 privacy.
[272] Section 14 of the National Health Act: **Confidentiality**
1. All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.
2. Subject to section 15, no person may disclose any information contemplated in unless-
   a) the user consents to that disclosure in writing;
   b) a court order or any law requires that disclosure; or

breach of confidentiality may lead to legal action unless a valid defence such as consent, statutory duty or medical privilege is applicable.[273]

12.2 THE RIGHT TO ACCESS TO HEALTH CARE SERVICES

Section 27(1) of the Constitution provides for the right to access to health care services and this provision thus entails positive and negative elements. Positively, the state is obligated to take measures to promote this right or the realisation thereof and negatively, the state must refrain from infringing or limiting the right to access to health care services. The states positive duty to achieve progressive realisation of access to health care services is limited by the availability of resources but the negative duties of the state is not limited in a similar fashion.[274] It may therefore be said that the states positive duty is dependent on the health care priorities and the budget which has been allocated to health care.[275] These variables are not taken into consideration when dealing with a negative duty.

It is necessary to consider health care services- related interests in context of stem cell banks. A new born has an interest in the banking of their cells as he or she may need these cells in future for therapeutic reasons.[276] A further interest is that of the newborns parents and siblings as the newborns banked cells possesses a greater possibility of histocompatibility.[277] These interests clearly fall within the scope of health care when viewed from a therapeutic perspective. Any limitation on the right to bank cells, or a ban on private stem cell banks for that matter, would undermine these interests. This dilemma is

c) non-disclosure of the information represents a serious threat to public health.

[273] McQuoid- Mason D (2010) "Termination of pregnancy and children: Consent and confidentiality issues" *South African Medical Journal* April 100(4): 213.

[274] See footnote 10 *supra* for more on the resources and the role the availability thereof plays in socio-economic rights disputes.

[275] See paragraph 12.6.2 *infra* for more on the states positive duty in context of stem cell banks.

[276] Currently this would entail the banking of umbilical cord blood.

[277] This is "Literally, tissue compatibility. With full histocompatibility between a donor and recipient, tissue can be transplanted without being seen as foreign and being attacked by the immune system of the recipient." See MedicineNet available at http://www.medterms.com/script/main/art.asp?articlekey=23075 accessed 6/9/2010.

accentuated when taking into consideration the genetic diversity of the South African populace.[278]

The separate provision for socio- economic rights of children[279] may be seen as an indication that some priority must be given to these rights although they do not have higher status than the other right in the Bill of Rights.[280] The Constitutional Court has refused to elaborate on and explain the meaning of children's socio- economic rights.[281] The court has also not defined the core socio- economic rights that are bestowed upon "everyone." The position in which children find themselves, calls for a prioritisation of children's needs in the division of resources.[282] Stewart argues that the basic socio- economic rights of children should thus be interpreted as granting enforceable entitlements to *inter alia* health care services.[283]

The states availability of resources is not relevant in context of private stem cell banking and is not an issue in the negative duty of refraining from limitation of access to health care services. The reason for this is that the parents or family of the newborn would cover the costs of storage.[284] A ban on stem cell banking would thus constitute a breath of the states negative duty to refrain from limiting the right to access to health care services. It is further submitted that section 27 will include the right to access to stem cell banking.

12.3 THE RIGHT TO BODILY INTEGRITY, FREEDOM AND SECURITY OF THE PERSON

This right,[285] as enshrined in the Constitution denotes bodily autonomy or self-determination.[286] Stem cells are derived from cord blood which is part of the human body[287]

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[278] Jordaan DW, Woodrow C & Pepper MS (2009) "Banning private stem cell banks: A human rights analysis" *South African Journal on Human Rights* 25: 126 at 139.
[279] Section 28(1)(c).
[280] Stewart (2008) *SAJHR* 24: 472 at 480.
[281] See *Government of the Republic of South Africa v Grootboom supra* and *Minister of Health v Treatment Action* Campaign 2002 (5) SA 72 (CC).
[282] Viljoen F (2002) "Children's rights: A response from the South African perspective" in Brand D & Russel S (eds) *Exploring the core content of socio- economic rights: South African and international perspectives* 201 at 203. See also Devenish (2005) 140-144.
[283] Stewart (2008) *SAJHR* 472 at 480.
[284] Whether or not stem cell banking will be covered by Medical Aid, is a matter which will deserve attention in future but it is outside the scope of this dissertation. It is however submitted that as the therapeutic use of stem cells becomes more and more common place, this will be seen as normal medical treatment and will have to be covered at least to some extent.
[285] See paragraph 6.2 *supra* for the discussion on section 12(2).

and the right to control over one's body thus entails the autonomy to decide how to use or "dispose of" the cells. This autonomy is protected by section 12(2) of the Constitution. The mother has the autonomy to make decisions regarding her stem cells and since the newborn cannot make such decisions, a parent would, in normal circumstances, act on behalf of the child.[288]

The banking of stem cells is an autonomous decision in context of the modern medical environment in which stem cell therapy functions and therefore the interests of the newborn and their next- of- kin as previously discussed are also protected by the right to bodily integrity. The recognition of the rights in section 12(2) means that paternalistic forms of interference in health care decisions must be minimised.[289] A person is thus entitled to make decisions regarding medical treatment based on section 12.

12.4 CHILDREN'S RIGHTS

The "best interests of the child" is regarded as the definitive factor in matters relating to children.[290] A child has an interest in the banking of their stem cells as they may be required for stem cell therapy in future. The banked cells will then guarantee a suitable supply of compatible cells. Stem cell banking is thus directly in the best interests of the child.[291] A child however also has an interest in their family's health and lives and therefore stem cell banking may be indirectly in the best interests of the child as their next- of- kin may also benefit from banked cells.

Any interference, a ban on private stem cell banking for instance, would thus constitute an infringement on the rights of a child in context of the best interest of the child. Any interference would impact children who currently have banked cells and children who in

[286] Currie & De Waal (2005) 308.
[287] The mother or the newborn baby's.
[288] Jordaan, Woodrow & Pepper (2009) 126 at 139.
[289] Bishop M & Woolman S "Freedom and security of the person" in CLoSA chapter 40.
[290] See paragraph 11*supra* for more on the best interests of the child.
[291] This is provided that the parents of the child can bear the financial burden of stem cell banking without compromising the other interests of the child. See Jordaan, Woodrow & Pepper (2009) *SAJHR* 25: 126 at 141.

future will have cells banked. This infringement may be on individual children, but also children as a group in South Africa.[292]

12.5 FREEDOM OF ECONOMIC ACTIVITY

This discussion focuses on the stem cell banks and not on the child or their relatives. Section 22 of the Constitution states that each citizen may freely choose their trade, occupation or profession.[293] Let us assume, for purposes of this discussion, that stem cell banks are considered citizens for the purpose of section 22. This assumption may be substantiated by the case of *Becket (TW) & Co v H Kroomer*,[294] in which it was held that a juristic person may be considered a citizen if it is controlled by South African citizens. Should section 22 however be interpreted strictly, stem cell banks may argue that the South African citizen employees right to free trade, occupation or profession has been infringed.

Stem cell banks make professions in this regard possible and any limitation of this right would restrict free choice of practice of an occupation. Thus the rights of natural persons would be infringed upon. Furthermore, this is not a right which should be underestimated as it is interconnected to human dignity. In *Ferreira v Levin*,[295] Ngcobo J held the following:

> "Freedom to choose a vocation is intrinsic to the nature of a society based on human dignity as contemplated by the Constitution. One's work is part of one's identity and is constructive of one's dignity. Every individual has a right to take up any activity which he or she believes himself or herself prepared to undertake as a profession and to make that activity the very basis of his or her life."

[292] *Ibid*.
[293] Section 22: **Freedom of trade, occupation and profession**
Every citizen has the right to choose their trade, occupation or profession freely. The practice of a trade, occupation or profession may be regulated by law.
See in general Devenish (2005) 135- 140. See also Davis D (2002) "Freedom of trade, occupation and profession" in CLoSA chapter 54.
[294] *Becket (TW) & Co v H Kroomer* 1912 AD 324 at 334.
[295] *Ferreira v Levin No supra*.

12.6 JUSTIFICATION OF A BAN ON STEM CELL BANKS[296]

To satisfy the limitation clause, the law in question must serve a purpose which is in line with the foundational constitutional values and may further not intrude upon the rights in the Bill of Rights to a greater extent than is necessary. Three popular arguments against stem cell banking exist, namely the low- recall argument, the diversion of resources argument and a characteristically South African argument, namely the equality argument. The three arguments will have to be tested against section 36 of the Constitution in order to be used as justification on any infringement on access to stem cell banks. A brief discussion of each of the arguments follows.

12.6.1 The Low- Recall Argument

The low- recall argument aims to promote the policy principle of protecting the public against any exploitative practices and is therefore very much in tune with the constitutional ethos. Section 36 requires that a limitation must be proportional to the purpose which it wishes to achieve. This entails that should less restrictive measures which will have the same end results exist, the less restrictive measures should enjoy priority above the more restrictive ones.[297]

In the case of stem cell banking, or more specifically the limitation thereof, less restrictive measures do exist, namely:[298]

1. Providing guidelines regarding what qualifies as adequate information in the process of giving informed consent;

2. Obliging health care practitioners to disclose any financial interests in the said procedure in order to prevent exploitative practices; and

[296] The focus of this section of the discussion is mainly on private stem cell banking in context of the National Health Act 61 of 2003 and the regulations made in terms of the National Health Act as it seems to ban private stem cell banks. This will be discussed in the course of chapter 6 of this dissertation.
[297] Section 36(1)(e).
[298] Jordaan, Woodrow & Pepper (2009) *SAJHR* 126 at 147.

3. The provision of a cooling- off period after the birth of the newborn after which, should the parents not "renew" consent, the original consent contract becomes null and void.[299]

Since less restrictive measures to protect the public from exploitative practices are available, the low- recall argument does not pass the limitation test as set out in section 36 of the Constitution and can therefore not be used to justify a ban on stem cell banks.

12.6.2 The Diversion- Of- Resources Argument

The diversion- of- resources argument[300] is specifically aimed at private stem cell banks and argues against banking of stem cells from a social solidarity point of view. It states that umbilical cord blood will be diverted from public banks and thus the establishment and maintenance of public banks will be limited.[301] The argument comes down to this: instead of fostering public banks from which the entire populace may benefit, private banks have the effect that only the wealthier portion of society will be able to benefit from the therapeutic options made available by stem cells.[302] This argument is based on the objective of protecting the ability to create a public stem cell bank against the supposed negative impact of private stem cell banks. The limitation clause requires a relationship between the limitation and its purpose and therefore a logical nexus must exist between the purpose and the limitation.[303]

In South Africa however there is currently no public stem cell bank. A public stem cell bank would enable the public's access to health care services and the establishment of such a bank is in line with the constitutional duty of the state to take reasonable steps, within the available resources to achieve realisation of the right to access to health care progressively.[304] Furthermore, private stem cell banks have offered to contribute their

[299] For a more detailed discussion of these less restrictive measures see Jordaan, Woodrow & Pepper (2009) *SAJHR* 126 at 143- 147.
[300] Hereafter referred to as the diversion argument.
[301] Johnson FL (1997) "Placental blood transplantation and autologous banking- *Caveat emptor*" *Journal of Pediatric Hematology- Oncology* 19: 183.
[302] Waldby C (2006) "Umbilical cord blood: From social gift to venture capital" *BioSocieties* 1: 55.
[303] Section 36(1)(d).
[304] Section 27(2).

resources towards the establishment and maintenance of a public stem cell bank. This may be done by way of staff, equipment or cryopreservation space.[305] Private banks are therefore in support of a feasible public bank, rather than being the competition.

It is therefore submitted that, in context of the constitutional duty of the state regarding access to health care services, reasonable measures would entail institutional support by way of championing and facilitating the process of establishment and maintenance of a public stem cell bank in South Africa.[306]

12.6.3 The Equality Argument

The redistribution of social goods, especially concerning health care and keeping in mind our history and ever-persistent inequalities, is one of the overriding factors in government policy. The core perception of equality, which lays at the heart of policy is this: unequal access to social goods may be remedied by denying everyone access to said social good. This is then the case concerning stem cell banking. The Department of Health is levelling access down due to the fact that the health priorities of the department do not include cell-therapy.[307] In other words, if not all groups in society can afford private stem cell banks, and since there are no resources available to create public stem cell banks, no one will have access to stem cell banks.[308] It is submitted that this is a "misery loves company" way of seeing the situation. Levelling down has however been rejected by South African courts as is evident by the judgement in *Minister of Home Affairs v Fourie*.[309] In this case it was stated that levelling down does not promote the achievement of the enjoyment of equality.

In conclusion, it is therefore submitted that interference in access to stem cell banks is unconstitutional and therefore any ban on stem cell banks is null and void. This is especially so as less restrictive means exist of protecting the community from exploitation, the private sector has undertaken to support the public sector in the context of the creation of public

[305] Pepper MS (2007) "A model for the co- existence of public and private stem cell banks" *CIP e- brief series* no 44/2007, 31 July available at http://en.scientificcommons.org/47449137 accessed 9/7/2010.
[306] Jordaan, Woodrow & Pepper (2009) *SAJHR* 126 at 149.
[307] Department of Health, South Africa (2004) *Strategic priorities for the National Health System 2004- 2009*.
[308] Jordaan, Woodrow & Pepper (2009) *SAJHR* 126 at 149.
[309] *Minister of Home Affairs v Fourie* 2006 (3) BCLR 355 (CC).

stem cell banks and therefore no discrimination is present on the grounds of wealth. It is submitted that a public stem cell bank be established which may then collaborate with any authorities regulatory body.[310]

13 CONCLUSION

The object of this chapter was an examination of the relevant constitutional provisions concerning stem cell research and in the course of the chapter the following conclusions were made. Firstly the trend towards embryo protection does not minimize constitutional values and a new approach to stem cell research debates will be necessary to facilitate this science. The conflicts between fundamental rights must be balanced by evoking the limitation clause as provided for by section 36 of the Constitution and it is also on this basis that the legitimacy of stem cell research overall must be tested.

It was found during the course of this constitutional examination of stem cell technology that section 9 applies to women and not to the fetus and embryo. Equality is rather sexual equality and not simply a form of protection against discrimination. Equality is intrinsically connected to human dignity and dignity to life and it was further found that the embryo is not entitled to human dignity or to the right to life as enshrined in the Bill of Rights as the use of the word “everyone” was not intended to create a new class of rights bearers. The debate surrounding the embryos right to life will however be eliminated by the advancement of new technology such as induced pluripotency. The embryo and fetus can also not qualify as a child in terms of section 28.

Regarding freedom and security of the person and specifically bodily and physiological integrity, the argument was made that destruction of a frozen pre- implantation embryo which is not yet viable is permissible as well as the decision to donate embryos or an aborted fetus for research purposes. Consent is however a complicated issue in context of the procurement and distribution of stem cells and this chapter only discussed section 12(2)(c) briefly. Consent is however further discussed in chapter 3 as well as chapter 5 which is dedicated to this concept. What should be mentioned here is that it was found that as the

[310] The establishment of such body is recommended in chapter 6 of this dissertation.

embryo can never consent, the consent of the donor is what is legally relevant in context of stem cell research.

Privacy as protected by section 14 of the Constitution was greatly discussed with reference to abortion and contraception as it was stated that similar interests were involved therein as are relevant in stem cell procurement and distribution. The donation and destruction of an embryo is thus protected by section 14 and it was further found that privacy has an impact on confidentiality matters which may arise. Another personal matter, that of conscience, religion, thought, belief and opinion was examined and it was found that it may serve as grounds for health care providers to refuse to participate in stem cell research and therapy. This right will however have to be balanced against the limitation clause in certain situations. Section 36 will then also play an important role in balancing certain rights and interests with the right to freedom of expression or more specifically the right to freedom of scientific research. The right to scientific freedom must be acknowledged and respected, especially concerning stem cells and it was recommended that the scientific community be allowed to pursue this field of study but under strict governmental supervision.

Socio- economic rights were discussed and it was argued that the right to reproductive health care services should include certain elements of stem cell therapy and especially so in circumstances where no alternative exists. State resources must however be kept in mind and it will most probably come down to the courts to finalise this matter. Lastly, certain constitutional aspects were discussed as pertaining to stem cell banking and it was concluded that state interference in access to stem cell banking is unconstitutional as it could not be justified. Also, a public bank which must work in collaboration with an independent regulatory body, must be established in South Africa.

Although the Constitution is the supreme law of South Africa, specialist provisions are required to regulate the procurement and distribution of stem cells. The constitutional aspects of stem cell research have far reaching influence and various constitutional values and norms have been incorporated into ethical frameworks and guidelines. For this reason it is thus imperative to now discuss the ethical framework in which stem cell research functions within South Africa.

CHAPTER 4

THE ETHICAL REGULATORY FRAMEWORK

1 INTRODUCTION

Ethics is a branch of philosophy that deals with the moral aspects of human behaviour. Medical or research ethics, especially in stem cell related technology, as a philosophy is an example of how certain of the deepest philosophical questions hold the key to some of the most fundamental practical decisions human beings have ever had to make.[1] Stem cell research may be exactly the area of ethical debate where conventional wisdom does not place the boundaries for society in the correct place.

Medical ethics, in a narrow historical sense may be described as a set of guidelines, written by physicians and is centred on the physician's ideal relationship with his peers and patients. The *Hippocratic Oath* is an example of this. Seen in a modern sense, it is the application of general and fundamental ethical principles to clinical situations in medical practice and this includes medical research. Recently, this term has been extended to include bioethics, which concerns medical and ethical principles relating to knowledge about life and death.[2] For this reason, both medical and research ethics are discussed in this chapter. Research is a systematic investigation which includes research development, testing and evaluation which is designed to develop or contribute to knowledge.[3] A distinction can also be made between therapeutic research and non- therapeutic research. The aim of therapeutic research is to benefit the individual patient or participant by the treatment or curing of his condition.[4] Non- therapeutic research is research which benefits people other

[1] Glover J (2006) *Choosing Children: Genes, disability and design* 3.
[2] Steinberg A (1998) "Medical ethics" available at http://www.medethics.org.il/articles/JME/JMEB1/JMEB1.1.asp accessed 3/ 6/ 2010. For further reading regarding medical ethics see Mason JK & Laurie GT (2009) *Mason & McCall smith's law and medical ethics* 8th edition.
[3] MRC "What is research?" *Guidelines on ethics for medical research: General principles* (Book 1) paragraph 2.1.2 available at http://www.mrc.co.za/ethics/ethics.htm accessed 5/7/2009.
[4] MRC "What is research?" (Book 1) paragraph 2.1.2.1.

than the research participant but the knowledge which is gained by the research may also benefit the individual patient or participant.[5]

Ethics is the science or criteria, norm and values of human conduct and it is engaged in reflection and analysis of morals. It intends to guard human dignity and promote justice and equality. Medical research is not only concerned with the behaviour of health care practitioners but with health care as a whole.[6] Research ethics is the application of fundamental ethical principles to various matters concerning scientific research. This includes the design and implementation of research on human subjects. The most developed form of research ethics is medical research ethics which is primarily based on the *Nuremburg Code* of 1974 and the 1964 *Declaration of Helsinki*.[7]

Scientific enquiry involves the study, pursuit and application of research. The possibility of human benefit is however subject to the possibility of harm which could be caused by a breach of values. The "values" referred to are known as ethics and are a systematic reflection of a community's' moral life. These values are convictions and are derived from natural philosophy, religion and intuitive principles. The Constitution of the Republic of South Africa[8] incorporates certain of these values to an extent and thus we find an overlapping of ethics and the Constitution.[9] Ethics thus examine and measure human conduct and the accepted practices or actions by persons within a certain country is referred to as normative behaviour. Ethics are thus used to evaluate and ensure the appropriateness of this behaviour. The South African Constitution is based on objective, normative values and this further explains the overlapping of the Constitution and certain ethical principles. An example of this is the statement that "human dignity, human rights and fundamental freedoms must

[5] *Idem* 2.1.2.2.
[6] MRC "What is meant by research ethics?" *(*Book 1) paragraph 3.1.1.
[7] National Academy of Science (2009) *On being a scientist* 3rd edition available at http://www.nap.edu/catalog.php?record_id=12192 accessed 3/6/2010.
[8] The Constitution of the Republic of South Africa Act, Act 108 of 1996.
[9] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.1 available at http://www.mrc.co.za/ethics/ethics.htm accessed 5/7/2009.

be fully respected"[10] as found in the *Universal Declaration on Bioethics and Human Rights*.

Ethics as soft law has acquired the status of hard law in the absence of in force legislation or regulations and it is important to mention the relationship between law and ethics, as law and ethics inherently differ from one another and at times conflict. Law demands to be followed to the letter and yet in some situations the law does not cover the issue at hand, leaving ethics as the measure against which the problem must be solved.[11] Although ethics may be used to supplement the law the law will however still trump ethics where a conflict exists.[12] Legislation regulating medical ethics is a topic of debate as some writers support the interaction of law and ethics, hoping this would lead to set ethical norms in society. This assumption is however based on the belief that the law is capable of keeping up with the developments in medical science. Other writers however argue that the law, judges and legislators, should be minimally involved in ethics and that ethics must only be seen as a last resort. This argument is based on the fact that the law is slow and conservative at times and incapable of dealing with the drastic changes which occur almost daily in the development of medical sciences.[13]

Research involving embryos is the most controversial and ethically debated aspect of stem cell research and therefore the greater part of this chapter is devoted to this and subjects related thereto. It is important to note that as this science develops, so does the ethical debate. Should the use of embryonic stem cells become obsolete due to the use of induced pluripotent stem cells, many if not all of the ethical issues examined here will be eliminated. This chapter starts with a brief discussion of modern medical ethics. Four ethical frameworks for the functioning of stem cell research are then examined as it is important to have an understanding of the differing schools of thought. General ethical principles and the application thereof in

[10] Article 3 of the *Universal Declaration on Bioethics and Human Rights*.
[11] See Pellegrino ED (1994) "Editorial response to Halevy and Brody" *American Journal of Medicine* 96:289 regarding the relationship between ethics and law.
[12] 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 Herring J (2008) Medical law and ethics 2nd edition 1-35.
[13] Steinberg (1998) "Medical ethics."

South African ethical instruments such as the MRC and HPCSA guidelines are discussed. Attention is then given to specific ethical issues such as the use of cloned embryos and a brief discussion of the ethics involving animals in research is provided. Lastly, the provisions of the National Health Act pertaining to ethics,[14] as well as the relevant regulations are discussed.

1.1 MODERN MEDICAL ETHICS

Ethics are as old and the practice of healing.[15] However, as times and technologies have changed, so has ethics. Modern medical ethics is therefore largely based on multidisciplinary concepts, including biomedicine and law and is therefore a form of applied ethics that attempts to clarify ethical dilemmas found in the practice of medicine.[16] Modern biotechnology has rapidly developed and has presented a number of new ethical and social challenges. The benefits of this increased knowledge are remarkable as it promises major advancement of human health. For this reason and limitation of freedom of scientific research and experimentation

[14] This will constitute the analysis of the proposed regulatory framework for the procurement and distribution of stem cells in context of ethics.

[15] Since the start of human history, laws, decrees and oaths have expressed concern for medical ethics and individual physicians or small groups thereof generally wrote codes of medical guidelines. The *Hippocratic Oath*, is considered the first organised and logical code to describe the relationship between the physician and patient. Another example of ancient medical codes is the *Code of Hammurabi* in Babylonia of approximately 1750 BC, as well as early rabbinic and Christian teachings. The Middle Ages produced some further writings, mostly by Muslim physicians such as Ishaq bin Ali Rahawi who wrote *Conduct of a Physician*, the first known book on medical ethics and Muhammad bin Zakariya ar- Razi. Furthermore, Jewish thinkers such as Maimonides and Roman Catholic scholars such as Thomas Aquinas contributed to the pool of knowledge. In 1849, Thomas Percival coined the term "medical ethics" in his writings on "medical jurisprudence." In the second half of the nineteenth century medical organisations began to write medical ethics codes. The American Medical Association published their code in 1847 and was the first code to outline the rights of patients and physicians. The British Medical Association then published the first code of *Medical Conduct of Physicians* in 1858. The World Health Organisation issued the first global code of medical ethics, namely the *Declaration of Geneva* in 1948 which is strongly based on the *Hippocratic Oath*. In the 1950's, modern medical ethics as a separate field of study began to develop and many changes were incorporated. The move away from a paternalistic form of medicine towards autonomy and the resulting need to give the patient adequate information, informed consent and sharing of the decision making process with the patient, are some of the drastic changes which occurred. In the 1970's, contemporary medicine influenced ethics by the creation of review boards and ethics committees as well as the inclusion of ethics courses in the curriculum of medical schools. See Percival T (1849) *Medical ethics*, The British Medical Association (1981) *Handbook of Medical Ethics* and Post SG (2003) *Encyclopaedia of bioethics* 3rd edition and Lakhan SE, Hamlat E, McNamee T & Laird C (2009) "Time for a unified approach to medical ethics" *Philosophy, Ethics and Humanities in Medicine* 4(3): 13.

[16] Steinberg (1998) "Medical ethics."

must be done only in exceptional circumstances so as not to impede scientific wisdom.[17] A duty however exists to ensure that research is performed in ethically acceptable ways.

The advances in medical diagnosis and treatment as well as the introduction of new technologies such as stem cell therapy, have produced various new ethical problems which have lead to the maturation of medical ethics as an individual and unique form of study, independent of ethics in general.[18] Modern medical ethics now involve numerous subjects of debate and branches off into firstly, biomedical ethics which deals with fundamental ethical principles, societal issues and policy determination and secondly, into clinical ethics.[19] The basic concept of medical ethics is however that the physician has a moral and sometimes legal obligation to act in a manner which promotes the patients good by using the most up- to- date information. It is submitted that the physician's moral obligation should include the newest techniques as means to achieve the good of the patient. Regarding research ethics, a moral duty exists towards the participant in that they, as well as their privacy must be protected. Confidentiality is essential and the participant must remain anonymous and his private information secure.[20]

Research may be medically justified when considering that health volunteers are required to gain knowledge regarding human biology and psychology as well as knowledge pertaining to medicines, cosmetics, medical devices and other agents.[21] Research on patients is however equally important as it may lead to benefit the patient and society. Research conducted with the help of patients may be divided into five categories. These categories are firstly, the determination of the cause of

[17] Dhai A, Moodley J McQuid- Masson D & Rodeck C (2004) "Ethical and legal controversie in cloning for biomedical research: A South African perspective" *South African Medical Journal* 94(11): 906 at 909.
[18] See Callahan D (1980) "Contemporary Biomedical Ethics" *New England Journal of Medicine* 302: 1228 and Steinberg A (1995) "The foundations and the development of modern medical ethics" *Journal of Assisted Reproduction and Genetics* September12(8): 473.
[19] Siegler M (1979) "Clinical ethics and clinical medicine" *Archives of Internal Medicine* 139:914 and Lo B & Jonsen AR (1980) "Ethical decisions in the care of a patient terminally ill with Metastatic cancer: An ethics case-analysis from the Health Policy Program, University of California, San Francisco"*Annals of Internal Medicine* 92:107-111.
[20] Shaw SE, Petchey RP, Chapman J & Abbott S (2009) "A double- edged sword? Health research and research governance in UK primary care" *Social Science & Medicine* 68: 912- 918.
[21] MRC "The medical justification of research" (Book 1) paragraph 4.1.

disease, secondly the improvement of diagnosis or assessment, thirdly the improvement of the treatment of disease, fourthly research may be used to assess health in different communities and finally such research assists in furthering knowledge about basic human biology.[22]

2 ETHICAL FRAMEWORKS AND THE STEM CELL DEBATE[23]

The public debate seems to be caught between the value of embryos and the promised benefits of stem cell research and it is therefore difficult to describe this debate.[24] The most logical way to examine the different points of view is to think of them as belonging to different schools of thought with unique frameworks within which moral deliberation takes place. There has always existed opposing ethical schools of thought, which differ in the principle justifications and validity of theories and in terminology, the specified principles and rules as well as the relationship between the person and the concerned subject of thought.[25] The various frameworks differ from one another as they have different ideas about the human condition as well as the central ethical questions. They do not engage and talk past each other.[26]

There have been mixed reactions to the prospect of cloning as some support it for the medical promises thereof and others oppose it due the destruction of potential and emerging life. They would argue that it undermines human dignity.[27] Society is divided on the subject of the moral status of the embryo and what the embryo is owed by society and this division stands in the way of coming to a conclusion on the

[22] MRC "The medical justification of research" (Book 1) paragraph 4.2.
[23] According to Slabbert there are four schools of thought on embryo research. The first states that any research is permissible, the second rejects any form of embryo research, the third rejects any destructive research but is prepared to accept therapeutic research which will benefit the embryo itself and the fourth which supports embryo research but only where spare IVF embryos which will be destroyed in any event are used. See Slabbert MN (2001) "Are the human embryo and foetus *extra uterum* sufficiently protected in terms of South African law?" *TSAR* 3: 495 at 502.
[24] Sowle Cahill L (2002) book *review in The Human Embryonic Stem Cell Debate in National Catholic Bioethics Quarterly*, Autumn 2(3): 559- 562.
[25] Steinberg (1998) "Medical ethics."
[26] Peters T (2007) *The stem cell debate* 24.
[27] Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906 at 907.

matter. Current debates will not, as previous debates have not, reach as solution as the core of the arguments have not been changed or altered in any degree.[28]

Each framework provides the background assumptions within which the moral reasoning takes place and unfortunately the frameworks have fallen into pro- and anti- stem cell research camps. The frameworks which will be discussed are the embryo protection framework and the nature protection framework which are decidedly against stem cell research as well as the medical benefits framework. The medical benefits framework is seen as being in support of stem cell research. The abovementioned frameworks rest upon a theological or philosophical basis. A fourth framework also exists and is referred to as the research standards framework and it may be regarded as a secular framework. Furthermore, each framework revolves around a unique central question.

The embryo protection framework asks whether human embryonic stem cell research is a form of abortion. It argues that the destruction of a blastocyst is the destruction of a human individual, or at least a potential human individual. Where research on adult stem cells could still pass as moral, embryonic stem cell research is undeniably immoral and scientists are dubbed "baby- killers" who promote a culture of death. The nature protection framework is predominantly comprised of groups who have been opposed to any form of genetic science since the 1970's such as the *Human Genome Project* and cloning. The fundamental question is whether the manipulation of human genes dehumanise us and includes issues such as scientist playing God and fear of the *Brave new world*[29] scenario. The pro- stem cell research camp, namely the medical benefits framework asks whether stem cell research could significantly provide relief to human suffering and if so, whether or not this morally justifies supporting this science. The question is further asked whether or not resources should be dedicated to the possibility of helping millions of people

[28] Most in the scientific community have agreed on a middle position. See Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906 at 907.

[29] Huxley A (1931) A Brave new world. In this novel, Huxley tells of a dystopian future set in London in AD 2540, which is 632 AF in the book. This novel anticipates certain developments in reproductive technology and sleep-learning which change society. This futuristic society is the embodiment of the ideals which form the basis of futurism. For more on this novel see "Brave new world? Defense of paradise- engineering" available at http://www.huxley.net/ accessed 1/12/2010.

suffering from genetic- based diseases. Finally, the research standards framework, which is shared by policy makers and scientists provides the ethical and legal procedures to be followed and provides the criteria to meet when applying for research funding.[30] Each of these frameworks will now be discussed in detail.

2.1 THE EMBRYO PROTECTION FRAMEWORK

Much of the debate surrounding stem cells revolve around the issue of the moral status of the embryo.[31] This is perhaps the most essential characteristic of the embryo protection framework and the most basic orientation thereof. Ethicists within this framework thus focus on the issue of whether the embryo, at the blastocyst stage and outside of the mother's body, requires protection.[32] Differently stated, whether or not the destruction of the blastocyst is a form of abortion and the scientists involved in this research baby- killers. It is therefore obvious that this ethical framework is not concerned with the potential patients who might be saved by stem cell therapy, but the potential persons who will be "aborted" in a petri dish. The decisive issue is thus the moral status of the embryo and whether or not an embryo has morally protectable dignity. If this should be the case, the question arises whether we are forbidden to pursue this research.[33] It should here be mentioned that this framework is strongly aligned with religious groups and their beliefs regarding stem cell research and such assumptions must be kept in mind.[34]

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[30] Peters (2007) 25- 28.
[31] The National Council of the Churches in the USA "Fearfully and wrongfully made: A policy on human biotechnologies" at http://www.ncccusa.org/pdfs/BioTechPolicy.pdf accessed 4/7/2009.
[32] Peters (2007) 29.
[33] *Idem* 29- 30.
[34] The fundamental assumption of theology is that human dignity established fully at conception irrespective of whether this occurs *in vivo* or *in vitro*. Origin is what defines a human as such and origin at conception establishes individuality, moral protectibility and dignity. This corresponds to the principle of ensoulment. Ensoulment is not physical but rather metaphysical. Although the exact time of ensoulment is uncertain, the embryo is still protection worthy as the proponents of this framework argue that the soul is still on the way if it has not arrived already. The potential for ensoulment or potential for personhood is sufficient to confer dignity and thus moral protectability upon the embryo. Ensoulment thus prohibits stem cell research. A further theory is that of genomic novelty which is strongly approved of by the Vatican and was first articulated in 1987 in *Donum Vitae*. *Donum Vitae* states that three elements are crucial to the creation of the moral protectability of an individual. These elements are the fathers' sperm, the mothers' egg and a soul and thus the genomic novelty is

Deontology is also used by this framework in arguing that no human person should be used as a moral means to an end. In context of stem cell research, the destruction of an embryo would thus violate the potential persons' dignity. This framework further states that although medical advances are good, protection of an embryo is more important and our first ethical responsibility is to do no harm towards the unborn, thus to embrace non- maleficence.

It is important to note that the embryo protection framework is characterised by the principle of non- maleficence. Therefore, regardless of what good might come from stem cell research, such as the relief of human suffering in the future, it cannot justify doing harm to an embryo. This is reminiscent, according to this framework, of Hippocrates who said to benefit but do no harm.[35] The first part of the Hippocratic phrase denotes beneficence and the second non- maleficence, but the embryo protectionists are of the opinion that non- maleficence trumps beneficence.[36]

2.1.1 Embryo Protection and Spare Embryos

The issue on whether or not spare embryos, originally intended for *in vitro* fertilisation may be argued from two camps and is referred to as the discarded embryo position within this framework. This principle is also referred to as "the principle of wastage avoidance." A powerful moral reason exists to use material to benefit society when that material will be destroyed in any event[37] and it is submitted that the first camp is neutral towards, or at least not against the idea of using these embryos. This is evident by their use of the term "the nothing is lost position." They argue that it is morally permissible to use these embryos as long as they were not specifically created for the purpose of being destroyed in the process

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proof of a unique individual and thus ensoulment. See Peters T (2007) 31-33 and Congregation of the Doctrine of the Faith (1988) "Instructions on respect for human life in its origins and on the dignity of procreation" *Acta Apostolicae Sedis* 80: 70- 102.

[35] Jones WHS (1959) *Hippocrates with an English translation* 165.

[36] See paragraph 3.4.1 *infra* for a discussion of non- maleficence.

[37] Harris J (2003) "Stem cells, sex and procreation" in Huhse H & Singer P (eds) (2006) *Bioethics: An anthology* 2nd edition 545 at 551.

of embryo research.[38] A further argument which is made by this camp is that at least the spare embryos are used for some good. This argument is however premised on the assumption that *in vitro* fertilisation is immoral to start with as it violates natural law. Thus the use of spare embryos at least draws some good from an otherwise immoral situation.[39] The second camp is expressly against the use of spare embryos as they argue that the original wrong of killing a potential person cannot later be redeemed by being used in medical treatment which saves another person. Not even a good end can justify an original evil.[40]

2.1.2 Possible Solutions to The Ethical Debate And Rebuttable

This section of the discussion examines some of the possible solutions which have been offered in order to mitigate the ethical debate from the embryo protectionists. Firstly, the 14- day cut-off rule is offered as a compromise as the appearance of the primitive streak could be regarded as proof of a human individual. Secondly, the use of induced pluripotent stem cells is offered as one alternative to embryonic stem cells and has the ability to completely silence the issues regarding the moral status of the embryo.

The 14- day rule was first formulated by Mary Warnock of the Warnock Committee and is a clear example of a theological influence on research ethics. This rule marks the time of development when the embryo attaches to the uterine wall and the appearance of the primitive streak as an ethical threshold.[41] The underlying assumption concerned here is that only when the primitive streak appears, about 14 days after conception, and only then does the human individual come into being. Fertilisation is therefore not the beginning of human development but rather the

[38] Outka G (2002) "The ethics of human stem cell research" in Waters B & Cole Turner R *God and the Embryo: Religious voices on stem cells and cloning* 31. See also Outka G (2007) "The ethics of using embryos in research" *Reproductive Biomedicine Online* 14(1):92-97.
[39] Engelhardt HT (2000) *The foundation of Christian bioethics* 261.
[40] Peters (2007) 38.
[41] See in general Warnock M (1984) *A question of life: The Warnock report on human fertilisation and embryology*.

beginning of the process and development into a human individual.[42] Research using an embryo of less than 14 days should therefore be permissible.[43]

The 14- day rule is remarkable in the manner in which it simultaneously provides a level of respect to the early embryo while also granting scientists permission to conduct experiments at the blastocyst stage. Furthermore, this rule enjoys acceptance by the embryo protectionists and the research standards framework.

The second possible solution is the use of induced pluripotent stem cells. Numerous embryo protectionists argue that embryonic stem cell research is not necessary and scientists may pursue regenerative medicine without killing a potential person.[44] The science of induced pluripotent stem cells means that stem cells can be created from adult cells and thus no embryos are destroyed. Induced pluripotent stem cells therefore offer a viable solution to the ethical issues within the embryo protection framework.

This framework is not unfaultable and thus certain arguments may be made against it. Firstly it is important to emphasise that potential dignity is not actual dignity and a potential person is not an actual person.[45] Potential murder is therefore not actual murder. Secondly, the argument can be made that although the zygote is a living entity directly after fertilisation and thus possesses human nature, it is a common human nature with various potentials. One of these potentials may just as well be personhood, but it is not yet a person and therefore does not have dignity. The second framework must now be discussed as it is closely related to the embryo protection framework on the grounds that it seeks to protect human nature.

[42] Peters (2007) 43.
[43] This is currently the cut- off time for the procurement of stem cells from an embryo. See paragraph 2.4.1 *infra* for a discussion of the 14- day rule form within the research standards framework.
[44] Peters (2007) 38.
[45] Peters (2007) 45.

2.2 THE NATURE PROTECTION FRAMEWORK

The nature protection framework is centred on the question of whether or not scientists are interfering with the genetic nature of human beings to such an extent that they are playing God and risk steering humanity into the direction of a *Brave new world*. This framework is thus largely based on fear, namely the fear of moving to far away from what is natural. Nature protection understands stem cells by firstly imagining all the undesirable and unforeseen consequences of stem cell research and secondly, working retroactively from these consequences to regulate present-day policies.[46]

The nature protection framework requires that "playing God" must be avoided. The proponents of this framework argue that while an individual case of advancement is ethically permissible, the cumulative effect thereof cannot be fully anticipated.[47] They fear the desire for advancement will go unbridled and produce a society of genetic haves and have- nots.[48] Kiessling and Anderson[49] state that this perception may be changed by the scientists themselves. The public as lay persons may conjure up ideas of scientists playing God or images of Doctor Frankenstein and view laboratories as sinister and mysterious places. This may also be ascribed to the loaded and baffling language used by physicians and scientists to explain stem cell research. It is thus submitted that the nature protection framework could be countered by better knowledge and understanding of the science of stem cell research by the public. This framework is largely premised on the wisdom of repugnance and the slippery slope argument and each is now briefly discussed.

2.2.1 The Wisdom of Repugnance

The nature protectionist subscribe to the wisdom of repugnance or "yuck factor" which is best described as amoral alarm telling us which direction ethics should

[46] *Idem* 49- 52.
[47] See paragraph 2.2.2 *infra* for more on the slippery slope.
[48] Kass LR & Wilson JQ (1998) *The ethics of human cloning* 18.
[49] Kiessling AA & Anderson S (2003) *Human embryonic stem cells* 196.

follow. It alerts us to the potential harm of "unnatural intervention."[50] This argument, as well as others used by the nature protectionist presupposes a commitment to naturalism and thus assumption that nature is good as is.[51] It is argued that biotechnical intervention such as stem cell research and regenerative medicine are violations or the moral order of nature.[52]

2.2.2 The Slippery Slope

Nature protectionists, like embryo protectionists portray the stem cell debate in terms of non- maleficence and thus the primary moral obligation is to guard against the potential negative consequences or harm of stem biotechnological or, in context of this dissertation stem cell research specifically. Nature protectionists seek to avoid harming human DNA and the human culture, while embryo protectionists avoid harm to the embryo or potential person.[53]

Both the nature and embryo protectionists often use the slippery slope argument as an articulation of the future harm which could possibly be inflicted should destruction of a blastocyst be permitted for the use thereof in medical research or therapy.[54] Supposedly, the commitment towards protecting human life in general will be lost.[55] It is submitted that the issue surrounding therapeutic cloning is an example of this. Many opponents to therapeutic cloning argue that should cloning be permitted, even for therapeutic purposes, it will eventually end up on the slippery slope to reproductive cloning. This argument is however rebutted by Scott[56] as it is obvious by previous medical and scientific advances that society does not allow the loss of control. It is further submitted that this is evidenced by section 57 of the

[50] Kass & Wilson (1998) 18.
[51] This may be referred to as neo- naturalism.
[52] Zoloth suggests that this protectiveness is due to nostalgia and a vague fear that modernity is moving too fast. See Zoloth L (2004) "Immortal cells, moral selves" in Lanza R (ed) *Handbook of stem cells volume 1* 749.
[53] Peters (2007) 59.
[54] The supposed harm is the result of allowing stem cell research and the slippery slope which will ensue if interference with humanity and human nature is allowed.
[55] Peters (2007) 56.
[56] Scott CT (2006) *Stem cell now* 187.

National Health Act,[57] to name but one provision found in legal instruments, which prohibits human reproductive cloning.

In conclusion it is thus clear that the nature protection framework applies to the fear that technological, scientific or medical, advances are separating humans from their humanness. Often the nature protectionists and embryo protectionists are partnered to form strong opposition to stem cell technology. It is therefore necessary to now discuss a framework which is in favour of stem cell research, namely the medical benefits framework.

2.3 THE MEDICAL BENEFITS FRAMEWORK

The embryo protection framework and the nature protection framework orientate themselves around the bioethical principle of non- maleficence and thereby avoid harming the embryo or human nature. This is, as stated above, part of the Hippocratic admonition to benefit and do no harm. The medical benefits framework however, focuses on the first part of the admonition and is thus centred on the principle of beneficence.[58] This framework is therefore concerned with those who may potentially be helped by stem cell research.[59] The medical benefits framework orientates itself around the question of whether regenerative medicine should be supported purely on the grounds that it could bring relief to human suffering.[60] Proponents of stem cell research therefore focus on the revolutionary therapeutic potential of stem cells.

[57] See chapter 6 paragraph 2.2.5 *infra* for an example of a statutory prohibition on reproductive cloning as found in the National Health Act.
[58] See paragraph 3.4.2 *supra* for a discussion of beneficence.
[59] Peters T & Bennett G (2003) "Defining human life: Cloning, Embryos and the origins of dignity" in Chan MLY & Chai R (eds) *Beyond determinism and reductionism: Genetic science and the person* 56-73.
[60] This sentiment is echoed in the Jewish concept of *tikkun olam* which means that we have a responsibility to join God in repairing and transforming a broken world or the Christian concept of *agape* which is the responsibility to love ones neighbour. See Peters (2007) 62.

To support stem cell research and regenerative medicine from within this framework, it is required that ethics should be future orientated and thus biomedical sciences become a means to an end.[61] Arguments within this framework are thus Deontological in nature and not utilitarian.[62] It is submitted that this is in line with the ideology of medical research. The promise of stem cell therapy lies in the future and is still largely uncertain. For this reason the benefits of such development is still undetermined.

2.3.1 Medical Benefits, Beneficence and Social Justice

Social justice is connected to the issues surrounding the potential exploitation of women[63] as it raises the question of who will be expected to produce the embryos and fetuses necessary for stem cell research. The question is further raised whether class, race and gender will colour the process of stem cell research and will profit instead of healing become the main driving force.[64] Justice is inextricably connected to beneficence and the issue of access is extremely relevant in context of the medical benefits framework.[65] It is submitted that in order to fulfil the requirement of justice, a system will have to be put into place to guarantee widespread access to regenerative medicine when the regulatory framework is in place. A possible solution to this problem is the establishment of public stem cell banks.[66]

Finally, it should be noted that some level of moral urgency is attached to scientific research by the medical benefits framework. Regenerative medicine should not be slowed down and when retarded, those responsible therefore must also bear the responsibility for those that they have chosen not to help.[67] This requirement of proactive measures towards the implementation or development of regenerative medicine and stem cell therapy is in line with section 27(2) of the Constitution which

[61] *Idem* 68.
[62] *Ibid* 70- 72
[63] See paragraph 2.4.1 *infra* for more on the exploitation of women.
[64] Farley MA (2004) "Stem cell research: Religious considerations" in Lanza R (ed) 766.
[65] See chapter 3 paragraph 10.1 *supra* for a discussion on access to health care services.
[66] See chapter 2 paragraph 4 *supra* for more on the process of stem cell banking.
[67] Juengst E & Fossel M (2000) "The ethics of embryonic stem cells: Now and forever, cells without end" *Journal of the American Medical Association* December 284(24): 3180.

requires the state to take reasonable legislative and other measures and section 7(2) which requires the state to respect, protect, promote and fulfil the rights in the Bill of Rights. The right which might be promoted and fulfilled in this case and which must not be retarded may be the right to access to health care services as enshrined in section 27 of the Constitution.

It is clear from the above discussion that the three discussed frameworks have presumptions regarding the use of someone or something as a means to an end. This denotes a commitment to dignity and thus all three frameworks may be seen as ethical and based on philosophical though. The research standards framework however, is a secular framework and must be discussed.

2.4 THE RESEARCH STANDARDS FRAMEWORK

In the previously discussed frameworks a consistency exists between the framework and the anthropological assumptions that underlie the framework. This is not the case when examining the research standards framework. It is rather a collection of principles which require neither justification nor coherence and therefore scientists work within a secular framework which sets the moral standard whereby they measure themselves. Ethics in its most mature form become policy which is the rules by which society attempts to guide their lives in a manner that is good.[68] It is therefore submitted that this framework is of great importance as policy makers are sure to examine the ethical guidelines used by the scientists in the field in any attempt to regulate stem cell research. This corroborates the previous statement that in the absence of hard law ethical guidelines may be presumed as such.

Arguments in favour of using embryonic stem cells from within this framework state that only when there is some medical benefit therein, may embryonic stem cells be

[68] Scott (2006) 149.

used.[69] There then also exists a sequence of preference for the derivation of human embryonic stem cells:[70]

1. Human embryonic stem cells should firstly be drawn from existing stem cell lines originating from embryonic cells which were derived from embryos of less that 14- days;[71] and

2. Surplus human embryos created for the purpose of *in vitro* fertilisation of no more than 14 days.[72]

A third option, namely the creation of human embryos for the purpose of research exists, but then only after the first two preferences have been tried and tested and found to be inadequate.[73] The creation of human embryos for research purposes can only be justified when strong merit in the potential medical benefit of such research exists, no acceptable alternative exists and there must be highly selective, case- by-case approval thereof by a statutory regulatory body.

2.4.1 Justice concerns

As mentioned above, the research standards framework is a secular framework and thus incorporates many of the principles of the previously discussed frameworks.[74] The process of donation entails certain risks and effects on women.[75] Specifically

[69] Perters (2007) 79.
[70] Bioethics Advisory Committee (BAC) Recommendation 4 in a report submitted to the Ministerial Committee for Life Sciences, June 2002. See Bioethics Advisory Council of Singapore *Ethical, legal and societal issues in human stem cell research, reproductive and therapeutic cloning* available at http://www.bioethics-singapore.org/ accessed 6/6/2009.
[71] This reflects then President George W Bush's position of 9 August 2001.
[72] This reflects the discarded embryo position.
[73] BAC Recommendation 5.
[74] The 14- day rule is accepted by scientists although it belongs to the embryo protection framework for example. Another example of this overlapping of frameworks is the concern for justice which is found in the research standards framework although it belongs to the medical benefits framework.
[75] The process of retrieving eggs from a woman's body is complicated and bears risks due to the hormonal stimulation which is necessary to stimulate production of numerous eggs. During clinical stimulation of a woman's cycle, she hyperovultes and produces a large amount of eggs at once and not just one as he naturally would. One of the risks involved it hyperovultaion syndrome, which a woman who has donated might experience in later pregnancies. Another risk is the enlargement of remaining eggs and short term bleeding. Also, the risk of ovarian cancer is increased. Informed consent which is freely given is thus an important factor and is ethically required in situations where

within the research standards framework question arises regarding payment for egg donations. Although women should not be paid for donations, they should be reimbursed for expenses made in the process of donation. Ethicists state that there should be no financial incentive and also that trafficking must be avoided at all costs. Nevertheless, women should receive reimbursement for costs such as travel, missed wages and child care. Regarding financial incentives or at least reimbursement, underpaying and overpaying must be guarded against. Underpaying will lead to the exploitation of well meaning donors and overpaying will lure poor women into a new form of social inequality.[76]

Holland[77] is particularly concerned with justice and states that women, especially poor women, women of colour and their children must be granted a fair hand with respect to the uses and social costs of genetic technologies and particularly, stem cell technologies. Within the medical benefits framework, justice thus entails two elements. The first being exploitation of women and the second concerns access to these technologies. Ethicists support the creation of regulatory structures which will ensure the dignified treatment of donating women as persons and not merely as bodies producing research material. A consideration of gender in the making and implementing policy and law is referred to as "gender mainstreaming." This involves the organisation, or rather re- organisation, improvement, development and evaluation of law and policy in order to include a gendered perspective at all levels of law. The practical implication of this is that the circumstances of women's lives must be kept in consideration such as their needs and priorities as well as their living conditions.[78] It is submitted that gender mainstreaming must become a normal part

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woman wish to donate eggs. There is however a golden standard for egg donation. Firstly, the highest quality of eggs comes from younger women between the ages of 21 and 35 and these donors are the moved to the top of the list. Even more preferential are the eggs from a woman who has had at least one biological child as this increases the promise of quality. Secondly, the eggs must be free of viruses and infections and are therefore screened. Thirdly, it has been indicated that clinics prefer to work with women who participate due to a genuine desire to share the fruits of their body for the purpose of wider human betterment. See Peters (2007) 83- 84.

[76] *Idem* 85.

[77] Holland S (2001) "Beyond the embryo: A feminist appraisal of the embryonic stem cell debate" in Holland S, Lebacqz K, & Zoloth L (eds) *The human embryonic stem cell debate: Science, ethics and public policy* 74.

[78] Amollo R (2009) "Advancing women's access to health services in South Africa: Legal and policy responses to HIV/AIDS" *ESR Review* 10(1): 3 at 4.

of the functioning of governmental departments and agencies and especially the law- and policy makers. At this juncture it is however interesting to note a different perspective on the exploitation issue.

Commodification is one of the main subjects of debate concerning stem cells as humans must be treated as more than mere commodities which can be traded and are entitled to having their personhood respected.[79] An alternative way to view exploitation does however exist according to Dodds. This form of exploitation does not view women as the victims from who reproductive material is simply taken, it views exploitation as the lack of compensation to women who provide material. Researchers, bioethicists and policymakers agree that women should not be treated as mere property which is ownable by others but there are reasonable profits involved in stem cell therapy and in the pursuit of biotechnology.[80] Often, the donors of biological material are unaware of the potential for their donation to enter the world of commerce and the profits which are made therein.[81] Women are thus denied access to recognition and therefore exploited as their own property rights in their bodies are not recognised.[82] It is thus unacceptable that women are alienated or differently stated, it is unacceptable that women are not paid. This alienation may then also be seen as a contributing factor to poverty and oppression of women and thus stem cell research policies mistreat women. Simply accepting donations from women is what must be understood as exploitation as stem cell research is set to become a very lucrative industry. Dickens states: [83]

> "A compulsory and one- way gift relationship is not a gift, but exploitation. Nor is it adequate to conceptualise the issue in terms of consent alone, any more than it is adequate to say that the worker consents to work and therefore retains no further rights to control the conditions of their labour."

[79] This is related to issues of trafficking and it is submitted that protective measures are necessary. Dodds S (2004) "Women, Commodification and embryonic stem cell research" in Humber JM & Almeder RF (eds) *Biomedical ethics review: Stem cell research* 151 at 151.
[80] *Idem* 155.
[81] *Ibid* 156.
[82] Dickenson D (2002) "Commodification of Human tissue: implications for feminist and development ethics" *Developing World Bioethics* 2(1): 55 at 56.
[83] *Idem* 61.

This must however not be understood as meaning that a full- scale market must be opened for the trade of reproductive material, but rather that women must have more options available to them. One such option could be to grant women more control, via legislation, over what is done to the reproductive tissue they have produced.[84]

In a post- apartheid South Africa, deliberate efforts have been made to stimulate a gendered perspective in law, policy and governmental actions. But as long as these efforts remain unresponsive, women's health care has had no victory but a pyrrhic one and is won at a horrible cost to women.[85] One of the most important issues however remains that poor women and their families should eventually have access to regenerative medicine. It is submitted that it is therefore imperative that pre-emptive measures are taken at the planning stage of policy making to ensure this.

In conclusion it is therefore obvious that the research standards framework incorporates the embryo protection and nature protection framework but is largely based on the medical benefits framework. A distinct characteristic thereof is the commitment to justice concerns.[86] At this juncture it becomes necessary to examine general ethical principles, such as justice, and the incorporation thereof in South African ethical guidelines.

3 GENERAL PRINCIPLES OF MEDICAL ETHICS

Certain arguments are regularly found in medical ethics debates and therefore some mention must be made thereof.[87] These arguments are human dignity,[88] the slippery slope[89] and the sanctity of life.[90] Principles which must always be applied to any research programme include recognising the participant as a person, human rights, the ethics of justice, fairness and objectivity as well as competence, integrity,

[84] Dodds (2004) in Humber & Almeder (eds) 151 at 165.
[85] Amollo (2009) *ESR Review* 3 at 6.
[86] See paragraph 3.5 *infra* for a general discussion of the principle of justice.
[87] See in general Pattinson SD (2006) *Medical law and ethics* 1st edition 13- 20.
[88] See chapter 3 paragraph 4 *supra* for a discussion surrounding the right to dignity
[89] See paragraph 2.2 *supra* and especially paragraph 2.2.2.
[90] See paragraph 2.1 *supra*.

sensitivity, confidentiality, a demarcation of different roles, communication and the consideration of all possible dangers such as objectification or fragmentation and coercion.[91] Any research must conform to the basic ethical principles of autonomy, non- maleficence, beneficence and justice.[92] Researchers must endeavour to address the inequities of the past and justice may also be described as a principle which necessitates equal distribution of the risks and benefits of research between communities.[93]

Values are generally not objectively determined and cannot be scientifically defined. For this reason, science is neutral towards most bioethical values. Values are subjective assessments of what is acceptable and for this reason it may be said that ethical dilemmas are created only in relation to human beings. Ethical dilemmas thus arise when two or more alternative actions, which are both inherently good, have conflicting outcomes. An action might benefit one person but cause harm to another. In the context of this dissertation, a person might benefit from stem cell therapy but at the cost of the destruction of an embryo. One must then search for the ethical justification of such action and thus in the case of conflicting values, ethics ask what should be done.[94]

Values have translated into ethical principles and in recent years certain fundamental ethical principles have been formulated as the basis of ethical discussions regarding medicine and are also applicable to scientific research in certain cases.[95] These principles are autonomy, non- maleficence, beneficence and

[91] For a more detailed discussion of these principles see MRC "What is meant by research ethics?" (Book 1) paragraph 3.1.3.
[92] HPCSA "General ethical guidelines for biotechnology research" Guidelines for good practice in the health care professions, Booklet 7: 10 available at http://www.hpcsa.co.za/hpcsa.default.aspx?id+152 accessed 8/7/2009.
[93] *Ibid*.
[94] In certain cases the ethical dilemmas is not based on conflicting values but on a factual basis. Debates may arise due to incorrect information or a lack of knowledge. Often a mere clarification of facts may resolve the issue. It is therefore submitted that the pertinent facts must first be gathered in the adjudication of medical ethical issues. See Steinberg (1998) "Medical ethics."
[95] For an in depth discussion see Beauchamp TL & Childress JF (2001) *Principles of Biomedical Ethics* 5th edition and Gillon R & Lloyd A (eds)(1994) *Principles of health care ethics.*

justice. Each principle will be discussed. Dignity and truthfulness[96] have also been mentioned as important principles.[97]

These values alone do not give the answers to a problem, but provide a useful framework in which conflicts may be understood. The *Health Professions Council of South Africa* (HPCSA) and the *Medical Research Council* (MRC) have complide ethical guidelines and these serve as examples of the manner in which ethical principles have been incorporated into frameworks which could be used as a regulatory tool in the absence of hard law. For this reason the provisions of the HPCSA guidelines as well as those of the MRC regarding each of the above mentioned principles will be discussed. Firstly however, some background on the MCR and HPCSA is necessary.

3.1 MEDICAL RESEARCH COUNCIL OF SOUTH AFRICA

The Medical Research Council is a creature of statute[98] and has as main objective the promotion and improvement of the quality of life and health of South Africans through research development and technology transfer.[99] The MRC recognises the injustices of the past and subscribes to the constitutional values. Their policy is clear in that all research sponsored by the MRC must be of the highest ethical standards. This means the research must first be approved by the Council and must operate in accordance with the MRC ethical guidelines. The MRC guidelines are concerned with research on humans and animals involved in therapeutic and non- therapeutic

[96] Truthfulness entails the concept of informed consent which in medical ethics usually refers to the idea that a person must be fully informed of and then also understand the benefits and risks involved in the proposed procedure. It is thus closely linked to autonomy. See in general Herring (2008) 133-191.
[97] Concerning dignity, it is submitted that both the recipient and the administrator of the treatment or experiment have the right to dignity while honesty and truthfulness concerns informed consent.[97] Society has been given elaborate promises regarding stem cell research and the hoped for benefits thereof. Researchers have an obligation to be honest with patients and research participants.
[98] Created by section 2 of the South African Medical Research Council Act, Act 19 of 1969. This Act was repealed by the South African Medical Research Council Act, Act 58 of 1991.
[99] Section 17 of the South African Medical Research Council Act, Act 58 of 1991. Hereafter referred to as the MRC Act of 1991.

research. It further promotes the biomedical principles of autonomy, non-maleficence, beneficence and justice.[100]

The MCR is the regulating body for any research on, or experimentation with *inter alia* human subjects and must determine ethical directives and take any other necessary control measures to ensure compliance with such directives.[101] In general, medical research must be approved by an ethics committee before such research may be undertaken and the MRC ethics committee is one such committee. It is responsible for the implementation of MRC policy and must advised the MRC board on matters relating to medical research and experimentation.

Other research institutes in South Africa base their own ethical guidelines on those of the MRC and Van Oosten states that where those other guidelines are in conflict with the guidelines of the MRC, the MRC guidelines should be followed provided that it adheres to international medical research principles.[102] The guidelines and policy statements of the HPSCA and MRC do not constitute law but are legally relevant. The reason for this is that in the absence of express legislation courts will turn to reputable members of a profession to determine what is acceptable and thus legally permissible.[103] Ethics and law in the field of medical research are interwoven to such an extent, that it could be said to assume legal import although guidelines *per se* are not legal rules.[104]

3.2 THE HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA

The HPCSA is a statutory body with the primary objectives of regulating the profession, to promote health care and set ethical standards for research and

[100] MRC "What is the South African Medical Research Council's ethics policy" (Book 2) paragraph 1.1.
[101] Section 17 of the MRC Act of 1991. It may be said that the MRC's control is exercised in a threefold manner. Firstly by way of codified board guidelines, secondly by careful scrutiny of individual applications for approval of research and thirdly, the ongoing control over research by way of follow up reports by evaluator and consultants. See Strauss SA (1992) "Legal aspects of genetic manipulation" in Hattingh J (ed) *Genetic engineering in ethical perspective* Unit of Biomedical Ethics, University of Stellenbosch: Stellenbosch 63 at 65.
[102] Van Oosten FFW (2000) "The law and ethics of information and consent in medical research" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 63: 5 at 9.
[103] Slabbert (2001) *TSAR* 495 at 498.
[104] Van Oosten (2000) *THRHR* 5 at 6.

practice.[105] The HPCSA has published a collection of booklets regarding ethical behaviour in various fields related to medicine and these guidelines are binding on members of the HPCSA.[106] For the purpose of this discussion, booklets 6 and 7 will be used. The HPCSAs General ethical guidelines for biotechnology research are also known as the code of ethical practice for medical biotechnology research in South Africa. This booklet is of particular importance as it was developed by *inter alia* Professor Dhai, who is currently a member of the National Health Research Ethics Council. Medicine and biotechnology is constantly developing and changing. The guideline is further intended as a live document which is subject to continuous amendment and change so as to be able to address new areas of ethical concern.[107] It is therefore submitted that ethical guidelines may be a useful tool in lending the proposed regulatory framework some flexibility.[108]

The HPCSA was established by the Health Professions Act.[109] According to section 3 of the Health Professions Act the objects of the HPCSA are the following:

(a) To co-ordinate the activities of the professional boards established in terms of this Act and to act as an advisory and communicatory body for such professional boards;

(b) To promote and to regulate interprofessional liaisons between registered professions in the interest of the public;

(c) To determine strategic policy and make decisions regarding the professional boards and the registered professions;

[105] Section 3 of the Health Professions Act, Act 56 of 1974.
[106] 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 at 210.
[107] HPCSA "General ethical guidelines for biotechnology research" Guidelines for good practice in the health care professions, Booklet 7:1.
[108] This guideline only addresses ethical issues related to biotechnology research. "Research" covers a broad spectrum of activities and may be defined as the "systematic search or enquiry for knowledge." A distinction exists between 'therapeutic' and 'non-therapeutic research'. The *Declaration of Helsinki* defines therapeutic research as "research which is potentially beneficial to the research participant" and non-therapeutic research is "research not intended to be beneficial to the actual participant but valuable to the development of health solutions and general medical and scientific knowledge." See Department of Health of South Africa (2004) *Ethics in health research: Principles, structures and processes*.
[109] The Health Professions Act, Act 56 of 1974.

(d) To consult with relevant authorities on matters affecting the professional boards in general;

(e) To assist in the promotion of the health of the population of the Republic;

(f) To control and exercise authority in respect of all matters affecting the training of persons in, and the manner of the exercise of the practices pursued in connection with, the diagnosis, treatment or prevention of physical or mental defects, illnesses or deficiencies in human kind;

(g) To promote liaisons in the field of training both in the Republic and elsewhere, and to promote the standards of training in the Republic;

(h) To advise the Minister on any matter falling within the scope of this Act; and

(i) To communicate to the Minister information of public importance acquired by the council in the course of the performance of its functions under this Act.

The HPCSA guidelines are drawn from various sources including the Constitution, the Department of Health's *Ethics in Health Research: Principles, structures and processes*, the MRC's *Guidelines for Ethics in Medical Research* and the *Declaration of Helsinki*.[110] The HPCSA have grouped the principles mentioned above into three groups and for the purpose of this discussion, the principles will be discussed according to the HPCSA format.

[110] HPCSA "General ethical guidelines for health researchers" Guidelines for good practice in the health care professions, Booklet 6: 1 available at http://www.hpcsa.co.za/hpcsa.default.aspx?id+152 accessed 8/7/2009.

3.3 THE PRINCIPLE OF RESPECT FOR PERSONS

3.3.1 Autonomy[111]

Voluntas aegroti suprema lex, autonomy, is a fundamental ethical value and is premised on the view that every person has intrinsic worth and dignity. Autonomy is rooted in respect for an individual's ability to make their own informed decisions. Many ethicists regard autonomy as the most important ethical principle,[112] while others consider it one of many important principles.[113] Either way, autonomy cannot be ignored in ethical debates. Article 5 of the *Universal Declaration on Bioethics and Human Rights*[114] requires that the autonomy of the person making decisions must be respected while special measures must be taken where a person is incapable of exercising their autonomy. Furthermore, autonomy is not only an ethical principle but also an enforceable right and it protected by section 12 of the Constitution.[115] A further example of the importance of autonomy and the embodiment thereof may be found in article 6 of the *Bioethics Declaration*. Article 6 requires that express written consent must be obtained prior to any medical procedure or scientific research. Participants who are capable of deliberating about personal choices should be treated with respect and should be given the opportunity to make informed decisions regarding their participation in the research. It is important to mention that special protection must be given to those participants with diminished or impaired autonomy.[116]

The patient is not the only party entitled to autonomy however and the physician's autonomy must be respected as well. For this reason a physician may refuse to partake in a certain treatment if it is in conflict with the physician's conscience.[117]

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[111] See in general Foster C (2009) *Choosing life, choosing death: The tyranny of autonomy in medical ethics and law* 50- 54. See also chapter 5 paragraph 3.1 *infra* for more on autonomy. See in general Beauchamp & Childress (2001) 57-112.
[112] See in general Engelhardt HT (1986) *The Foundations of Bioethics*.
[113] See in general Pellegrino ED and Thomas DC (1988) *For the Patient's Good*.
[114] *Universal Declaration on Bioethics and Human Rights.* Hereafter referred to as the Bioethics Declaration.
[115] See chapter 3 paragraph 6.3 *supra* regarding consent.
[116] HPCSA "General ethical guidelines for health researchers" Booklet 6: 1.
[117] This is then also in line with the constitutional protection of freedom of conscience as provided for in section 15. See chapter 3 paragraph 8 *supra* in this regard.

The health care provider may not use their freedom of conscience to abuse the patient or participant and must still display a positive disposition and demonstrate courtesy, human dignity, patience, empathy and tolerance towards the patient, even where they personally do not agree with the choices of the patient or participant.[118]

3.3.2 Confidentiality[119]

Confidentiality has traditionally been viewed as a non- negotiable requirement of medical practice and is generally associated with conversations between physician and patient. For this reason it is commonly known as patient- physician privilege.[120] A participant's right to both privacy and confidentiality must be protected and the researchers must ensure that personal information is collected, stored, used or destroyed in a manner which does not violate the confidentiality or privacy of the research participant.[121] Information includes information regarding the specific treatment.[122] According to article 9 of the *Bioethics Declaration*, the privacy of persons and the confidentiality of personal information must be respected. Information must, to the greatest extent possible, not be used or disclosed for any purpose other than what consent has been obtained for. Any form of a list which contains details of persons who have participated in research or treatment procedures must remain confidential and the use of a system of coding to ensure this.[123] This sentiment is echoed in the modern version of the *Hippocratic Oath*.[124]

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[118] Department of Health (2002) National Patients Rights Charter.
[119] See in general Siegler M (1982) "Confidentiality in medicine: A decrepit concept" *New England Journal of Medicine* December 307(24): 1518-152. See also *Jansen van Vuuren v Kruger* 1993 (4) SA 824 (A) wherein the importance of confidentiality was recognised by a South African court. See also Herring (2008) 191- 238.
[120] Appel JM (2006) "Must my doctor tell my partner? Rethinking confidentiality in the HIV era" *Medicine and Health Rhode Island* June 89(6):223- 224. See also Foster (2009) 65- 82.
[121] HPCSA "General ethical guidelines for health researchers" Booklet 6: 2.
[122] National Patients Rights Charter.
[123] MRC "Research participants" (Book 1) paragraph 7.2.3.
[124] Lasagna L (1964) *Modern version of the Hippocratic Oath* available at http://www.pbs.org/wgbh/nova/doctors/oath_modern.html accessed 4/ 3/ 2010.

Health researchers should always recognise the right of research participants to expect that the researchers will not communicate any personal and confidential information which is attained in the course of their professional duties, unless the research participants agree thereto and to not breach confidentiality without sound reasons therefore or without the knowledge and consent of the participants. Furthermore, the research data and other disclosures made by research participants must be protected.[125]

Privacy, which includes the protection of a person's private information obtained in a situation to which confidentiality may be applied, is a constitutional right and is protected by section 14 of the Constitution. The right to confidentiality is then also protected by section 14 of the NHA.[126] Researchers therefore have an additional duty to take precautions to protect confidentiality by the use of codes in research records as means of identification for example.[127] The Department of Health[128] provides the following examples of protection of confidentiality. Firstly potentially identifiable coded storage methods may be used. This would entail the removal of data- identifiers and being replaced with a code. This method is however not fail proof as the code may still be used to re- identify the relevant person. Secondly, a de- identified storage method may be incorporated. This method ensures the utmost protection of information as identifiers are permanently removed from data. The de-identified information will remain anonymous and thus confidentiality is ensured.

Confidentiality may be broken where it comes to light that a participant has a notifiable disease. In such cases the researcher will have a duty to disclose this information. The participant must be informed of this duty when consenting to the research.[129] The best way to appropriately share information is with information, so as to avoid misconceptions, and counselling procedures.[130] The Department of

[125] HPCSA "General ethical guidelines for health researchers" Booklet 6: 6.
[126] See chapter 3 fn 275 for this section.
Section 15 states that personal information may be disclosed if it is necessary for a legitimate purpose within the ordinary course and scope of their duties and the disclosure is in the interest of the user.
[127] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 20.
[128] Department of Health of South Africa (2004).
[129] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 21.
[130] The MRC recommends the following guidelines for disclosure of confidential information: 1.The accepted standards of confidentiality of medical information must be, as far as possible, adhered to;

Health should however pay attention to this issue as it is of paramount importance and thus arrangements should be made to protect confidentiality.

3.4 THE PRINCIPLE OF BEST INTEREST OR WELL- BEING[131]

Acting in the best interest of the research participant or patient is a combination of non- maleficence and beneficence. This is described as one of the duties a researchers has towards a research participant. In order to act in the best interest of the research participant, a researcher must always:[132]

1. Place the life, well being, health, privacy and dignity of the research participant before all other interests;

2. Honour the trust that research participants place in them and recognise that they are in a position of power and should therefore avoid abusing their position;[133]

3. Abstain from engaging in research which involves human research participants unless they sure that the risks involved have been adequately assessed and can be managed throughout the project. Researchers should further stop the involvement of participants if it may be harmful to them or where it becomes obvious that the risks are outweighing the benefits;

4. Researchers must ensure that their personal beliefs do not influence their choice of research participants. Such beliefs will be unethical; and

5. Research participants should not partake in research due to financial incentives but researchers should ensure that research participants are compensated for reasonable expenses or loss of income as a result of their

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2. Should the application of such standards result in damage to the interests of family members, the health professionals must attempt to persuade the individual to permit the disclosure of the information; and 3. In exceptional circumstances, health professionals might justifiably disclosing information to family members despite an individual's desire for confidentiality.

[131] See article 4 of the Bioethics Declaration which states that during the development and application of scientific knowledge the benefits must be maximised while possible harm must be minimised.

[132] HPCSA "General ethical guidelines for health researchers" Booklet 6: 3- 4.

[133] See chapter 5 regarding the relationship between the physician and patient.

participation and such compensation should be specified in the relevant research protocol or proposal. Participants should also be compensated for trail related injuries.

In order to demonstrate respect for their research participants, health researchers should *inter alia* respect the privacy and dignity of participants and respect the right of research participants to safeguard their integrity and should treat research participants politely and with consideration. Researchers must listen to the research participants and respect their opinions and guard against human-rights violations and avoid participating in any actions that violate the rights of others.[134]

3.4.1 Non- Maleficence[135]

Non- maleficence or *primum non nocere* may be defined as the obligation not to harm others and to remove and prevent potential harm.[136] Health care practitioners must have the appropriate qualifications and training[137] as to not cause harm due to a lack of knowledge or skill.[138] The risks and harms of research must therefore be minimised.[139]

The non- maleficence concept is applied to the physician- patient relationship and is based on the phrase "above all, do no harm."[140] Some writers argue that to do no harm should be re- defined to strive not to do harm by finding a balance between the supposed benefit and the feared harm of the proposed procedure.[141] This

[134] HPCSA "General ethical guidelines for health researchers" Booklet 6: 4.
[135] See in general Beauchamp & Childress (2001) 113- 164.
[136] See in general Frankena WK (1973) *Ethics* 2nd edition.
[137] According to the HPCSA , health research studies should be conducted by health researchers who are suitably qualified and all health researchers should always maintain and improve the standard of their performance by keeping their professional knowledge and skills up to date by particularly, taking part in educational activities which enhance their scientific and research ethics knowledge. Researchers must further acknowledge the limits of their professional knowledge and competence and observe and keep up to date with the ethical and regulatory frameworks which may impact health research. See HPCSA "General ethical guidelines for health researchers" Booklet 6: 8.
[138] This subject will be eluded to in the course of this dissertation.
[139] HPCSA "General ethical guidelines for health researchers" Booklet 6: 1.
[140] This adage stems from the *Hippocratic Oath*.
[141] Steinberg (1998) "Medical ethics."

principle is however not absolute and cannot be applied fully in practice.[142] Non-maleficence must therefore be balanced against beneficence.

3.4.2 Beneficence[143]

Salus aegroti suprema lex, or beneficence is defined as the moral obligation to do good to others and help others actively since ethically, to avoid harm is not sufficient and active steps must be taken. Beneficence may be interpreted as the necessary actions to serve the best interests of the patient. Factors which may have an impact on this principle include for example, the ease and ability with which help can be given or the nature of the relationship between the physician and patient. The benefits of health research must outweigh the risks to the research participant.[144] The status of beneficence in ethical issues, as with autonomy, is debated. Beauchamp and Childress[145] are of the opinion that beneficence is one of the core values of health care ethics. Pellegrino however argues it is the only fundamental principle in medical ethics.[146]

3.5 THE PRINCIPLE OF JUSTICE[147]

In the development and application of scientific knowledge human vulnerabilities must be taken into account and individuals and groups which may be seen as vulnerable must be protected and the personal integrity of such persons must be respected. [148] Justice is the granting and fulfilment of the rights of others.[149] This principle requires the division of rights and assets in an equal manner but also a fair

[142] See Gillon R (1985) " 'Primum non nocere' and the principle of non-maleficence" *Britishe Medical Journal (Clinical research Edition)* July 291:130 and Brewin T (1994) "Primum non nocere?" *Lancet* 344:1487.
[143] See in general Beauchamp & Childress (2001) 165- 225.
[144] HPCSA "General ethical guidelines for health researchers" Booklet 6: 1.
[145] Beauchamp & Childress (2001) 165- 224.
[146] Pellegrino ED (2000) "Medical professionalism: Can it, should it survive?" *Journal of the American Board of Family Practice* 13(2): 147- 149.
[147] See in general Beauchamp & Childress (2001) 225- 335.
[148] Article 8 *Universal Declaration on Bioethics and Human Rights.*
[149] Injustice is thus the denial thereof. See also article 10.

distribution of duties and burdens.[150] It is thus concerned with the distribution of scarce health resources or the fairness and equality of medical treatment. This principle imposes an ethical obligation on the researcher to treat each person in accordance to what is right and proper and in research this is primarily distributive justice whereby an equitable distribution of both the burdens and benefits of research is required. The research must leave the community in a better position and not a worse position. Where research thus involves participants from vulnerable communities, added protection will be necessary.[151] Researchers need to consider the possible adverse effects the research may have on vulnerable groups and therefore have a duty to observe the highest level of ethics to protect research participants and guidelines need to be followed to ensure that research is ethical.[152] The position of women then requires considerable attention.[153]

Health researchers must be aware of the rights and laws concerning unfair discrimination on the grounds listed in section 9 of the Constitution. In the context of stem cell research, researchers must be particularly vigilant so as to balance the burdens and benefits of research within the different population groups of South Africa and avoid imposing an unfair burden of participation on certain groups and communities, who are likely to be subject to over-researching.[154] Furthermore, South Africa presents a unique research environment as a result of the duality of the country. On the one hand South Africa possesses a sound infrastructure, well equipped research facilities and skilled researchers. On the other hand however, a large amount of South Africans fall under the category of vulnerable persons.[155] It is

[150] Steinberg (1998) "Medical ethics."
[151] HPCSA "General ethical guidelines for health researchers" Booklet 6: 3.
[152] HPCSA "General ethical guidelines for health researchers" Booklet 6: 1.
[153] Preamble of the *Universal Declaration on Bioethics and Human Rights*.
[154] HPCSA "General ethical guidelines for health researchers" Booklet 6: 6.
[155] Vulnerable groups may be defined as "persons who may have insufficient power, intelligence, education, resources, strength, or other attributes which make them capable of protecting their own interests" and they may further be characterised by the following:

1. Limited economic development;
2. Inadequate human rights protection;
3. Discrimination on health related grounds;
4. Inadequate understanding of scientific research;
5. Limited availability of health care or treatment options; and
6. Limited availability of persons who could provide informed consent.

for this reason that safeguards must be incorporated into guidelines or legislation to protect these vulnerable groups.[156]

Not all activities in the sphere of biotechnology may attract commercial interest and research may in instances be undertaken for purely strategic purposes or for community or public service. This research is supported and has great value. Research should therefore be pursued which may benefit the poor and disadvantaged communities even if it does not result in commercial gain. The transactional costs associated with intellectual property must thus not obstruct access to biotechnology and the new discoveries in this field.[157]

The general ethical principles have now been discussed and it must be kept in mind that these form the foundation of any ethical debate. The following section of this dissertation thus focuses on the particular issues involved in stem cells specifically.

4 SPECIFIC ETHICAL CONCERNS IN CONTEXT OF STEM CELL RESEARCH

The fact that the source of stem cells is a human embryo is problematic in itself due to the fact that the derivation of stem cells destroys the embryos potential to become a human life and not due to the sentimentality associated with research involving human tissue. This response can never fully be rationalised.[158] In reality there is no resolution to the issues involved in embryonic stem cell research and ethics can never be as restrictive as the mores of society as determined by the law. The development of adult stem cell research may allow the scientific world to sidestep this issue as the use of adult stem cells and new technology such as induced pluripotency may eliminate the need for research on human embryos. No compromise will however be reached and thus clarity on the status of adult stem cell research is essential.[159]

[156] Department of Health of South Africa (2004).
[157] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 32.
[158] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.
[159] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.

4.1 RESEARCH USING HUMAN TISSUE AND EMBRYOS

The use of stem cells is highly controversial as most of the current research is centred on deriving stem cells from human embryos and cadaveric fetal tissue. The embryo must thus be treated with respect as it is genetically unique, has the potential to become human life and is one of the main points of focus in the ethical debate surrounding stem cell research.[160] There is no controversy surrounding totipotent cells as it is not permitted.[161]

One of the most popular arguments against stem cell research is that is it wrong to create life to destroy it. This argument is however false as, if this is the case, contraception would also be seen as unethical. All humans die and thus all life is created to eventually be destroyed. Most would however argue that this is a ridiculous conclusion and thus the differential factor must be that the destruction of life is at the hands of a researcher and thus not the creation of the embryo, but the destruction thereof leads to the unease surrounding this particular research.[162] Dodds states that it is the prevention of further development that constitutes destruction,[163] while Parfit argues that a person may be harmed by preventing their conception.[164]

Moral precedent exists however, when taking into account that abortion is permitted, to subordinate emerging human life for a more developed form thereof.[165] The Choice on Termination of Pregnancy Act[166] is an example hereof and thus ethically and legally no protection or rights are owed to the embryo.

Werner argues that before the development of the capacity for brain activity, sentience or consciousness, the unborn is not- yet- alive. The not- yet- alive unborn

[160] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 44.
[161] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.
[162] Werner R (2004) "An analogical argument for stem cell research" in Humber & Almeder (eds) 3 at 16.
[163] Dodds (2004) in Humber & Almeder (eds) 151 at 153.
[164] Parfit D (1973) "Rights, interests and possible people" in Huhse H & Singer P (eds) (2006) Bioethics: An anthology 2nd 108 at 109.
[165] Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906 at 907.
[166] The Choice on Termination of Pregnancy Act, Act 92 of 1996.

is equated to a dead human body as both are human but not alive. Research may be done on a dead human body with the proper consent and thus research on the unborn should be permitted with the proper consent. The creation of embryos for research must then be legitimate as the embryo is not yet a living being. Werner states that nonsentient embryos are exactly the kind of humans to destroy for research as they are not alive yet.[167] Pre- embryo research may yield valuable medical information but it will only be regarded as ethical if the embryos were not created for the specific purpose of research.[168]

Jordaan is of the opinion that some of the opposition to stem cell research or research involving embryos in general is due to remnants of deeply ingrained emotional and subconscious beliefs of previous generations who instinctively and intrinsically feel the need to protect embryos. Jordaan is referring to a generation who were raised in a society where abortion was seen as murder.[169] The new generation should thus confront the value remnants of the old, not only for the present but for the future. [170] It is recommended that currently only research utilising cadaveric fetal tissue and spare embryos from *in vitro* fertilisation should be allowed.[171] These MRC recommendations, to use only cadaveric fetal tissue and spare embryos, are perhaps too restrictive and stifle scientific progress according to Dhai, McQuiod- Mason and Rodeck.[172] Embryos and cadaveric fetal tissue should however under no circumstances be the object of trade and thus bought or sold.[173]

[167] Werner (2004) in Humber & Almeder (eds) 3 at 17- 18.
[168] MRC "Reproductive biology: Pre- embryo manipulation and research" (Book 2) paragraph 2.17.
[169] Jordaan DW (2009) "Hoity- toity morality and embryo research" *South African Journal on Bioethics and Law* December 2(2): 39.
[170] *Idem* 40.
[171] The use of cadaveric fetal tissue for research purposes is a sensitive issue in research and although the use of human or fetal tissue in itself is not objectionable, the fetus and the parents thereof must be treated with the utmost respect. The same issues are raised in the case of tissue from a deceased adult or child is used. It must however be guarded against that women undergo elective abortions with the intent of donating fetal tissue to research. See Schrock P (1997) "Fetal tissue transplantation" available at http://www.hsc.missouri.edu accessed 10/7/2009. See also MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.
[172] Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906 at 909.
[173] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.

Also, written consent to use gametes or per- embryos must be obtained from the donors as well as their spouses.[174]

Research involving embryos and embryonic stem cells is the source of deep moral divisions with the value of the human embryo as the focus thereof. It could be argued that moral duties are owed to the embryo in two ways.[175] Directly, due to the characteristics which the embryo possess and indirectly as a manner of protecting others who have moral status.[176] Therefore we need not have duties to an embryo but we may have duties in relation thereto.

4.1.1 Spare *In Vitro* Fertilisation Embryos

A distinction can be made between research on spare embryos left over from *in vitro* fertilization and research on embryos which were specifically created for research. This distinction can however not be founded on moral status and some other factor than status must be relied on to support such an argument.[177] The risk to the health of a woman is once such factor.[178]

Since the rate of failure in *in vitro* fertilisation is high, three of four pre- embryos are usually transferred to the uterus. Due to this, numerous pre- embryos are not used immediately are obtained and cryopreserved. If these pre- embryos are no longer required they become available for donation and since these embryos may be used in couples who might not otherwise produces a pregnancy, this is seen as ethically acceptable.[179] The MRC guidelines however omit to mention whether or not these embryos may be donated to research.

Physicians and scientists should take care to limit the number of embryos which are created for *in vitro* fertilisation in order to respect the potential life of the embryo.

[174] MRC "Reproductive biology: Consent" (Book 2) paragraph 2.11.
[175] Pattinson (2006) 316.
[176] *Idem* 317.
[177] *Idem* 318.
[178] The risks involved in the removal of eggs from the body are not justified where the sole purpose of the creation of an embryo is research. It is however justified when the created embryo is intended for *in vitro* fertilization. See Pattinson (2006) 319.
[179] MRC "Reproductive biology: Pre- embryo from IVF for donation" (Book 2) paragraph 2.9.

The potential for abuse of the spare embryos is then minimised and the creation of surplus embryos limited. This could be done by minimising ovarian stimulation, limiting the number of fertilised embryos which are stored and by postponing new treatment cycles when viable embryos are in storage.[180] Consent must be obtained prior to *in vitro* fertilisation concerning the use of surplus embryos and all relevant information related thereto must be disclosed.[181]

A pre- embryo should be treated with the utmost respect as it is a genetically unique viable human entity. The production of excess embryos for the sole purpose of research should be discouraged.[182] The use of spare embryos has been suggested as it is perceived to be "less problematic." These embryos would however be subjected to the same arguments regarding moral status and thus the use of cloned embryos might be proposed. Cloned embryos would then also minimize immune rejection problems.[183] The fear of the "slippery slope" towards reproductive cloning is totally unsubstantiated as, despite the possibility that this technology could be misused, appropriate legislation which addresses this does exist and South Africa has moved passed this.[184]

4.2 CLONED EMBRYOS[185]

"Clone" is strictly defined as a precise copy of a life form[186] and at a molecular level cloning may be described as the copying of DNA. Cloned cells may be used in the testing and production of new medical products[187] and therefore distinction is made between reproductive and therapeutic cloning and each has its own ethical problems.

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[180] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 45.
[181] Section 57(4) of the NHA.
[182] MRC "Reproductive biology: Research on pre- embryos" (Book 2) paragraph 2.1. For a discussion on this see Jordaan (2007) *SALJ* 618 at 623- 627.
[183] Dhai, McQuiod- Mason & Rodeck (2004) 906 at 907.
[184] *Idem* 908.
[185] See in general Tooley M (1998) "The moral status of the cloning of humans" in Huhse & Singer (eds) (2006) 162.
[186] MRC "Techniques of cloning" (Book 2) paragraph 3.4.2.
[187] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 44.

Reproductive cloning and any research into cloning an entire human being is not ethically or legally permitted and is widely prohibited.[188] The NHA permits therapeutic cloning for specific medical purposes where the Minister has approved thereof as well as the relevant health research ethics committee. The following practices, most of which have been named in section 57 of the NHA, are also impermissible and thus researchers and physicians may not engage in the following:[189]

1. Research on embryonic stem cells more than 14 days after fertilisation;
2. The manipulation of genetic material, including the genetic material of human gametes, zygotes or embryos for reproductive cloning purposes;
3. Any activity, including nuclear transfer or embryo splitting with the purpose of reproductive cloning;
4. Import or export of human zygotes or embryos without the Minister of Health's prior written approval;
5. Implanting a cloned human embryo into the body of a human or animal;
6. The creation or development of a human embryo which contains the genetic material of more than two persons;
7. The intentional alteration of a human genome in a manner which makes the alteration inheritable by descendants of that person whose cell was altered;
8. Removing or withdrawing a viable human embryo from the body of a woman and implanting a cloned human embryo into the body of a woman;
9. Implanting an animal embryo into the body of a human for any period of gestation or creating a chimeric or hybrid embryo;[190]
10. Commercial trading in the eggs, sperm or embryos of humans; and

[188] Section 57 of the NHA.
[189] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 45.
[190] See chapter 2 paragraph 3.3 *supra* for a discussion on chimera.

11. Research involving totipotent stem cells.[191]

4.2.1 Regulation of Cloning Research

It may be argued that formulating guidelines for the research and practice of cloning is only uncontroversial in circumstances where the norms of the community are reflected but in a pluralistic community, various differing values may be found and thus any attempt at regulating cloning is complex and greatly contested.[192]

It is recommended that an expert supervisory body be established to regulate any further research into cloning as there is at present no such a body in South Africa. This body must have sufficient power to regulate cloning but must also have the support of existing research ethics committees and the public. The supervisory body should be responsible for advising on the content of proposals which should include the details of research protocols for therapeutic cloning research, advising on the design and conduct of cloning research as well as on the facilities necessary for the proper conduct of such research. When proposed research is assessed, the body must make recommendations on whether the proposal should be approved and what the conditions for approval are. Further responsibilities of the body should include:

1. To act in co-ordination with existing research ethics committees;[193]
2. Act as a repository of up-to-date information on human cloning research at a national and international level;
3. The body must oversee and monitor research; and
4. Advise the Minster on the scientific and medical developments which may have a bearing on the safety and efficacy of cloning.

[191] Research involving totipotent cells is strictly forbidden.
[192] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.1.
[193] Any research in the field of cloning should preferable be approved by both the supervisory body and the relevant research ethics committee.

A further requirement is that of informed consent. Consent must be obtained prior to donation.[194] It is further recommended that prospective donors be granted timely, relevant and appropriate information in order to enable them to make an informed and voluntary decision regarding the donation.[195]

4.3 iPS CELLS

Induced pluripotent stem cells are not without ethical issues, although they are far less than the issues surrounding embryonic stem cells or cloning. According to Kidson[196] the ethical issues surrounding iPS cells are those regarding adult stem cells and not the same problems of embryonic stem cells. The safety of iPS cells[197] and the efficacy thereof are contested issues.[198] Obtaining of consent in context of stem cell research with iPS cells is a complex issue and it is suggested that consent must also be obtained for secondary work or application of the cells.

4.4 ETHICAL ISSUES RELATED TO STEM CELL BANKING

Stem cell banking is a new field of technology which is essentially linked to the development of stem cell research. This does however not mean that stem cell banking is without ethical problems. Some of these problems include payment, storage and confidentiality matters and intellectual property rights. It is therefore necessary to examine some of the ethical guidelines which might have a bearing on stem cell banks.

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[194] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.1.
[195] MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.4.3.2.
[196] Kidson S(2010) "Legal, IP and ethical issues of iPS cells" presented at the Transplantation Indaba, BMW Pavilion, Waterfront Cape Town 2- 3 August. Hereafter referred to as the Transplantation Indaba.
[197] For example, the use of viral vectors is problematic as this may lead to the formation of cancerous cells.
[198] In the process of induction, only some of the cells become pluripotent. The low recall of iPS cells must therefore also be ethically justified.

Various parties may have an interest in banked material such as cord blood which is currently the most banked material. This may influence the processes and consequences of efficacy.[199] Further conflicts of interest may arise should material be transplanted into the body of a different person than the original new born donor thereof. Some other issues include the cost and feasibility of collection,[200] the appropriate system of banking,[201] as well as the role that parents will play in decision making. Advertising of banking services also requires some attention as to not mislead the public[202] by stating that banking is a biological insurance policy which insures a spare immune system for the child.[203]

4.4.1 Collection

Important ethical dilemmas which must be mentioned here are firstly, the safety of the newborn. The desire to collect a high cell dose may lead to early clamping of the umbilical cord which would deprive the new born of much needed normally circulating blood. The collector may also become distracted due to the anxiety of collecting adequate material and thus neglect their other duties which may lead to harm coming to the mother and the new born. Also the collector themselves may suffer from needle- stick injuries. The collected sample must then also be meticulously labelled and packaged to avoid contamination thereof.[204]

4.4.2 Consent

Consent to donate involves discussions related not only to the donation itself, but also to maternal and cord blood testing. It is necessary to discuss the option that the

[199] Sozos J, Fasouliotis MD, Joseph G & Schenker MD (2000) "Human umbilical cord banking and transplantation: A state of the art" *European Journal of Obstetrics and Gynecology and Reproductive Biology* 90: 13- 25 at 21.
[200] This is related to equal access.
[201] Public banking or private banking.
[202] Sozos, Fasouliotis, Joseph & Schenker (2000) *Eur J Obstet Gynecol Reprod Biol* 13- 25 at 21.
[203] Dhai A & Moodley J (2004) "Umbilical cord blood banking ethico- legal issues" *Obstetrics & Gynecology Forum* August 7-11 at 9.
[204] *Idem* 8.

material will be made available to other recipients and that material may be held in storage for long periods of time and for further testing which may only occur years later than the collection thereof. Also, consent will have to be obtained to share any information regarding the material with potential recipients.[205] Some of the ethical issues regarding consent in context of banking include:[206]

1. The optimal time for obtaining consent as it may be questioned whether or not a woman approaching labour is in the best position to give consent;
2. Collection of cord blood should not interfere with any actions during child delivery;
3. Maternal consent must be obtained for all uses and procedures related to cord blood; and
4. Specific detailed consent must be obtained for commercial purposes or research where units are unsuitable for transplantation.

4.4.3 Data and Specimen Storage

Although there are currently no specific guidelines for the ethical operation of a stem cell bank, guidelines do exist regarding storage of specimens. These guidelines are actually intended to regulate research institutions but may be applied to stem cell banks. Data and specimens obtained as a result of research activities should be stored in a secure manner and should be stored for no less than 2 years after publication of the findings or 6 years in the absence of publication thereof. In context of stem cell banks, it could be inferred that all banked material must be kept safely and securely. Should it be required that data and specimens leave the country, there must be justifiable reasons which should be provided to the relevant research

[205] Warwick R & Armitage S (2004) "Cord blood banking" Best Practice & research Clinical Obstetrics and Gynecology 18(6): 995- 1011 at 1001.
[206] Warwick R & Fehily D (2002) "Ethics of cord blood banking" Current Obstetrics & Gynecology 12: 175- 177 at 175.

ethics committees.[207] Also accurate and up-to-date records about research participants, or the bankers and recipients of cells or cord blood, must be kept.[208]

The linkage between the donor and the material which is required may compromise confidentiality but this may be necessary to identify unsafe units of material at a later stage.[209] Quarantine periods have been suggested but this is complicated by the fact that the optimal time period therefore is unsure as well as the effect of prolonged storage and the immediate unavailability of the material is undesirable. Some other issues related to confidentiality include *inter alia* recipients attempting to trace and locate their donor in order to obtain further donations; donors could be informed of genetic diseases which may be relevant to their own health; the "ownership" of the material, in this case cord blood, must still be determined; and banks may require the donor to be re-tested or recall certain material in order to determine whether or not the donor has certain genetic predispositions.[210] The privacy of a donor must however be protected as far as possible.

4.4.4 Intellectual Property Rights[211]

Intellectual property rights concerning the techniques used is cause for some ethical concern as patenting of such technology could limit access thereto. There are also questions regarding whether or not the human body should be the subject of property rights or whether the human genome is the common heritage of mankind.[212] It is submitted that legislation must regulate and prevent such practices. The regulation of stem cell and cloning technologies has a global context and therefore any attempts at regulation will be affected by the patients, researchers

[207] This should only be done after a Material Transfer Agreement has been signed and submitted to the local Research Ethics Committee. See HPCSA "General ethical guidelines for health researchers" Booklet 6: 11.
[208] HPCSA "General ethical guidelines for health researchers" Booklet 6:8.
[209] Sozos, Fasouliotis, Joseph & Schenker (2000) *Eur J Obstet Gynecol Reprod Biol* 13- 25 at 22.
[210] Warwick & Fehily (2002) "Ethics of cord blood banking" *Curr Obstet Gynecol* 12: 175- 177 at 175.
[211] See MRC "Ethics in genetic research and practice" (Book 2) paragraph 3.5 for more on patenting of human genes. See also paragraph 3.6.2 for more on intellectual property rights.
[212] Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906 at 908.

and research which is being conducted elsewhere. Furthermore, these technologies also have a medical context as they enable medical practices.[213]

4.4.5 Payment for Donated Tissue, Embryos and Fetal Tissue[214]

Payment for any human tissue is not only unethical, it is unlawful and is punishable as an offence in terms of the NHA.[215] According to the NHA a donor of tissue, a gamete, blood or a blood product may not receive any financial or other reward for the donation but may be reimbursed for the reasonable costs which were incurred in the course of the donation. Any trade of tissue, gametes, blood or blood products is also an offence. This however leads to questions regarding the justification of the profits made by private stem cell banks versus a cost recovery basis, which would have to be employed by a public bank. This would however have implications on freedom of trade for example as enshrined in section 22 of the Constitution.

The use of embryos in research is connected to the debate on the commodification of human body parts. Ethical codes regulating research which is conducted on human participants attempt to be as protective as possible and such research is subjected to strict review.[216] For this reason attention must now be given to the ethical regulations which are provided for by legislation and are in practice in South Africa.

5 THE NATIONAL HEALTH ACT[217]

Chapter 9 of the National Health Act[218] is concerned with national health research and information and is important in context of the discussion regarding ethics as it provides for the establishment of the National Health Research Committee,[219]

[213] Pattinson (2006) 311.
[214] See in general Foster (2009) 173- 180.
[215] Section 60 of the NHA.
[216] Dhai, McQuiod- Mason & Rodeck (2004) 906 at 908.
[217] The National Health Act, Act 61 of 2003.
[218] Hereafter referred to as the NHA.
[219] Section 69 of the NHA.

National Health Research Ethics Council[220] and national health research ethics committees.[221] The importance of taking cognisance of this chapter of the NHA is further emphasised when taking into account that the NHA is the proposed legislation which will eventually regulate stem cell research in South Africa. Chapter 9 of the NHA will now be discussed according to the sections thereof which are relevant in context of this dissertation. This will then constitute the analysis of the proposed regulatory framework for the procurement and distribution of stem cells in context of ethics.

5.1 SECTION 69: THE NATIONAL HEALTH RESEARCH COMMITTEE[222]

Any research must be subject to review by a South African ethics committee to measure the scientific and ethical rigor of the research.[223] According to the HPSCA's General ethical guidelines for biotechnology research, the objects of research ethics committees are to maintain ethical standards of practice in research, protect participants from harm or exploitation and preserve the rights of the research participant as it takes precedence over the rights of society and to provide assurance to the public that research is being conducted in an ethical manner.

Sections 69(1) and 69(2) requires the Minister[224] to establish a committee known as the National Health Research Committee,[225] which must consist of no more than 15 persons and who may only be appointed after the Minister has consulted the National Health Council.[226] The Committee will then have the following duties:[227]

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[220] Section 72 of the NHA.
[221] Section 73 of the NHA.
[222] Article 19 of the *Bioethics Declaration* also requires the establishment of independent, multidisciplinary and pluralist ethics committees and that such a committee must (a) assess the relevant ethical, legal scientific and social issues related to research projects which involve humans; (b) provide advice on ethical issues in clinical settings; (c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues; and (d) foster debate, education and public awareness of, and engagement in bioethics.
[223] HPCSA "General ethical guidelines for biotechnology research" Booklet 7: 9.
[224] Section 1of the NHA defines Minister as the member of Cabinet responsible for health.
[225] Hereafter referred to as the Committee.
[226] As established by section 22(1) of the NHA.
[227] Section 69(3)(a)- (d) of the NHA.

(a) Determine the health research which must be carried out by the public health authorities;

(b) To ensure that health research agendas and research resources are focused on priority health problems in South Africa;[228]

(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.

Research ethics committees are of great importance in the regulation of any research which involves humans or animals as the investigator should never be the only judge of whether or not their research conforms to ethical norms and standards.[229] Research ethics committees must keep in mind that society is benefitted by research and thus research must not be unnecessarily hindered.[230]

The manner in which the Committee conducts its affairs and the procedures thereof, such as the decision making procedure must be prescribed by the Minister.[231] Section 69 is supplemented by the Regulations relating to the National Health Research Committee of 23 February 2007.[232] The Research Committee Regulations supplement the Act by providing for the constitution of the Committee[233] as well as

[228] As stated in section 69(3)(b) the Committee must ensure health priorities receive the attention and resources necessary. In order to however ensure this, it is imperative to know what the priority health problems are. Section 70(1) of the NHA states that the Committee is further tasked in identifying these priorities and advising the Minister thereon. According to section 70(2), in identifying the health research priorities, the Committee must have regard to the burden of disease and the cost-effectiveness of interventions aimed at reducing this burden, the availability of human and institutional resources for the implementation of an intervention, the health needs of vulnerable groups such as women, older persons, children and people with disabilities, and communities' health needs. Research in South Africa should be responsive to the health care needs of the community and in line with the health priorities identified in the NHA according to HPCSA "General ethical guidelines for health researchers" Booklet 6: 3.
[229] MRC "Assessment of research" (Book 1) paragraph 9.5.2.
[230] *Idem* paragraph 9.6.1.
[231] Section 69(4) of the NHA.
[232] Regulations Relating to the National Health Research Committee No. R136 in Government Gazette No. 29637 of 23 February 2007 17. Hereafter referred to as the Research Committee Regulations. For more on the functions of a research ethics committee see MRC "Functions of research ethics committees" (Book 1) paragraph 9.8.
[233] Regulation 2 of the Research Committee Regulations.

the nomination and appointment of committee members[234] and their remuneration,[235] the duties of the chairperson[236] and the secretariat,[237] meetings of the Committee[238] and the quorum and procedures at meetings or during decision making[239] and the procedure of appeal against such decisions.[240] Furthermore the offences and penalties for any contravention of the regulation is provided for.[241] For the purpose of this discussion the Research Committee Regulation must only be noted and will not be discussed in greater detail.

5.2 SECTION 71: RESEARCH ON OR EXPERIMENTATION WITH HUMAN SUBJECTS

Research or experimentation on a living person may only be conducted in the prescribed manner and after consent has been obtained. Sections 71(2) and 71(3) make provision for research or experimentation on minors for therapeutic and non-therapeutic purposes respectively. Section 71(3)(b) states the circumstances in which the Minister may not consent to research on experimentation on a minor. The Regulations relating to Research on Human Subjects of 23 February 2007 supplement section 71 and deserves some attention.

Chapter 1 of the Regulation relating to research on human subjects[242] deals with general principles regarding research such as the principles of health research,[243]

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[234] Regulation 3 of the Research Committee Regulations. Membership of a research ethics committee should firstly be influenced by two principles. The first is that committees must command the technical competence and judgement to reconcile the consequences of participation with the objects of the research and secondly, committees must respect the opinion of lay persons. See in general Häyry H (1998) "Should the decisions of ethics committees based on community values?" *Medicine, Healthcare and philosophy* 1: 57-60.

[235] Regulation 9 of the Research Committee Regulations.

[236] Regulation 4 of the Research Committee Regulations. Regulation 1 defines the chairperson as "chairperson of the Committee."

[237] Regulation 10 of the Research Committee Regulations. The secretariat is defined as the directorate responsible for research in the national Department by regulation 1.

[238] Regulation 5 of the Research Committee Regulations.

[239] Regulation 6 of the Research Committee Regulations.

[240] Regulation 7 of the Research Committee Regulations.

[241] Regulation 8 of the Research Committee Regulations.

[242] Regulations Relating to Research on Human Subjects No. R135 in Government Gazette No. 29637 of 23 February 2007 10. Hereafter referred to as the Human Subjects Regulations.

[243] Regulation 2 of the Human Subjects Regulations. See chapter 5 paragraph 6.4 *infra* for a discussion of this regulation.

obligations of researchers,[244] participation of special groups of people, research which requires additional consideration and consent. Chapter 3 deals with research involving animals.[245] For the purpose of this section of this dissertation, the focus falls on Chapter 2 of the Human Subjects Regulations as it provides for genetic, stem cell research and reproductive health.

Chapter 2 of the Human Subjects Regulations provides some regulatory supplementation to the NHA with specific regard for stem cell research. Section 7(1) states that informed consent[246] must be obtained from the donor of stem cells before stem cell research or therapeutic cloning may be conducted and the research findings emanating from such research will not be subject to intellectual property rights.[247] The donor will be entitled to reimbursement for any reasonable expenses which they incurred in making such donation.[248]

5.3 SECTION 72: THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL

Section 72(1) provides for the establishment of the National Health Research Ethics Council,[249] which has the following duties:[250]

(a) To determine guidelines for the functioning of health research committees;

(b) To register and audit health research ethics committees;

(c) Set norms and standards whereby research on humans and animals as well as clinical trials must be conducted;

(d) Adjudicate complaints regarding the functioning of health research ethics committees;

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[244] Regulation 3 of the Human Subjects Regulations. See chapter 5 paragraph 6.4 *infra* for a discussion of this regulation.
[245] See chapter 2 paragraph 3.3 *supra* regarding the use of chimeric embryos.
[246] Consent must also be obtained from the gamete donor before artificial insemination may be performed according to regulation 7(4) of the Human Subjects Regulations. The donor of the gamete is then also entitled to reimbursement.
[247] Regulation 7(2) of the Human Subjects Regulations.
[248] Regulation 7(3) of the Human Subjects Regulations.
[249] Hereafter referred to as the Ethics Council.
[250] Section 72(6)(a)- (g).

(e) Refer violations or potential violations of ethical or professional rules to the relevant statutory health professions council;

(f) Institute necessary prescribed disciplinary action; and

(g) Advise the national department as well as provincial departments on any ethical issues regarding research.

Section 72 is further supplemented by the Regulations relating to the National Health Research Ethics Council of 23 February 2007.[251] The NHA is supplemented by the Ethics Council Regulations in that it provides for the functioning of the Ethics Council in greater detail than determined by the NHA. The constitution of the Ethics Council[252] as well as the powers thereof,[253] nomination and appointment of members[254] and remuneration of council members are aspects which are provided for by the Ethics Council regulations.[255] The Ethics Council Regulations further determine the duties of the chairperson[256] and secretariat,[257] council meetings[258] and the quorum and procedure to be followed at such meetings in decision making[259] as well as the procedure to follow when an appeal is brought against such decision.[260] Offences and penalties are also provided for.[261] For the purpose of this dissertation a more detailed discussion of the Ethics Council Regulation is not necessary.

[251] Regulations relating to the National Health Research Ethics Council No. R134 in Government Gazette No. 29637 of 23 February 2007, 13. Hereafter referred to as the Ethics Council Regulations.
[252] Regulation 2 of the Ethics Council Regulations.
[253] Regulation 3 of the 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.
[254] Regulation 4 of the Ethics Council Regulations.
[255] Regulation 10 of the Ethics Council Regulations.
[256] Regulation 5 of the Ethics Council Regulations. The chairperson is the chairperson of the Council.
[257] Regulation 11 of the Ethics Council Regulations. The secretariat is the directorate who is responsible for research in the national Department as defined by regulation 1.
[258] Regulation 6 of the Ethics Council Regulations.
[259] Regulation 7 of the Ethics Council Regulations.
[260] Regulation 8 of the Ethics Council Regulations.
[261] Regulation 9 of the Ethics Council Regulations.

5.4 SECTION 73: HEALTH RESEARCH ETHICS COMMITTEES

The importance of a section 72 Ethics Council is emphasised by section 73 which requires that every health agency, institution or establishment at which research is conducted, must establish or have access to an ethics committee which is registered with the Ethics Council. All research ethic committees must review research proposals[262] and protocols to ensure that the research will promote health, contribute to the prevention of diseases[263] or disability or result in cures for diseases.[264] Ethics committees must further approve research where the research proposal and protocol is on par with the ethical standards set by the research ethics committee.[265]

6 CONCLUSION

The ethical aspects of stem cell research raise numerous controversial and important issues and most of the issues relate to the sources of stem cells. Currently consensus exists that stem cells derived from embryos are preferred but as the science changes and develops this is bound to change as well.[266] This chapter focused largely on the ethical dilemmas surrounding embryonic stem cells and the guidelines provided for by the HPCSA and MRC were discussed in relation thereto.

Both embryonic stem cell research and research on adult stem cells should, at least for the time being, be pursued. Abandoning one form of stem cell research for another may lead to dire consequences. It is submitted that four reasons exist to support the above mentioned statement. Firstly, it is still uncertain whether or not adult stem cells will deliver the same quality stem cells as embryonic stem cells, secondly adult stem cells might be utilised for certain therapies but not useful in

[262] Health research ethics committees use a protocol review procedure to ensure ethical standards are met and to consider all questions regarding research. The NHA requires all protocols must be approved by a research ethics committee before the commencement of such research. See HPCSA "General ethical guidelines for health researchers" Booklet 6:1.
[263] Communicable or non- communicable.
[264] Section 73(2)(a) of the NHA.
[265] Section 73(2)(b) of the NHA.
[266] Harris (2003) in Huhse & Singer (eds) (2006) 545 at 545.

others, thirdly it has long since been established that genes in embryonic stem cells can be modified but the scope of this changeability of adult stem cells is still largely unknown and lastly, to gamble with human lives by supporting only one form of research is hugely socially irresponsible. Four schools of thought, some in favour of and others against stem cell research were examined in order to justify this form of science and research.

Women's rights issues were also raised as women are the most proximate source of embryos and fetal material. Further issues involved in stem cell research include voluntary and informed consent by the donors and recipients of material, issues surrounding the anonymity and thus confidentiality and privacy of donors and recipients, the safety and security of stem cell banking as well as issues pertaining to remuneration and payment.[267]

Scientific and technological developments have been and can be of great benefit to humanity and such developments must always attempt to promote the welfare of individuals and humankind as a whole by recognising the dignity of persons and by respecting human rights and freedoms. For this reason bioethics should play a predominant role in the decisions which are made in the development and application of research[268] and biomedical research has made spectacular strides in the past century.

Medical practice and the law which regulates medical practices operate in a moral arena and thus ethics have played a pivotal role since medicine deals with deeply ethical and spiritual issues such as the creation, process of and end of human life.[269] As medical law is inseparable from medical ethics, medical law can never be understood without understanding the ethical tensions which factor in.[270] The ethico- legal issues involved are vexing and on the one hand the medical profession and public struggle with the promise of this research which could lead to knowledge which may benefit society and science. On the other hand the moral problems

[267] *Idem* 546 & 550.
[268] Preamble of the *Universal Declaration on Bioethics and Human Rights*.
[269] Pattinson (2006) 2.
[270] *Idem* 4.

surrounding this research require consideration as to whether reasons exist to limit such research or prohibit it in its entirety.[271] The possible medical gains from this research are extraordinary and an ethical imperative exists to continue work in this field.[272]

Issues relating to the practice of stem cell banking were briefly discussed in this chapter. This was however not a main focal point in this chapter. What is important to note here is the fact that more research will have to be done relating to the regulation of stem cell banks and institutions and it is submitted that perhaps specialised legislation will be necessary in this regard.

In conclusion it may be submitted that ethics as a whole attempt to protect patients and research participants during the course of treatment and experimentation. Ethics however are not hard law, even where it has assumed the status thereof and it is important to note that ethical principles are not legally enforceable. For this reasons ethics play an advisory role in stem cell regulation and also provide for flexibility but is insufficient on its own as regulatory instrument. The ethical sphere is permeated by certain values which have been enshrined in the Constitution by South African society. The South African Constitution is greatly value orientated and articulates these values in enforceable, legally binding human rights. This leads to a close connection and interaction between human rights and medical ethics.[273] This dissertation must however examine further legal rules which may be incorporated to protect the public from unruly medical or scientific procedures. The doctrine of informed consent has long since been applied in South African medical law and is an enforceable concept with legal power as it is an expression of a persons' right to be respected. Informed consent must thus be discussed.

[271] Dhai, McQuiod- Mason & Rodeck (2004) *SAMJ* 906.
[272] *Idem* 908.
[273] Jordaan DW , Woodrow C & Pepper MS (2009) "Banning private stem cell banks: A human rights analysis" *South African Journal of Human Rights* 25: 126 at 138.

CHAPTER 5
CONSENT

1 INTRODUCTION

Consent in terms of medical or scientific procedures must be understood as informed consent but a difference does however exist between scientific and medical consent. This distinction however, in no way mitigates the importance of the requirement that a person must, prior to any medical or scientific procedure, give their consent to such procedure. Due to the unsurpassable nature of this requirement, consent must be analysed on all levels. When examining the role of consent as underpinning stem cell research, it is therefore important to follow a layered approach. For the purposes of this dissertation the common law or more specifically, medical law framework, constitutional framework, the framework established by the National Health Act and the regulations created under the Act as well as any relevant case law will be discussed. Also autonomy will be discussed and Shared Decision- Making will be recommended as alternative method of obtaining consent.

Medical law and the doctrine of informed consent is firstly discussed as consent obtained for stem cell therapy will have to conform to these established rules. The common law must however be developed by the Constitution and for this reason the interpretation of section 12 of the Constitution wherein consent is entrenched, is discussed. The complex nature of stem cell technology necessitates an in depth examination of certain key issues regarding consent such who may consent, what the process must entail and cover and the time of obtaining consent. These are discussed theoretically and thereafter national legislation is analysed in context of such issues. This is then followed by a discussion of the National Health Act and the regulations pertaining to the Act. In the course of this chapter certain recommendations are also made as to what the process of obtaining consent should entail.

For the purpose of this dissertation and the multi- layered approach followed in the analysis of the proposed regulatory framework, the "common law layer" consists of English law, as South African medical law is mostly based on English medical law. It is thus against this backdrop that the common law provisions regarding consent are discussed.

1.1 THE DISTINCTION BETWEEN MEDICAL AND SCIENTIFIC CONSENT

In the course of this dissertation mention has been made of stem cell therapy and of stem cell research and it must therefore be apparent that therapy and research must not be viewed as having one and the same meaning. The Constitution also makes such a distinction as section 12(2)(c) expressly states that a person may not be subject to any "medical or scientific experiments without their informed consent." Van Wyk states that research and medical treatment are two distinct activities and are regulated by different ethical principles and regulatory requirements.[1] Throughout the discussions of various subjects related to stem cells, the use of the term therapy has been used in context of a medically related procedure while research has been used as the scientific act of investigation and study.[2] It is important to distinguish between "medical treatment" and "research" but this is not a simple exercise as no clarification of these terms is offered in Chapter 9 of the NHA which deals with research, nor do the regulations define the term "research." In context of stem cells this distinction is relevant as the consent process will differ according to the purpose of the consent. In other words, where consent it sought for the application of stem cell therapies medical law principles in general may be followed and consent may almost be obtained in the "normal" manner. For example, the scope of the procedure can easily be explained to the patient. Where consent is

[1] 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.
[2] This may or may not include experimentation.

obtained for use of material in research, consent becomes a much more complicated aspect. Where the scope of the procedure can easily be explained in stem cell therapy,[3] the scope of stem cell research is uncertain due to the vast amounts of methods and techniques and the ultimate object of the research. It thus becomes important to briefly discuss this distinction.

1.1.1 Treatment or Therapy

According to the Medical Research Council Guidelines, treatment is an activity with the sole purpose of benefiting the patient where a reasonable chance of success exists.[4] Any progressive modification of treatment methods by the physicians due to their experience is regarded as a normal feature of treatment and not as research. An important aspect to take note of is that treatment aims to benefit the individual patient. Van Wyk[5] states that treatment may also be described as an intervention which is governed by the principles of beneficence and non- maleficence. The patient's health must be promoted and any risk which may be related to such promotion thereof should be justified by the prospect of medical benefit to the patient.

Treatment must occur according to scientifically validated standards of care and aims at providing optimal care for the individual patient. The treating physician is also not placed in a position where it is required of him or her to further or develop scientific knowledge which may be used to help future patients.[6] In context of stem cells, stem cell therapy or treatment utilising stem cells thus only concerns the individual patient undergoing such treatment and who will be benefitted thereby. This is the person whose consent must thus be obtained.

[3] The transplantation of stem cells into a specified muscle or organ for example.
[4] MRC *Guidelines on ethics for medical research: General principles* (Book 1) paragraph 2.1.1.
[5] Van Wyk (2010) Transplantation Indaba.
[6] *Ibid*.

1.1.2 Research

Research may be defined as the "systematic search or inquiry of knowledge" according to the South African Department of Health.[7] When looking at the guidelines published by the MRC, research is regarded as a systematic investigation[8] designed to develop or contribute to generalised knowledge.[9] The MRC adds that any activity which aims to obtain knowledge affecting a person in any way and which is additional to normal clinical care must be regarded as research. A rule of thumb may thus be stated as should new knowledge be generalised, transferred to others or presented at a scientific meeting, submitted for publication or for higher qualification, it must be considered research.[10]

A further opinion holds that research is any activity which is designed to answer a scientific question.[11] The researchers seeks to learn about disease and treatment with the object of developing scientific knowledge that will ultimately improve medical care for future patients. Research is thus population- focused rather than individualised.[12]

1.1.2.1 Therapeutic and non- therapeutic research

Some mention has been briefly made regarding the distinction between therapeutic and non- therapeutic research. In context of stem cell research and specifically consent, this distinction is also relevant.[13] Therapeutic research is characterised by the fact that it is of direct benefit to the person undergoing or participating in such research. Non-

[7] Department of Health (2004) *Ethics in health research: Principles, structures and processes* available at http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html accessed 12/ 10/2009. Van Wyk C states that this is the only document which clarifies the meaning of research.
[8] This includes research development, testing and evaluation.
[9] MRC (Book 1) paragraph 2.1.2.
[10] MRC (Book 1) paragraph 2.1.3.
[11] Van Wyk (2010) Transplantation Indaba.
[12] It could thus be stated that research is utilitarian in approach with a common medical good at heart. This is also the reason why research may be an exploitative practice.
[13] Specifically when a minor is the research subject of recipient of therapy or treatment. See paragraph 5.3 *infra*.

therapeutic research may then be characterised by the fact that it may be of benefit to general scientific knowledge and thus does not directly promote the health of the participant.[14]

The distinction thus rests upon the likelihood of benefit the particular participant will receive. Both in therapeutic and non- therapeutic research however the aim of the activity is not personal therapy but the acquisition of knowledge.[15]

2 MEDICAL LAW AND INFORMED CONSENT

The concept of consent is not new and has played a vital role in medical ethics since the time of Hippocrates. In recent years the focus has however shifted from the physician's duty to give information to the quality of the patients understanding of such information and his consent thereto.[16] The practice of obtaining consent and specifically informed consent originates predominantly in medicine and medical research wherein the disclosure of information as well as withholding information are aspects of daily encounters between the patient and the physician or research participant and researcher.[17] In order to assess informed consent in medical law it is necessary to examine certain aspects thereof. It must be asked why informed consent is controversial, the reasons for the requirement of informed consent and what the concept of patient autonomy entails. Also, attention must be given to the purpose,

[14] See in general Department of Health (2006) *Guidelines for good practice in the conduct of clinical trials in human participants in South Africa* available at http://www.doh.gov.za/docs/policy/trials/trials_01.html accessed 12/10/2010.
[15] The same ethical principles are therefore applicable to both therapeutic and non- therapeutic research and many bioethicists have abandoned the distinction. In certain cases it may be difficult to distinguish between the two forms of research as research may entail therapeutic and non- therapeutic components. The line between therapeutic research and treatment may also be difficult to draw. This was taken into account by the legislator in the drafting of the National Health Act as section 11 deals with experimental treatment which requires a certain procedure to be followed where a health service is provided for research purposes. See Van Wyk (2010) Transplantation Indaba. See also paragraph 6.4 *infra*.
[16] Carstens P & Pearmain D (2007) Foundational principles of South African medical law 875 footnote 20. See also Van Oosten FFW (1989) *The doctrine of informed consent in medical law* (LLD thesis unpublished, UNISA) for a discussion on the development of the doctrine of informed consent.
[17] Carstens & Pearmain (2007) 875.

function and scope of consent. Lastly, the duty to disclose and the required standard thereof in medical research must be examined.

2.1 THE CONTROVERSY SURROUNDING INFORMED CONSENT

Various opinions exist pertaining to the reason for the controversial nature of the doctrine of informed consent and it has been a subject of debate in different forms of legal writing. The following reasons have been proposed and may be viewed as a summary of the reasons for the controversy:[18]

1. Informed consent is undoubtedly the foundation or core of the relationship between the patient and physician which arises from the law of obligations[19] and is underscored by ethics;[20]
2. The introduction of informed consent into South African law shifted the focus from medical paternalism to patient autonomy and this is further emphasised by the Bill of Rights;[21]
3. Obtaining consent is difficult and it is often asked whether this is the physician or attending nurse's obligation;[22]
4. The application of the doctrine is uncertain in context of the multi- layered approach;[23]
5. The doctrine exposes the delicate balance and tension of the power and respect in the patient- physician relationship and therefore ultimately points in the direction of the difficult process of shared decision- making;[24]

[18] *Idem* 877.
[19] The Law of Obligations is complied of the Law of Contract and the Law of Delict.
[20] See *Stoffberg v Elliott* 1923 CPD 148, *Castell v De Greef* 1994 (4) SA 408 (C) and *Oldwage v Louwrens* [2004] 1 All SA 532 (C).
[21] See paragraph 3.1 *infra*.
[22] See paragraph 4.1 *infra*.
[23] In the course of this dissertation an attempt was made to discuss consent within layers.
[24] Strauss SA (1987) "Geneesheer pasiënt en reg: 'n Delikate driehoek" *Tydskrif vir die Suid- Afrikaanse Reg* 1. See also paragraph 6.3.1 *infra*.

6. Informed consent challenges the physician to "rise to the occasion" and establish a rapport with the patient by improving "bedside manner;"[25]
7. Informed consent is procedure specific;[26]
8. There exists a discrepancy between the private and public health sector, especially in a developing country such as South Africa;
9. Many physicians feel that it is impossible to obtain informed consent as many patients are illiterate and ignorant;[27]
10. Issues surrounding liability exist;[28]
11. Court decisions have been greatly unsatisfactory; and
12. Courts are hesitant to find that the medical practitioner failed to inform the patient properly.

2.2 REASONS FOR THE REQUIREMENT OF INFORMED CONSENT

As seen from the above discussion, consent is a controversial and complex issue. Why then is it necessary to complicate an already complicated subject such as stem cells even further? It may be stated that the foundational requirements for lawful consent are knowledge, appreciation and acquiescence on the part of the patient and that there can be no mention of consent unless the consenting party knows and appreciates what consent has been given for.[29] The physician can therefore be seen as having a legal duty to provide the patient with such information as is necessary to ensure knowledge, appreciation and acquiescence.[30] The physician is not required to inform the patient of

[25] This once again emphasises that consent concerns the relationship between the person giving consent, the patient, and the person obtaining consent, the physician.
[26] Thus the difference between medical treatment and scientific research is important. See paragraph 1.1 *supra*.
[27] This issue is addressed by section 6 of the NHA. See paragraph 6.1 *infra*.
[28] See paragraph 2.5 *infra* regarding the liability which accrued in the absence of consent.
[29] Van Oosten FFW (2006) in Blanpain R & Nys H (eds) *International Encyclopaedia of Laws* paragraph 119.
[30] The legal duty of disclosure should not be regarded as one of negligence but one of consent, which has a contractual nature. See Strauss SA (1991) *Doctor, Patient and Law: a Selection of Practical Issues* 268.

matters which could be detrimental to the health of the patient[31] or which is immaterial.[32]

2.3 PURPOSE AND FUNCTION OF THE INFORMED CONSENT DOCTRINE

In order to understand the status of the doctrine of informed consent in context of South African medical law, it is necessary to establish the purpose and function thereof. Firstly, informed consent ensures the patients right to self- determination or autonomy and secondly it encourages rational decision making by allowing the patient to come to a decision whether or not to undergo an intervention[33] after a consideration and weighing of the potential benefits and risks of such an intervention.[34] The patient must therefore be given sufficient time to contemplate and decide on a proposed intervention or treatment option.[35] The importance of the doctrine of informed consent may then also be influenced by ethical principles, the opinions thereof in the medical profession and the legal position thereon.[36]

[31] This is referred to as therapeutic privilege. See Coetzee LC (2004) "Medical therapeutic privilege, a separate and independent defence *eo nomine*?" *Tydskrif vir die Suid- Afrikaanse Reg* 3: 464- 481 and Van den Heever P (2005) "Pleading the defence of therapeutic privilege" *South African Medical Journal* 95(6): 420- 421.

[32] See paragraph 2.4 *infra* for a discussion of when a risk is deemed material. See also Carstens & Pearmain (2007) 883- 887.

[33] Section 12(2)(b) of the Constitution ensures security in and control over the body and in *Castell v De Greef* 1994 (4) SA 408 (K) it was stated that this means that a person is entitled to refuse medical treatment as a manifestation of this right. See also *Oldwage v Louwrens supra*.

[34] Van Oosten (1989) LLD thesis 446. See also Van Oosten (2006) in Blanpain & Nys (eds) *International Encyclopaedia of Laws* paragraph 121 and Strauss SA (2006) in Blanpain & Nys (eds) *International Encyclopaedia of Laws* paragraph 126. See also section 11 of the NHA as discussed in paragraph 6.4 i*nfra*.

[35] Van Oosten (1989) LLD thesis 448.

[36] *Idem* 438.

2.4 THE AMOUNT OF DETAIL AND THE DUTY OF DISCLOSURE

Section 6 of the NHA[37] requires that the patient[38] must, in laypersons terms, be given a broad and general idea of the nature, scope, consequences, risks, dangers, complications, benefits, disadvantages and the prognosis of treatments. The patient must also be informed of relevant costs, alternative treatments and their right to refuse treatment.[39] It is not difficult to identify the problems regarding detailed consent in context of stem cell research. Scope becomes problematic especially in obtaining consent for research on stem cells as stem cells may yield infinite possibilities which may need to be explored. To explain the scope of such research would thus, at best, be informing the patient with educated guesses. For this reason, the possible consequences can also not be explained completely. It is therefore submitted that in the case of stem cells, consent must be specific and cannot be given generically.

More specifically, the patient must be informed of expected or associated risks and dangers. It is however not required of the physician to disclose such risks which are unusual or remote.[40] While the doctor must inform the patient of all relevant facts regarding a medical treatment, the doctor must however still be careful to not cause the patient distress or anxiety by disclosing information which is not necessary and thus only information which is deemed material information must be disclosed.[41] Currently, the patient will have to be informed of the risk of the formation of cancerous cells for example. This is a material risk and must be disclosed. The determination of material

[37] See paragraph 6.2 *infra* for a more detailed discussion of the provisions regarding consent as contained in chapter 2 of the Act.
[38] The National Health Act refers to the patient as the health care user.
[39] Carstens & Pearmain (2007) 885.
[40] Where a risk is very unusual and no stretching of the imagination could have expected such a risk the risk is deemed remote and immaterial. See *Richter v Estate Hammann* 1976 (3) SA 226 (C). See also *Oldwage v Louwrens supra* in which it was held that a likelihood of occurrence of 2% was not sufficient to constitute a material risk.
[41] Carstens & Pearmain (2007) 886. See also Strauss (1991) 19 and Van Oosten (1989) LLD thesis 199- 200.

risks or dangers was formulated in the *Castell* case.[42] Here it was held that a risk, inherent to the procedure,[43] is material if:

1. A reasonable patient, where warned of the risk or danger would attach significance thereto;[44] and

2. Where the physician is or should reasonably be aware thereof that the specific patient, if warned of the risk or danger, would likely attach significance thereto.[45]

The information which a careful and reasonable doctor would disclose depends on the circumstances involved which may include *inter alia* the nature of the information, the nature of the medical intervention, the patient's desire to be informed of matters as well as the patient's medical history, temperament, intelligence and understanding of the intervention and their mental condition.[46] It is submitted that the mental condition of the person includes the person's strength of character, resilience and general attitude or personality traits and is not limited simply to a mental capacity.

It is important to note that the duty to disclose may be extended but also restricted. Where the patient asks further questions or refuses a medically indicated treatment, the duty of disclosure is extended and the physician must give full information to the patient and also impress upon the patient the necessity to undergo a proposed treatment.[47] Restrictions of the duty to disclose may be seen as justifiable limitations regarding the patient's freedom of choice and self- determination. The right to informed

[42] *Castell v De Greef* 1994 (4) SA 408 (K). See also Wilson M (2006) "When is a risk of medical treatment material?"*De Rebus* 22.
[43] Expert evidence will however be relevant in determining whether or not risks and dangers are inherent to a certain procedure. See in general Carstens & Pearmain (2007) 599- 867 and Carstens P (2002) "Setting the boundaries for expert evidence in support of defence of medical negligence" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 430.
[44] This is referred to as objective disclosure. See Strauss (2006) in Blanpain & Nys (eds) paragraph 128, footnote 14.
[45] This is referred to as subjective disclosure. See Strauss (2006) in Blanpain & Nys (eds) paragraph 128, footnote 15.
[46] Van Oosten (1989) LLD thesis 450 footnote 68.
[47] *Ibid*. See also Strauss (2006) in Blanpain & Nys (eds) paragraph 131.

consent is not absolute and in certain cases the physician does not have to disclose information to a patient. An example of this is therapeutic privilege.[48]

2.4.1 The Standard of Disclosure in Medical Research

Section 12(2)(c) of the Constitution expressly entrenched informed consent in context of medical research and experimentation involving human subjects.[49] According to Carstens and Pearmain,[50] section 12(2)(c) must be articulated, interpreted and applied in context of guidelines on ethical aspects of medical research such as the MRC guidelines.[51] Chapter 9 of the NHA further deals with national health research and information and provides specifically for the requirement of informed consent in situations of research on, or experimentation with human subjects.[52] Carstens and Pearmain further opine that in context of medical research the minimum standard of disclosure should be full disclosure. This means that the patient must be informed that the proposed medical intervention involves research and that the patient must be furnished with comprehensive and detailed information regarding:[53]

1. The exact scope, nature, duration and purpose of the research;[54]

2. The scope, nature and consequences of the proposed research intervention;

[48] See in general Carstens & Pearmain (2007) 887- 890.
[49] Section 12(2)(c) states that "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." See also chapter 3 paragraph 6.3 *supra* regarding section 12(2)(c) of the Constitution.
[50] Carstens & Pearmain (2007) 893.
[51] For a discussion of the interpretation of section 12(2)(c) see Van Wyk C (2001) "Guidelines on medical research ethics, medical 'experimentation' and the Constitution" *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 64. See also paragraph 3.2 *infra*.
[52] See paragraph 6 *infra* for a detailed discussion on chapter 9 of the National Health Act.
[53] Carstens & Pearmain (2007) 894.
[54] For example whether the research is therapeutic or non- therapeutic.

3. The expected benefits and advantages of the proposed research for the patient themselves and society at large and how these benefits and advantages compare to available therapies; and

4. The foreseeable prognosis and any additional risks, dangers and complications.

It is important to note that the research participant should be informed that they are under no obligation to participate in the research and that participation is voluntarily. Once again, the research participant must have sufficient time to consider and make decisions regarding their participation.[55]

Lastly, medical law may require some further conditions to be met to obtain lawful consent. Van Oosten lists these as the following:[56]

1. Consent must be given freely and voluntarily;[57]

2. Consent must be clear and unequivocal and this may be aided by a comprehensive consent document. To be comprehensive, the consent must cover the entire transaction which includes the consequences of the proposed treatment;[58] and

3. Formalities may be necessary. Consent is more often than not implied by the conduct of the patient[59] but it may be expressly granted. This may be done orally or in writing which is sometimes required by statute.[60]

[55] Van Oosten FFW (2000) "Law and ethics of information and consent in medical research" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 6. See also Van Wyk (2001) *THRHR* 3 and Van Wyk C (2004) "Clinical trials, medical research and cloning in South Africa" *Tydskrif vir Hedendaagse Romeins- Hollandse Reg* 1.
[56] Van Oosten (1989) LLD thesis 456.
[57] Consent is freely in voluntarily given in the absence of fear, force and fraud.
[58] See also sections 6 and 7 of the National Health Act, Act 61 of 2003 and *Castell v De Greef supra.*
[59] See *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T).
[60] For example: section 18 of the Human Tissue Act.

2.5 CONSEQUENCES OF THE ABSENCE OF CONSENT

Where a patient has not given the required consent the physician or institution, such as the hospital where the patient was treated may incur legal liability. This liability may then be founded upon various grounds which include breach of contract,[61] civil or criminal assault as this constitutes a violation of bodily integrity,[62] civil or criminal *inuiria* as it may constitute a violation of dignity or privacy or medical negligence.[63] The physician or institution may additionally be unable to recover the normal professional fee for whatever services were rendered.[64]

As any procedure performed in the absence of consent constitutes a violation against the bodily integrity, dignity or privacy of a patient it is irrelevant whether or not the procedure was ultimately beneficial to the patient and whether or not due care was applied by the physician. Carstens and Pearmain thus reason that this is in accordance to the Constitution and the absence of consent must be viewed in light of section 12(2)(b) of the Constitution. A lack of consent is thus an infringement on bodily psychological integrity rather than a violation against the patient's health.[65] As is illustrated here, the Constitution is ever present and it is thus important to once again pay attention thereto and specifically regarding the provisions regulating consent.

3 CONSENT AND THE CONSTITUTION

Section 12(2) of the South African Constitution provides for the protection of bodily and psychological integrity and is in support of the concept of the right to health. It states that every person has the right to bodily and psychological integrity and that this includes the right not to be subjected to medical or scientific experiments without their

[61] See *Castell v De Greef supra*. See in general Carstens & Pearmain (2007) 283- 488.
[62] See *Stoffberg v Elliott supra* which is also allocable to *iniuria* and Carstens & Pearmain (2007) 767.
[63] See *Lymberg v Jefferies* 1926 AD 236, *Allot v Paterson & Jackson* 1936 SR 221 and *Louwrens v Oldwage* 2006 (2) SA 161 (SCA).
[64] See *Recsie's Estate v Meine* 1943 EDL 277.
[65] Carstens & Pearmain (2007) 891. See in general Van Oosten (1989) LLD thesis 455, Van Oosten (2006) in Blanpain & Nys (eds) paragraph 109 and Strauss (2006) in Blanpain & Nys (eds) paragraph 110.

informed consent.[66] Section 12(2)(c) may therefore be seen as a legal expression of a person's entitlement to autonomy and to have this entitlement respected and protected as a right. For this reason it is important to pay some attention to autonomy and to the interpretation of section 12(2)(c).[67]

3.1 AUTONOMY

The last few decades have heralded a change in discussions regarding the relationship between the physician and the patient and the focus has been shifted from the physician's duty of disclosure to the quality of understanding on the part of the patient. Autonomy as ethical concept has been discussed in the course of this dissertation and previously, significance was attached to the paternalistic beneficence- model which allowed doctors to rely solely on their own judgment concerning the patient's needs and what information was relevant. This model was however, gradually at first, challenged.[68] Due to factors such as constitutional developments and civil and consumer rights movements the demand of a patient to be involved in medical decision making was heard and a move was made from a paternalistic form of medical decision making[69] towards one which recognised the autonomy[70] of the patient.[71] Autonomy is "a principle of medical ethics according to which a person should respect the rights of other individuals to freely determine their own choices and decisions" and in South

[66] Section 12(2)(c) of the Constitution. See also paragraph 1.1 *supra*.
[67] See also paragraph 3.2 *infra*.
[68] Carstens & Pearmain (2007) 875.
[69] 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 http://medical-dictionary.thefreedictionary.com/paternalism accessed 16/ 8/ 2010. See in general "Paternalism" Stanford Encyclopedia of Philosophy available 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* August 42(361): 340- 342.
[70] It could also be described as the personal capacity to consider alternatives, make choices and to act without undue influence or interference of others. See http://medical-dictionary.thefreedictionary.com/autonomy accessed 16/ 8/ 2010.
[71] Strauss (1991) 14.

African medical law, this concept was recognized in the watershed case of *Stoffberg v Elliott*.[72] Here it was held by Watermeyer J that:

> "In the eyes of the law every person has certain absolute rights which the law protects. They are not dependant on statute or contract, but they are rights to be respected, and one of the rights is absolute security of the person."

As mentioned previously,[73] constitutional rights are not absolute and since the rights enshrined in the Bill of Rights do not necessarily replace the common law rights an apparent distinction exists between the constitutional right to freedom and security of the person and the right to bodily and psychological integrity on the one hand,[74] and the common law right to absolute security of the person, as eluded to by Watermeyer J, on the other. The question thus arises whether the Constitution limits the absolute common law right to security of the person or whether it remains unchanged and absolute.[75]

In *Pharmaceutical Manufacturers Association of SA: In re Ex parte President of the Republic of South Africa*,[76] Chaskalson P held that the common law and constitutional law must not be viewed as separate spheres of law. This is further reiterated by the statement by Hodes AJ in *Pennington v Friedgood*,[77] that only one system of law exists and it is shaped by the Constitution, as the supreme law of South Africa, and all other law, which then includes common law derives power from the Constitution and is subject thereto. Section 39 of the Constitution must also be mentioned in this discussion as section 39(2) requires that the spirit, purport and objects of the Bill of Rights must be

[72] *Stoffberg v Elliott supra*.
[73] See chapter 3 paragraph 2 *supra* regarding the limitation clause.
[74] Section 12 of the Constiution.
[75] Carstens & Pearmain 881.
[76] *Pharmaceutical Manufacturers Association of SA: In re Ex parte President of the Republic of South Africa* 2000 (2) SA 674 (CC).
[77] *Pennington v Friedgood* 2002(1) SA 251 (C).

promoted in the development of the common law[78] and section 39(3) explicitly states that, in the absence of inconsistency with the Bill of Rights, no rights which are conferred by the common law are denied.[79]

Common law rights are thus also subjected to proportional weighing against other rights and can therefore not be regarded as absolute.[80] The supposed difference between the common law right to security of the person and the constitutional right to freedom and security of the person as well as bodily and psychological integrity is thus essentially non- existent.

Autonomy is, as the above discussion illustrates, therefore not the be all and end all of entitlements and it becomes relevant here to perhaps examine autonomy from another angle. In context of embryonic stem cell research arguments are often made that any research performed on an embryo infringes on the embryos autonomy. Should a person however be forced to carry the embryo to term, it would constitute a violation of such a person's autonomy. Parenthood can therefore not be forced on persons. Concerning gametes the law seems to be clear in that a person may do with their gametes whatever they wish.[81] This freedom of choice may be classified as falling under reproductive

[78] "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."
[79] "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." See also Van Wyk (2001) *THRHR* 4 at 13 and section 39(1) of the Constitution which states that when interpreting the Bill of Rights, a court, tribunal or forum must (a) 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. This read with section 233 of the Constitution which provides therefore that courts must prefer an interpretation of the Constitution which is consistent with international law indicated that the common law must be developed in accordance with international trends. Concerning stem cells, South Africa must have regard for the following international documents when developing the common law: the *Declaration of Helsinki*, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* and the *Harmonised Tripartite Guideline for Good Clinical Practice of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals*. In accordance with section 39(1)(c) cognisance may then be taken of the *European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention of Human Right and* Medicine and the American guidelines in the form of the *Belmont Report*.
[80] Carstens & Pearmain (2007) 881.
[81] Foster C (2009) *Choosing life, choosing death: The tyranny of autonomy in medical ethics and* law 31-34.

autonomy. Autonomy may be described as freedom and this freedom includes the freedom of choice or free will and thus the exercise of some mental power or function. An embryo or cell of any kind cannot exercise this power and it is submitted, has no sense of autonomy. When issues which may relate to autonomy arises, it is thus submitted that it is the autonomy of the donor of the material whose autonomy is at stake or relevant.

Foster opines that the law is nowhere as uncertain as it is about the status of the fetus and embryo.[82] As example he states that while in one court room a fetus is seen has a bearer of rights for the purpose of the law of succession, down the hall in the same courthouse it is regarded as not human in a case where the very existence of the fetus is at stake. In fact, the law has shown a tendency to deny the independent humanness of the fetus or embryo. In the case of *S v Mashumpa and Another*[83] the court had to decide whether or not the killing of a fetus amounted to murder. The facts of the case are briefly that on the evening of February the 14th 2006, Ms. Shelver, a woman who was 38 weeks pregnant, and Mr. Best, the father of the fetus, were the victims of an armed robbery during which Ms. Shelver was shot in the stomach, an injury which ultimately resulted in the death of the unborn. The robbery occurred after the victims had visited a gynaecologist who had revealed during the examination that the fetus was in a healthy condition and that birth was imminent. After the appointment with the gynaecologist, the couple had entered their car and at this time so did Mr. Mashumpa who then threatened the couple and ordered Mr. Best to drive the car to a secluded area where Mr. Best was shot in the shoulder and his wallet, cell phone and watch were stolen. Before fleeing, Mr. Mashumpa shot Ms. Shelver in the abdomen twice. Facts later revealed that Mr. Best had due to personal reasons, instigated and orchestrated the robbery and was shot in the shoulder simply to appear to be a victim as well. The court was confronted with the question of whether the death of the fetus as result of the shooting constituted murder. The court decided that murder is the killing of a person

[82] Foster (2009) 41.
[83] *S v Mashumpa and Another* 2008 (1) SACR 126 (E).

and a person must have been born alive. The fetus is seen as one and the same entity as the mother.[84]

In context of stem cell research a difficult situation thus arises when it comes to questions surrounding autonomy. Whose autonomy should prevail over whose? The putative parents' rights must surely be considered but then also the rights of the putative child. Assisted reproduction facilities often need to deal with circumstances in which this question arises and thus this discussion largely focuses on such encounters. The reason for this is that during assisted reproduction the potential parent or parents must make decisions regarding the ultimate disposition of the fertilised embryo and in the exercise of this autonomous decision the "autonomy" of the embryo and later fetus is taken into the hands of said parents. Some have argued that once an embryo is created for infertility treatment and then donated to research, the research accords greater respect to the embryo than simply destroying it would.[85]

The debate surrounding whose autonomy should be regarded as trumping the others may be settled by the following actual illustration. Zain Hashmi suffered from beta thalassaemia[86] and his only chance of survival and leading a normal life depended on

[84] For a discussion of this case see Isaak-Teklehaimanot K "S v Mashumpa and Another (CC27/2007) [2007] ZAECHC 23 (11 May 2007) South Africa, High Court-Eastern Cape" available at http://www.law.utoronto.ca/documents/reprohealth/LG016%20%20S%20Africa-S%20v%20Mashumpa%20and%20Another.pdf accessed 18/10/2010. See also the English case of *A- G's Reference (No 3 of 1994) [1998] AC 245* in which a pregnant woman was stabbed and went into premature labour. The fetus died of the stab injuries 121 days later and the court held that the fetus was and should be treated as an integral part of the mothers' body which is no different than her "foot or arm." The fetus was not seen as possessing a distinct human personality. See in particular paragraph 255-256, 261 and 267 of this case. Further authority dealing with this subject matter as found in English law include: *Re F (in Utero)* [1988] Fam, *Paton v Trustees of the British Pregnancy Advisory Services* [1979] QB 276 and Re MB *(An adult: Medical Treatment)* [1997] 2 FCR 541.

[85] 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 and Sterility* September 82(3): 559 at 559. See also Kukla HJ (2002) "Embryonic stem cell research: An ethical justification" *Georgetown Law Journal* 90: 503- 543.

[86] The thalassemias are a group of inherited genetic blood disorders which share the common feature of defective haemoglobin production. Haemoglobin is the protein that enables red blood cells to carry oxygen and carbon dioxide. Beta thalassemia is the most familiar of the thalassemias and involves decreased production of normal adult haemoglobin from soon after birth until death. A child with thalassemia becomes dependent on blood transfusions and, although transfusions do help to some degree, they create further problems including iron overload. Currently there is only treatment for

the obtaining of stem cells from the umbilical cord of a tissue- matched sibling. The chances of natural successful creation of such a sibling were low and thus reproductive technology was utilised to formulate a proposed treatment plan. Embryos were to be created *in vitro* and a sample taken from each embryo at the morula stage of development. The matching embryo would then be implanted into Zain's mother who would then carry the pregnancy to term. The necessary cells could then be harvested at birth. The judicial reasoning which ultimately resulted in the allowance of this proposed procedure may be simply summarised as the judges saw this as the right thing to do. Where the decision had to be made between a three- year old boy, who would otherwise be doomed, and an eight cell embryo the courts chose the autonomy of Zain above the autonomy of the embryo.[87] Foster opines that the events of the Hashmi case may be explained purely on the principle of autonomy.

Zain's autonomy rights were seen as dependant on his continued existence which was in turn dependant on the procedure being undertaken. The embryos which had been "invaded" during the biopsy to obtain samples could at best be described as possessing rudimentary autonomy. It could be stated that the selected embryo was advantaged by the invasion as, had it not been invaded, it would not have been selected for implantation and subsequently implanted. It would thus never have developed to term and been born at which stage the newborn would have proper autonomy rights.[88] If something does not exist, it therefore does not have autonomy.

This discussion has now largely focused on the supposed autonomy of the unborn and hopefully this issue has now been laid to rest. Where attention is thus turned to the newer forms of stem cell research, such as induced pluripotent stem cells, the only autonomy- issues should be related to the donor or the recipient of research material or

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relieving the symptoms of this illness in the form of Gene therapy which remains a potential treatment for the future. See MedicineNet "Beta thalassemia" available at http://www.medicinenet.com/beta_thalassemia/article.htm accessed 19/09/2010.

[87] See Sheldon S & Wilkinson S "'Saviour Siblings': Hashmi and Whitaker. An unjustifiable and misguided distinction" available at http://www.prochoiceforum.org.uk/irl_rep_tech_2.php accessed 10/09/2010.

[88] Foster (2009) 58.

the patients involved in stem cell therapy. As previously stated, a patient is entitled to choose the form of medical treatment which they will undertake and it is submitted that this choice may include stem cell treatments and falls under the umbrella of autonomous decisions concerning health. It has also now been established that autonomy as a right may be limited and some attention is thus briefly given to the interpretation and ultimate limitation thereof.

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

Section 12(2)(c) of the Constitution requires that a person must give their consent prior to participation in any medical or scientific experimentation. As mentioned previously, a strict interpretation of this would result in an environment wherein only the research subject may consent to the proposed research or medical procedure and thus stem cell research would be unconstitutional as a cell cannot by nature consent. It was thus submitted that the consent which must be sought is that of the donor of the material which will be used in the medical or scientific experimentation. It is therefore necessary to discuss the interpretation of section 12(2)(c) in the context of research.

3.2.1 The First Stage of Constitutional Interpretation

During the first stage of interpretation of a constitutional provision the first question to be addressed is what the content of the right is which seems to have been infringed upon.[89] When it comes to the interpretation of section 12(2)(c) the questions which must thus be asked are which constitutional values are entrenched in this right, which interests does this section aim to protect and what purpose does this guarantee aim to serve? In other words it must be answered what the content, ambit and boundaries of

[89] For more on the two stage approach which is followed during interpretation see chapter 2 *supra*.

the right not to be subjected to medical or scientific experimentation without a person's informed consent entails.[90]

When considering the value- based approach to interpretation, effect must be given to the inherent values of the Constitution. In *S v Zuma*[91] it was stated that the purpose of the right in question must be found with reference to the character and the lager objects of the Constitution. The chosen language with which the right is expressed, the historical origins of the concept and the meaning and purpose of other rights with which the right in question is associated are further factors which must be kept in mind. Although this is true, care must be taken to not overshoot the actual purpose of the specific right which is being scrutinized.

The Constitution does not define the terms "experimentation" or "research" nor does it specify whether this is therapeutic or non- therapeutic research but as seen in the *Zuma* case,[92] language plays an important role during interpretation. The Constitutional Court further supports the notion that language is an indispensable interpretive tool as seen in the dictum of Kentridge AJ in the *Zuma* case. It was held that:

> "While we must always be conscious of the values underlying the Constitution, it is nonetheless our task to interpret a written instrument. I am well aware of the fallacy of supposing that general language must have a single 'objective' meaning. Nor is it easy to avoid the influence of one's personal intellectual and moral preconceptions. But it cannot be too strongly stressed that the Constitution does not mean whatever we might wish it to mean."

Due to this, use may be made of traditional statutory interpretive rules and as such the plain language meaning of words may be examined in dictionaries.[93] Medical

[90] Van Wyk (2001) *THRHR* 4 at 13.
[91] *S v Zuma* 1995 2 SA 642 (CC). The *Zuma* case cited the Canadian case of *R v Big M Drug Mart Ltd* [1985] 1 S.C.R. 295.
[92] *S v Zuma supra.*
[93] Botha C (2005) *Wetsuitleg: 'n Inleiding vir Studente* 4de uitgawe 28 & 88-89.

dictionaries however are of little help when trying to determine the meaning of experiment or research. For a definition of these terms ethical guidelines must be employed.[94] The distinction between experiment and research is thus uncertain and a conclusion may be drawn that the concepts are interlinked and that research may include one or more experiments and could thus be used interchangeably.[95]

3.2.2 The Second Stage of Constitutional Interpretation

During this stage of inquiry, the limitation of the right is examined and it must be determined whether the infringement is reasonable and justifiable in terms of section 36 of the Constitution.[96] The importance of the right in question is now tested against the strength of the infringement's justification or social objectives. Section 12(2)(c) seeks to protect human dignity, autonomy and freedom and security of the person and thus a serious limitation of this right will not be easily allowed. Section 36 then requires the court to weigh and counter the purpose, effects and importance of the infringing legislation against the nature and importance of the right which is infringed upon. This must then be done keeping in mind that South Africa is an open and democratic society based on human dignity, equality and freedom. The limitation of this right will then be justified by the promise of imperative new knowledge which will benefit both science and mankind.[97]

It must then be determined whether or not less invasive means could have been implemented which would have achieved the same goal. A balancing of competing rights thus takes place and the competing rights of others must also be considered. In

[94] A further point which is of some importance is that Constitutional interpretation and normal statutory interpretation differ and therefore words cannot be definitive within themselves.
[95] Van Wyk (2001) *THRHR* 4 at 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.
[96] Section 36 provides a mechanism whereby the government may take an action which is prima facie unconstitutional but serves a pressing public interest.
[97] See in general Burchell JM (1987) "Non- therapeutic medical research on children" *South African Law Journal* June 95(2): 193-216.

context of section 12(2)(c) or then the right not to be subjected to medical or scientific experimentation without consent thereto, the rights of others may include the right to life,[98] human dignity and the right to access to health care services. Constitutional rights are difficult to balance as they are incommensurable and a choice must often be made between competing visions of the world and the manner in which society should be arranged.[99] In context of stem cell research and section 12(2)(c) a primary commitment made by the Constitution may have to be sacrificed for a subordinate one in order to enable scientific progress, even if such progress then comes at the cost of somewhat limiting the research participant's rights to dignity and autonomy.[100] It is however pertinent to examine the specific issues which may limit this right which are involved in the process of obtaining consent for the purpose of stem cell therapy or research.

4 CONSENT ISSUES REGARDING STEM CELLS[101]

Research utilising human stem cells and stem cell lines is necessary to address certain scientific questions in the quest of fulfilling the promise of stem cell therapies and stem cell transplantation for degenerative diseases. For this to be accomplished guidelines must be set in place to regulate stem cell research and this will in turn foster public trust and acceptance of this astonishing new form of medicine and research. Consent however is a complex and important aspect of garnishing an environment which is conducive to stem cell research. This section of this dissertation thus focuses on certain pertinent issues or questions regarding consent in context of stem cell research. The first aspect which must be investigated concerns the person whom may give consent

[98] Persons suffering from the same affliction as the research subject who may be helped by such research.
[99] Chaskalson M (1999) *Constitutional law of South Africa* 12-61- 12-63.
[100] 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 secion 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) *THRHR* 4 at 20-21.
[101] The discussion which takes place here may be considered the academic or theoretical ideal situation. The practical application of this ideal is then discussed in the examination of chapter 9 of the NHA in paragraph 6 *infra*.

and who should obtain consent. Secondly, what should be covered in the consent process will need some attention and lastly the time at which consent should be obtained will be discussed.

4.1 WHO SHOULD GIVE CONSENT AND WHO SHOULD OBTAIN CONSENT?

Where human biological material is donated, the donor is usually required to give informed consent for any research related to the donation.[102] Where consent may be waved by review boards, the donated material is de- identified and cannot be traced to the donor thereof and often general provision is made therefore in the initial consent form where consent is obtained for a clinical procedure which involves the removal of such material which would normally be discarded.[103] In the context of stem cell research and embryonic stem cell research in particular, this is however not allowed, greatly due to the emotional and moral significance of reproductive material. Consent must thus be explicit and specific.[104] Even in circumstances where the material cannot be linked back to the donor, donors may feel offended or violated should their biological material be used in particular research processes without their prior consent. It may also not be desirable to remove all identifiers from stem cells and stem cell lines.[105] Biological

[102] National Bioethics Advisory Commission (1999) *Research involving human biological materials; Ethical issues and policy guidance* available at http://bioethics.georgetown.edu/nbac/hbm_exec.pdf accessed 11/10/2010.

[103] Certain federal regulations in the United States of America allow for the donation of biological material without consent in circumstances where such material has been anonymized, meaning that the donor thereof cannot be identified as no code has been assigned to the material which links it to the donor. An example of this is where cancerous tissue is removed in surgery and would otherwise be discarded.

[104] Lo, Chou, Cedars, Gates, Taylor, Wagner, Wolf & Yamamoto (2004) *Fertil Steril* 559 at 560.

[105] *Ibid*. Where cells are to be used in therapy or transplantation a link to the donor may be necessary in order to assess which tests were performed in order to determine the possibility of genetic or infectious diseases. See regulation 9 of the Regulations Relating to Human Stem Cells 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 products 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." See the discussion of this Regulation in chapter 6 *infra*.

material such as embryos or stem cells may therefore only be used in research which has been specifically consented to.[106] The donors of sperm and oocytes also share this ethical interest in consenting to research performed on their donations.[107] Depending on the material which is donated, consent and the obtaining thereof will differ. The consent process related to the donation of embryos will be more complex that the process followed for the donation of sperm for example, as it entails more risks and removal is a more complicated procedure than in the case of sperm.

As previously discussed, an embryo by nature cannot give consent and the wording of section 12(2)(c) must therefore not be interpreted as a prohibition on stem cell research as no consent could ever be obtained.[108] The above discussion thus reiterates the fact that the donor of the biological material must consent to the donation and what this entails. The donation may require removal or withdrawal of the material and specific consent must be obtained for the chosen or indicated method. The donor can however only give his or her informed consent after they have in fact been informed and have knowledge, appreciation and acquiescence of the proposed procedure. The donor as a layperson will have to be given the information and this raises the question of who must inform the user and obtain consent.

Various opinions exist regarding who should obtain consent and one such opinion holds that in the case of donation of spare embryos not used in *in vitro* fertilization or artificial fertilization, someone other than the treating physician should, where possible, request the potential donor to donate such material for stem cell research purposes.[109] This is done to ensure that the reproductive needs of the potential donor are the primary focus

[106] See paragraph 7.1 *infra* for a discussion of the proposed research protocol and submitted essential aspects of a consent form.
[107] 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* August 301(5637): 921 at 921.
[108] See also paragraph 3 *supra*.
[109] Ethics Committee of the American Society for Reproductive Medicine (2002) "Donating spare embryos for embryonic stem cell research" *Fertility and Sterility* November 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* September 82(1): 224-227.

of the relationship and to avoid any conflicts of interest. Patients are in a state of dependence during infertility treatment and may consent to any suggestion made by the treating physician.[110] In such cases someone other than the treating physician, who is not involved in research, may help to ensure that consent is given in a truly voluntary and informed manner.[111]

When the physician is not involved in the research study as opposed to a researcher or scientist, he or she is more likely to be focused on the well- being of the patient in stead of the potential scientific and social benefits of the research.[112] It is therefore preferable for the treating physician in the case of infertility treatment to discuss possible research options with prospective donors of embryonic material. An exception to this is where the physician is also a researcher in the field, has limited knowledge regarding stem cell research or where the physician is uncomfortable with such discussions. In cases such as these, another clinician may be asked to partake in the discussions and explanations.[113]

The above discussion is indicative towards the protection of the research participant or donor by attempting to remove possible bias from the process of consent by suggesting that the physician should only be involved in obtaining consent where he or she is not involved in the research for which the donated material will be used. The process of consent can thus be designed to minimise any potential conflicts of interest or undue influence. This may be done by following three steps during the consent process:[114]

1. Patients and potential participants or donors must be informed that their treatment will not be influenced by their decision to partake in the research;

[110] Lo, Chou, Cedars, Gates, Taylor, Wagner, Wolf & Yamamoto (2004) *Fertil Steril* 559 at 562.
[111] Infertility specialists are usually able to provide nondirective counselling without violating the patients values or preferences. In research in other contexts a physician may however be considered an impartial source of information and advice. 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.
[112] National Bioethics Advisory Commission (2001) *Ethical and policy issues in research involving human participants* available at http://bioethics.georgetown.edu/nbac/human/oversumm.pdf accessed 11/ 10/ 2010.
[113] Lo, Chou, Cedars, Gates, Taylor, Wagner, Wolf & Yamamoto (2004) *Fertil Steril* 559 at 562.
[114] *Idem* at 562.

2. Any relationships, financial or research related, between the person obtaining consent and the research project must be disclosed to the potential participant or donor; and

3. The actual treating physician may be removed from the signing of the consent form and need never know the ultimate decision of the patient thus decreasing any pressure the patient may experience.

In conclusion, it has now been determined that the donor of the research material must consent to the removal, withdrawal or donation thereof. In situations where the potential donor is a minor certain other provisions become relevant and these are discussed later in this dissertation.[115] The treating physician must then also be the person to obtain consent but only where there are no potential conflicts of interest or any interests have been disclosed to the patient.[116]

4.2 WHAT SHOULD THE CONSENT PROCESS COVER?

Informed consent deals with the process whereby a patient is given information in order to establish knowledge, appreciation and acquiescence on the part of the patient. For this reason the consent **process** generally should provide patients or research participants with all the information that is reasonably considered pertinent to their decision to participate in or to donate to the research study.[117] Participants must understand that their donation may lead to products with commercial value and may be shared with other researchers. In the context of embryonic stem cell research, it must further be clearly explained that the embryo will be destroyed.[118] An important aspect of the consent process is assuring the patient or participant that their donated material

[115] See paragraph 5.3 *infra.*
[116] See paragraph 5.3 *infra* regarding the provision of consent from a minor.
[117] See in general Berg J, Lidz CW & Appelbaum PS (2001) *Informed consent: legal theory and clinical practice* 2nd edition.
[118] National Bioethics Advisory Commission (1999) *Research involving human biological materials; Ethical issues and policy guidance.*

will only be used in research which has been reviewed on a scientific and ethical basis. Patients should further be allowed the opportunity to ask questions and participate in the consent process in order to identify information which they consider relevant to the decision- making process.[119]

In circumstances where embryos will be frozen and used at a later stage in research protocols which have not been designed, the donors or participants should consent to general categories of research or research methods rather than specific protocols.[120] It is suggested that different research categories should be identified and provided to the participants. Firstly, donors could be presented with various groups of research categories from which they may choose options which they find acceptable. For example, one such group may describe the purpose of the proposed research such as human development, genetic disease studies or transplantation in the case of degenerative diseases. Patients or participants may consent to all the mentioned groups or to only those they feel comfortable donating to. A second set of research categories may then list techniques and methods. Participants may have concerns related to moral grounds and thus attention must be paid thereto in the consent process.[121] Examples of these categories may include the creation of embryos specifically for research purposes, the creation of stem cell lines,[122] somatic cell nuclear transfer[123] and protein induced pluripotency.[124]

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[119] 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.

[120] National Bioethics Advisory Commission (1999) *Research involving human biological materials; Ethical issues and policy guidance*. See also Ethics Committee of the American Society for Reproductive Medicine (2002) *Fertil Steril* 957- 960 and Deech R (2002) "Regulation of therapeutic cloning in the UK" *Reproductive BioMedicine Online* 5(1): 7- 11 available at http://www.rbmojournal.com/article/S1472-6483(10)61589-1/abstract accessed 10/10/2010.

[121] 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* available at http://bioethics.georgetown.edu/pcbe/reports/cloningreport/ accessed 10/10/2010.

[122] Donors must understand that stem cell lines may develop indefinitely and may be used in future transplantations.

[123] It must be clearly explained that with the exception of mitochondrial DNA, the resulting cells will be genetically identical to the donors somatic cells but will not be used to create a pregnancy.

[124] Institute of Medicine (2002) *Stem cells and the future of regenerative medicine* available at http://www.nap.edu/catalog.php?record_id=10195 accessed 8/10/2010. See also National Bioethics

Issues of confidentiality must be discussed during the process of obtaining consent. In certain cases an identifying code will be required which links the material to the donor. This will be necessary in circumstances where the donated material is destined to be used in transplantation in order to determine whether or not the material has undergone the appropriate screening procedures to test for any genetic or infectious diseases.[125] Donors must further be informed of anyone who may have access to the code and the extent to which confidentiality will be protected. Participants must therefore consent to the retention of a link between themselves and the donated material.[126]

In summary it is thus recommended that the consent process cover the explanation of pertinent aspects of stem cell research which includes the objects or the proposed research topic and the methods or techniques which will be employed. Donors must also be informed of matters regarding confidentiality and privacy.

4.3 WHEN SHOULD CONSENT BE OBTAINED?

The time of obtaining consent is of importance as the topic of stem cell research may be an emotionally loaded one which carries various connotations and conceptions. Thus the time of consent may influence whether or not a possible donor participates in research at all. According to the American National Institute of Health and the National Bioethics Advisory Commission, discussions regarding consent for the donation of material for embryo research must occur only after infertility treatment has been completed and a decision has been made to discard of any spare frozen embryos.[127]

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*.

[125] Lo, Chou, Cedars, Gates, Taylor, Wagner, Wolf & Yamamoto (2004) *Fertil Steril* 559 at 561.

[126] Lo B *et al.* opine that it may be preferential to undertake only research with material where consent has been given by the patient to be recontacted.

[127] 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

Some however argue that it is wise to discuss embryo donation at the onset of fertility treatment and two motivations are offered for these arguments.[128] Firstly it is argued that decisions concerning the disposition of embryos or gametes arise during the process of fertility treatment and patients generally discuss their preferences on harvesting and fertilisation, the number of embryos to be implanted and the possibility of embryo storage. The disposition of embryos after the completion of treatment would thus logically fit into these discussions. An additional issue that must be considered here is that certain embryos may only be useful as research subjects as they may be of poor quality and cannot be fertilized or frozen due to abnormality or immaturity. In such cases discussing consent to research may be insensitive towards the patient or couple undergoing treatment. It further does not allow for an appropriate time of contemplation.[129]

The second argument states that women and couples are urged to plan for the disposition of frozen embryos in future. Usually fertility programs are required to obtain written directives from couples in case of "death, divorce, separation, failure to pay storage charges, the inability to agree on future disposition or lack of contact with the program."[130] The donation of embryos for research is an option which must be discussed during such advanced planning. Where possible consent must later be reaffirmed at the time of actual research as considerable time may have elapsed since the time of consenting to donation and the donors may have changed their minds. If contact between the donor and the fertility treatment institution has been broken and consent has not been revoked, it is considered ethically permissible to use the donated

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also National Institute of Health (1994) *Report of the human embryo research panel* available at http://www.bioethics.gov/commissions/ accessed 8/10/2010.

[128] When consent is obtained for later research at the onset of fertility treatment it becomes a matter of how the embryos will be used and not whether they will be used. This is due to the fact that some embryos may remain frozen years after fertility has been completed and are then discarded. See in this regard Lo B *et al* 561.

[129] Lo B *et al* 561.

[130] Ethics Committee of the American Society for Reproductive Medicine (1997) "Ethical considerations for assisted reproductive technologies" *Fertility and Sterility* May 67(5)1: S1- S9.

material for research purposes.[131] Where consent has not been obtained for the donation of embryos such embryos may not be used for research as this would be a gross violation of autonomy.

As the above discussion relates to embryonic stem cell research it is submitted that where other material is donated to stem cell research, such as umbilical cord blood, consent must be obtained prior to the removal or withdrawal thereof.

5 CONSENT IN NATIONAL LEGISLATION

Informed consent is a keyword in research as the right to self- determination and autonomy lay at the basis of consent. Originally derived from the common law and entrenched in the Constitution, it is further based on various rights which include dignity, privacy as well as freedom and security of the person.[132] Section 71(1) of the NHA confirms the need for informed consent and provides for the following:

> **"**Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-
>
> *(a)* in the prescribed manner; and
>
> *(b)* with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences for his or her health."

The required information is wider than that which is required for medical treatment as the patient need only be informed of benefits, risks and the consequences generally associated with their treatment option. The regulations additionally require that a research participant be informed of the expected benefits of participation and of the

[131] Lo B *et al* 561.
[132] Van Wyk (2010) Transplantation Indaba.

potential or real harm and risks which are involved in participation.[133] Participants must further be informed of the methods and procedures which will be followed in the course of the research as well as how confidentiality and privacy will be protected and maintained. All the above mentioned will be discussed in detail in the following section of this dissertation. The NHA as well as the regulations are however silent on how consent must be obtained and during the course of this dissertation an attempt is made to provide a recommended research consent protocol.

Currently however, various South African legislative documents exist which regulate consent or aspects thereof. The provisions found here relate mostly to consent in context of a medical intervention but are still applicable. In context of this dissertation the NHA is of the utmost importance as it is considered the legislative tool whereby stem cells in South Africa will be governed and it will therefore be discussed in greater detail below.[134] Other Acts do however exist which regulate particular aspects of consent and attention must be give thereto before an examination of the NHA may be undertaken. These Acts include the Mental Health Care Act,[135] the Child Care Act,[136] the Choice on Termination of Pregnancy Act,[137] the Sterilisation Act[138] and the Human Tissue Act[139] which will be repealed by the NHA. As the aforementioned legislation deals with aspects of consent, the following broad categories may be identified wherein consent is specifically discussed and wherefore, express provisions have been made. Firstly adults, capacitated or incapacitated. Secondly, the mentally ill while minors constitute a third category and lastly the consent to terminate a pregnancy and the consent to sterilisation. Each of these groups will be discussed shortly in order to provide further background and understanding of the various complexities of informed consent.

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[133] Van Wyk opines that such consequences include financial and social consequences. See chapter 2 *supra* for a discussion of these rights.
[134] See chapter 6 *infra*.
[135] The Mental Health Care Act, Act 17 of 2002.
[136] The Child Care Act, Act 74 of 1983 which was repealed by the Children's Act, Act 38 of 2005.
[137] The Choice on Termination of Pregnancy Act, Act 92 of 1996.
[138] The Sterilisation Act, Act 44 of 1998.
[139] The Human Tissue Act, Act 65 of 1983.

5.1 ADULTS

Patients must be legally capable of giving consent and adults are regarded as possessing such capacity to validly consent to medical interventions provided they are sane and sober.[140] Legally, a person over the age of 18 years is considered an adult and may consent to any medical procedure which they themselves will undertake.[141] Age however is not an absolute measure of capacity as a person above the age of 18 years may be incapacitated due to various reasons including unconsciousness, intoxication, delirium, coma, shock or trance.[142] Section 7 of the NHA, which is discussed below,[143] may be applied in such circumstances as it provides for proxy consent to be given by another person on behalf of the patient who cannot give consent to a medical procedure. A person who is above the age of 18 years and who, according to law, has the capacity to do so, may consent to any medical procedure or treatment and it is submitted that such a person may thus give their consent to undertake stem cell therapy or participate in stem cell research.

Neither the NHA nor the regulations address the issue surrounding the level of risk to which adults may consent for research purposes. The MRC guidelines limit risk to the minimum in both therapeutic and non- therapeutic research.[144] These guidelines state that the risks or harm must not outweigh the benefits which are likely to accrue to the participant. Generally research which involves human subjects should not involved risk which is greater than minimal and the only exception thereto is where there is great potential benefit to the particular participant.[145]

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[140] *Recsei's Estate v Meine* where it was held "ordinarily the consent of an adult in full possession of his mental faculties… would be sufficient authority for the performance o a surgical operation."
[141] Section 1 of the Children's Act defines a child as a person under the age of 18 years. An adult is thus a person above the age of 18. See section 129 of the Children's Act for the provisions regarding medical treatment of children and the required consent.
[142] Carstens & Pearmain (2007) 899.
[143] See paragraph 6.2 *infra*.
[144] MRC (Book 1) paragraph 9.12.
[145] The possibility or even probability which may be accrued to humanity does not offer a legal defence. See in general Van Wyk (2010) Transplantation Indaba.

5.2 THE MENTALLY- ILL[146]

The Mental Health Care Act[147] provides for the requirements to be met in the process of obtaining consent from a person suffering from a mental illness. Mental illness is defined in the Mental Health Care Act 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." Persons who qualify as mentally- ill patients are viewed as mental health care users and include persons receiving care, treatment and rehabilitation services,[148] or are making use of a health service at a health establishment which attempts to enhance the mental health status of that user, a State patient or mentally ill prisoner and a person below the age of 18 years or who is incapable of making decisions.[149] The legislator assumes that a mentally ill person may generally be capacitate to give his or her consent to care, treatment of rehabilitation as a distinction is made between voluntary[150] and involuntary care,[151] treatment or rehabilitation. A person who is mentally ill is not *per se* unable to give consent to care, treatment or rehabilitation.[152]

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[146] See in general Van Staden CW & Krüger C (2003) "Incapacity to give consent owning to mental disorder" *Journal of Medical Ethics* 41. See also Struass SA (1998) "Clinical trials involving mental patients: some legal and ethical issues" *South African Practice Management* 1: 20.

[147] The Mental Health Care Act, Act 17 of 2002.

[148] "Care, treatment and rehabilitation" have corresponding meanings.

[149] In certain circumstances this may also include a prospective user, the persons next of kin, a legally authorised persons who acts on behalf of the mentally ill patient and an administrator or executor of a deceased estate. See section 1 of the Mental Health Care Act.

[150] Voluntary care, treatment and rehabilitation, according to section 1 of the Mental Health Care Act means that the provision of health interventions are provided to a person who gives consent to such interventions.

[151] Involuntary care, treatment or rehabilitation means the provision of health interventions to people incapable of making informed decisions due to their mental health status and who refuse health intervention but require such services for their own protection or for the protection of others according to section 1 of the Mental Health Care Act. See also Van Staden CW & Krüger C (2007) "Can involuntary admitted patients give informed consent to participation is research" *South African Journal of Psychiatry* February 13(1): 10-12.

[152] See in general Strauss (2006) in Blanpain & Nys (eds) paragraph 116. See also sections 26 of the Medical Health Care Act for provisions regarding consent where a person is incapable thereof to give such consent, section31 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 patients regains the ability to make informed decisions regarding their care, treatment or rehabilitation. See further paragraph 6.1 *infra* for a discussion of section 6 of the National

5.3 MINORS[153]

Before the discussion surrounding minors continues, it is imperative to briefly examine the provisions of section 129 of the Children's Act,[154] which came into force on the 1st of April 2010, as it relates to consent of a minor to medical treatment and surgical operations.[155] In context of this dissertation the provisions regarding consent to medical treatment will be discussed. Section 129 makes provision therefore that a child as young as 12 years of age may consent, for themselves or for their children, to medical treatment. Factors which are taken into account in such circumstances are not merely the age of the minor, but also the level of maturity[156] and the capacity to understand the benefits, risks and implications, social or otherwise, of such treatment.[157] This is in accordance with section 71 of the NHA which is discussed below.[158] Where a child is however deemed to not be able to give consent due to a lack of maturity or understanding, the parent or guardian of the child will have to become involved in the process of obtaining consent for said procedure. A parent or guardian for purposes of the Children's Act include the biological mother, the biological father of the child if married to the biological mother, a caregiver with no formal parental rights or responsibilities,[159] the superintendent of the hospital, the Minister of social

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Health Act which provides for circumstances where a person other than the health care user consents to medical intervention.

[153] See paragraph 5.3 *infra* for a discussion of the regulation of the consent of minors in context of stem cell research.

[154] Children's Act, Act 38 of 2005.

[155] The Children's Act does not provide definitions of "medical treatment" or "surgical operations". According to the guide on the Children's Act as published by the Children's Institute of the University of Capet Town, see footnote 157 *infra*, "medical treatment" refers to a non- invasive procedure such as inoculation whereas "surgical operation" denotes an invasive procedure.

[156] A determination of a child's level of maturity requires that the child must have full knowledge of the proposed procedure and must understand the risks involved. Different treatments will then also require different levels of understanding and responsibility as the level of risk involved will differ. See also in this regard the distinction between consent to therapeutic and non- therapeutic research *infra* as it also pertains to this difference of risk and what the procedure entails.

[157] Mahery P, Proudlock P & Jamieson L (2010) *A guide to the Children's Act for health professionals* Children's Institute: University of Cape Town 9.

[158] Specifically section 71(2)(d) and section 71(3)(a)(iii).

[159] Section 32 read with section 129(3) of the Children's Act.

Development or the court.[160] A child may thus, in conclusion consent to a medical intervention without the consent of a parent or guardian where such child sufficiently understands what he or she is consenting to. The following discussion now focuses on the consent of a minor in circumstances related to research.

As previously mentioned in the course of this dissertation, a strict interpretation of section 12(2)(c) of the Constitution would not permit research to be undertaken on people who are not capable of giving legal consent. Children would thus be excluded from partaking in research. If such an interpretation were to be followed, South Africa would be left behind in the development of research which is allowed as long as strict limitations are adhered to. Chapter 9 of the NHA provides for a measure of certainty regarding this matter and states that children may participate in research even though they are not deemed legally competent to consent thereto.[161] Strict conditions must however be met and the minor's consent must be accompanied by the consent of a parent or guardian and in certain cases the consent of the Minister of Health. It must be noted however that the legislator is less liberal in its approach towards minors consenting to research.[162] The distinction made previously in this dissertation between therapeutic and non- therapeutic research now becomes relevant as the NHA makes provisions for a minor consenting to therapeutic research on the one hand and to non-therapeutic research on the other.

Section 71(2) of the NHA provides for circumstances where consent is sought for therapeutic research. Such research may only be conducted when the following requirements are met:[163]

(a) The research must be in the child's best interests;[164]

[160] Section 129(9) of the Children's Act.
[161] See section 71 of the NHA.
[162] See paragraph 5.4 *infra* for an example of the legislators' leniency towards minors consenting to medical procedures.
[163] Section 71(2)(a)- (d).
[164] The NHA uses "child" and "minor" interchangeably. In the course of this dissertation these words also have the same meaning.

(b) Research must be done according to a specific manner and under the prescribed conditions;

(c) The parent or guardian of the child must give their consent to the research; and

(d) The child may consent where he or she is capable of understanding what he or she is consenting to.[165]

Section 71(3)(a) on the other hand provides for non- therapeutic research to be conducted on a minor and states the following prerequisites:[166]

(i) Non- therapeutic research may only be done under the prescribed conditions;

(ii) With the consent of the parent, guardian or child;

(iii) Where the child has the capacity to understand, the child may consent; and

(iv) The Minister of Health must consent to such research.

In certain situations however the Minister may not consent to non- therapeutic research performed on a minor. These situations are as follows:[167]

(i) The research object can just as easily be achieved by research performed on an adult;

(ii) The research is unlikely to yield improved understanding of the condition, disease or disorder of the child to an extent which significantly benefits the child or children;

[165] The consent of the minor precedes that of the parent or guardian and where the child thus refuses to undergo a research study, the consent of the parent or guardian is void. This is also the case for non-therapeutic research. In a medical context however, where a child cannot or will not consent to a procedure, the parent or guardian may consent thereto. See in this regard Mahery, Proudlock & Jamieson (2010) 13- 14.
[166] Section 71(3)(a)(i)- (iv).
[167] Section 71(3)(b)(i)- (v).

(iii) Where the motivation behind the consent of the child, their parent or guardian is *contra boni mores*;[168]

(iv) The research poses a significant risk to the minor's health; and

(v) Some risk to the health or well- being of the child exists and the potential benefit of the research does not outweigh such risk.

The question regarding risk is of importance in context of the participation of a minor in research and the regulations state that only where the research, therapeutic or non-therapeutic, poses minimal risk may such research be conducted. "Minimal risk" is defined 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."[169] Van Wyk submits that "daily life" means daily life in a stable society.[170] A child may thus, in conclusion, consent to therapeutic and non- therapeutic research provided that such consent is accompanied by the required consent of a third party[171] and all other requirements are met.

5.4 TERMINATION OF PREGNANCY, STERILISATION AND CONSENT[172]

The discussion surrounding consent for the termination of pregnancy is relevant in context of this dissertation as it is connected to the abortion issue which has been

[168] *Contra boni mores* means "against good morals."
[169] Regulations Relating to Research on Human Subjects No. R135 in Government Gazette No. 29637 of 23 February 2007 10. Hereafter referred to as the Human Subjects Regulations. See section 1 of the Human Subjects Regulations.
[170] Van Wyk (2010) Transplantation Indaba.
[171] The parent or guardian of the child or the Minster of Health or a person to whom the Minster has delegated such power.
[172] See in general McQuoid-Mason D (2010) "Some consent and confidentiality issues regarding the application of the Choice on Termination of Pregnancy Act to girl-children" *South African Journal on Bioethics and Law* 3(1): 12.

previously discussed,[173] as well as the debate surrounding the destruction of potential life in the process of embryonic stem cell research.

A woman or child of any age may consent to the termination of a pregnancy. Should she be under the age of 18 years, a physician will advise her to consult her parents but no obligation exists on the part of the patient to adhere to this advice and in the absence of a legal grounds of justification therefore,[174] no such female person may be prevented from terminating a pregnancy.[175] Where a woman is incapacitated due to health related circumstances or is mentally ill, section 5(4) of the Choice on Termination of Pregnancy Act allows for proxy consent as prescribed by the Mental Health Care Act.[176] The implications of proxy consent on behalf of an incapacitated person for the termination of a pregnancy in context of stem cell therapy and research is a complicated and abstract subject and falls outside the scope of this discussion.

6 CONSENT AND THE NATIONAL HEALTH ACT[177]

The purpose of this dissertation is an analytical examination of the proposed regulatory framework for stem cell research in South Africa. The NHA is currently perceived to be the legislative tool by which stem cells will be regulated and for this reasons, Chapter 2 of the NHA must be discussed as it provides for the rights and duties of users and health care personnel.

A "user" is defined in section 1 of the NHA as the person receiving treatment in a health establishment,[178] which includes receiving blood or blood products,[179] using a health

[173] See chapter 3 paragraph 7.1 *supra* regarding abortion and embryo destruction.
[174] An example of this would be where a woman attempts to undergo an elective abortion after the twelfth week of pregnancy, as the fetus is legally deemed viable after such time. Should circumstances exists wherein maternal and/ or fetal life would be threatened by continued pregnancy, an abortion may still be legally undergone. See section 2 of the Choice on Termination of Pregnancy Act.
[175] Section 5(3) of the Choice on Termination of Pregnancy Act.
[176] See paragraph 5.2 *supra*.
[177] The National Health Act, Act 61 of 2003.
[178] 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

service[180] or receiving treatment. This includes a person below the age of 18 years[181] where the parent or guardian acts on such a person's behalf and also a person who is incapable of making decisions, whose spouse or partner, parent, grandparent, adult child, brother or sister or another person who is authorized by law to act on such a person's behalf. "Health care personnel" means health care providers and health workers.[182] Health care providers are persons providing health services in terms of any law.[183]

The relevant sections in Chapter 2 are sections 6, 7, 8 and 11. Section 6 gives the health care user the right to be informed of possible treatment options, the benefits and risks of each option and the costs thereof before such treatment is administered. Sections 7 and 8 further provide a right to participate in decision making regarding which treatment will be undertaken. Before a detailed discussion of the most relevant sections, it is preferential to at least mention that the other sections in Chapter 2 deal with emergency treatment,[184] heath service without consent,[185] discharge reports,[186] the duty to disseminate information,[187] confidentiality[188] and the laying of complaints.[189] Health records are provided for since Chapter 2 provides for an obligation

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treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services."

[179] According to Van Wyk C (2010) the definition of "blood product" is considered wide enough to include stem cells. A stem cell however, is not a blood product and is not exclusively connected to blood. It is submitted that a separate definition for stem cells is necessary. See also chapter 6 paragraph 3.2 *infra*.

[180] 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(l)(c) of the Constitution, (c) medical treatment contemplated in section 35(2)(e) of the Constitution and (d) municipal health services."

[181] As contemplated by section 39(4) of the Child Care Act, Act 74 of 1984 which was repealed by the Children's Act, Act 38 of 2005.

[182] Section 1 of the NHA.

[183] This includes a person rendering health services under 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 No. 53 of 1974 and (e) Dental Technicians Act, Act No. 19 of 1979.

[184] Section 5.

[185] Section 9.

[186] Section 10.

[187] Section 12.

[188] Section 14.

[189] Section18.

to keep records,[190] access to health records[191] and access to health records by a health care provider[192] as well as the protection of such records.[193] Lastly, the duties of the users and health care personnel respectively are listed.[194] The relevant sections are of importance for the purpose of this dissertation as they may have a bearing on stem cell research and must now be discussed in more detail.[195]

6.1 SECTION 6: USER TO HAVE FULL KNOWLEDGE

Section 6 requires the health care provider to inform the user, preferably in a language which the user understands and in a manner which takes cognisance of the users' level of literacy,[196] of the following:[197]

(a) The users health status;[198]

(b) The generally available diagnostic and treatment options;

(c) The benefits, risks, costs and consequences which are associated with each of the available options which have been discussed in accordance to section 6(1)(b); and

(d) The user's right to refuse any health services must be explained as well as the implications, risks and obligations related to such a refusal.[199]

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[190] Section 13.
[191] Section 15.
[192] Section 16.
[193] Section 17.
[194] Sections 19 and 20.
[195] These are sections 6- 8 and 11.
[196] The Department of Health reiterates the need to take the patient or participants background into regard by stating "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 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.*
[197] Section 6 (1)(a)-(d).
[198] This is not required where substantial evidence exists that such a disclosure of information may be contrary to the users best interests.

Health status is not specifically defined in the NHA and thus it is submitted that it must be understood as a wider concept which denotes not only HIV status, as is currently the most popular understanding of "health status," but a term which encompasses all aspects of a person's physical and mental health. In context of stem cell research, the health status of the user may be relevant where a user is confronted with the fact that they are suffering from a disease, such as Alzheimer's, which might possibly be cured or treated by the application of stem cell therapy. The knowledge of one's health care status could then promote enquiry into possible treatments and treatment options as in general, only once a person becomes aware of a certain condition, will such a person attempt to remedy that condition. One cannot address a subject of which one is not aware. Since stem cell therapy has various applications[200] the range of treatments which are available and applicable to the specified disease must be explained to the patient. It is submitted that what the treatment entails, such as the method and side effects, should be explained as well.

Sub- sections (c) and (d) require that the patients be informed of the benefits and risks as well as the costs and consequences. Also where the patient refuses treatment, the risks involved must be explained. Stem cells may cure diseases which have previously been thought of as incurable, such as spinal cord injury, or difficult to cure, such as cancer for example. Some diseases which may be helped by stem cell therapy, such as diabetes, is incurable and most medical treatments currently only allow for the management of the condition. Stem cell therapy thus holds the benefit of not only a potential cure, but also the improvement of a person's quality of life. The flipside of this is however that certain risks are involved in this form of medical treatment. Currently, the formation of cancerous cells is one of the greatest concerns. The patient should therefore be made aware of the risk that stem cell therapy may lead to the later formation of cancerous growths. It is also important to be cautious to not foster false hope of miracle recovery. It is submitted that the risks and benefits as well as side

[199] In *Castell v De Greef supra*, the court confirmed a patient's right to refuse any medical treatment.
[200] See chapter 2 paragraph 2.7 *supra* for a discussion of the potential of stem cells.

effects and change in quality of life are what is meant by the requirement for the divulgence of information regarding the consequences. The costs related to the proposed treatments and procedures must then further be discussed with the patient. Stem cell therapy is quite expensive and the University of California at Berkeley stated that stem cell therapies are likely to be rather costly due to high development expenses and potential high use.[201]

6.2 SECTION 7: CONSENT OF USER

According to section 7, which is subject to section 8, no user may receive any form of health service without their informed consent. Certain situations do however exist where consent cannot be obtained from the user and specific provision is made therefore in section 7(1)(a)- (e) which must be briefly discussed.[202] It reads as follows:

> "7. (1) Subject to section 8, a health service may not be provided to a user without the user's informed consent, unless-
>
> (a) the user is unable to give informed consent and such consent is given by a person-
>
> (i) mandated by the user in writing to grant consent on his or her behalf; or
>
> (ii) authorised to give such consent in terms of any law or court order;
>
> (b) the user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent,

[201] California Stem Cell Report (2010) "High cost of stem cell therapy: Will stem cell firms share more risk?" available at http://californiastemcellreport.blogspot.com/2010/03/high-costs-of-stem-cell-therapy-will.html accessed 18/8/2010.
[202] Section 9 of the NHA is relevant in regard to health services without the consent of the user.

grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;

(c) the provision of a health service without informed consent is authorised in terms of any law or a court order;

(d) failure to treat the user, or group of people which includes the user will result in a serious risk to public health; or

(e) any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, impliedly or by conduct refused that service."

Sub- sections (1)(a) and (b) almost repeat the provisions stated in the definition of a user regarding the person who may give consent by proxy when the user is incapable thereof. A situation where a patient must be treated regardless of consent in the public interest is not relevant to this discussion, but an example of such circumstances may occur in the case where persons with drug resistant Tuberculosis, Ebola or the H1N1 virus[203] are quarantined. Section 7(1)(e) refers to emergency medical treatment. In the case of emergency medical treatment, the provision of section 5 will be applicable.[204]

The draft Regulations regarding Communicable Diseases[205] set certain proposed requirements which must be met before a court order, such as mentioned in section 7(1)(c), may be obtained to compel a person to be forcibly treated.[206] It must be shown that:[207]

[203] Commonly known as "Swine Flu."
[204] See also *Soobramoney v The 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 largely clarified by the court. This is however not pertinent to the discussion at hand.
[205] 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."
[206] Regulations regarding Communicable diseases No. R27 in Government Gazette No. 30681 of 25 January 2008 31.
[207] Section 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).

1. The disease or health risk was determined previously as being hazardous to the public health;

2. Other measures besides forced isolation and treatment must firstly 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 without intervention.

In context of this dissertation, section 7(2) and section 7(3) are of importance. Section 7(3) provides a definition of informed consent as it is not provided for in section 1 of the NHA. "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.[208] As mentioned previously, consent in context of medical interventions, means informed consent. The health care provider is also required to obtain consent prior to any treatment and must take all reasonable steps to obtain such consent. It is not perfectly clear what constitutes reasonable steps, but some clarity might be found in the South African case of *Stoffberg v Elliott*,[209] which was later confirmed by *Louwrens v Oldwage*.[210] For a patient to give informed consent, in a hospital setting, they must know and understand what form of health service will be provided to them and they must also know and understand the risks of such a service. A physician, or attending nurse, does however not have to inform the patient of every possible risk where such as risk is unlikely or will only cause minimal harm.[211] It is thus submitted that reasonable steps which must be taken in order to obtain consent consists of an understandable and knowledgeable explanation of the relevant benefits, risks, costs and implications or consequences of a proposed medical procedure or treatment.

[208] Section 7(3) of the NHA.
[209] *Stoffberg v Elliott supra*.
[210] *Louwrens v Oldwage supra*.
[211] The issue surrounding risks which need not be explained to the patient has previously been discussed in this chapter.

6.3 SECTION 8: PARTICIPATION IN DECISIONS

A user has the right to participate in any decision which affects their personal health and treatment.[212] Where a person, other than the user gives informed consent for a treatment to be administered to or on the user, the user must be consulted with if possible and where the user is capable of understanding, but lacks the legal capacity to give the consent themselves, the user must be informed according to the requirements as stipulated in section 6.[213] A user who is not able to participate in decision making which will have an effect on their health and treatment, as in emergency treatment, must be informed of the treatment after it has been provided. The only exception to this is where such a disclosure would be against the best interests of the user.[214]

The provisions in section 8 clearly demonstrate a desire to have a patient involved in decision making procedures which surround their personal health and treatments. This is a departure from paternalism and takes into account the autonomy of the patient. Furthermore, it indicates a regard and respect for the patient's treatment preferences. It is submitted that section 8 alludes to shared medical decision making and at this juncture it thus becomes necessary to discuss shared decision making as a proposed model of obtaining informed consent in context of stem cells.

6.3.1 Shared Decision Making

Successful management of disease requires two types of knowledge and thus a new form of doctor- patient relationship is necessary. The patients' point of view, preferences, attitude and values must be acknowledged as well as the doctors' expertise in an environment where information is shared.[215] Shared medical decision making is a process whereby patients and providers of medical services consider the outcome

[212] Section 8(1) of the NHA.
[213] Section 8(2)(a) and (b) of the NHA.
[214] Section 8(3) of the NHA.
[215] Karnieli- Miller O & Eisikovits Z (2009) "Physician as partner or salesman? Shared decision making in real- time encounters" *Social Science & Medicine* 69: 1 at 2.

probabilities and patient preferences and thereby reach a health care decision based on mutual agreement.[216] Shared decision making is best used and also propagated in situations of medical uncertainty and may therefore offer a viable model of medical decision making in context of stem cell therapy. During the process of shared decision making, the provider- patient dyad must consider the treatment options[217] and the consequences of each option and must further explore the expected benefits and risks according to the patient's preference to the various outcomes.[218] The provider must then offer his knowledge in such a process. According to Charles, Gafni and Whelan the following characteristics of shared decision making may be identified:[219]

1. At least two participants, the physician and patient, must be involved. The participation of the physician and the patient seems obvious, but it must be mentioned that other persons such as family members are often also involved in the process of medical decision making. Friends and family can therefore play different roles which relate to the treatment decision making process;[220]

2. Both parties must share information. Knowledge on the part of the physician and preferences on the part of the patient. In order for shared decision making to occur, complimentary role expectations and behaviour between the physician and patient must exist. This means that both the involved parties must be willing

[216] Frosch DL & Kaplan RM (1999) "Shared decision making in clinical medicine: Past research and future directions" *American Journal of Preventative Medicine* 17(4): 285 at 285.
[217] The available options of treatment can only be evaluated in context of the patients' preferences. The patient thus brings information to the table which a physician cannot know. For example, the patient alone knows what they are willing and able to tolerate. See Frosch & Kaplan (1999) *Am J Prev Med* 285 at 287.
[218] *Idem* 285.
[219] Charles C, Gafni A & Whelan T (1997) "Shared decision making in the medical encounter: What does it mean? (or it takes at least two to tango)" *Social Science and Medicne* 44(5): 681 at 681- 688.
[220] These roles might include being a gatherer of information, acting as a coach who prompts the patient to ask certain questions, an advisory role, a role as a negotiator or a caretaker. See Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 685.

to participate in the shared decision making process and must share information with the other persons involved;[221]

3. Both parties must take steps to ensure that a consensus is reached regarding the preferred treatment. For this to be possible there must be information sharing. The physician must lay out the treatment options as well as the consequences of each option and apply his or her expertise to the treatment. The patient must then inform the physician of their preferences and other information which they may have obtained elsewhere. The physician and the patient must then discuss each option with regard to the patient's preference until a consensus is reached; and

4. An agreement must be reached. Both parties need not be fully convinced that the chosen treatment is the best treatment for the patient. Both parties must however endorse the chosen treatment and by this mutual acceptance, both parties share responsibility for the final decision.

Shared decision making is regarded as having social, economic and technical advantages and underscores ethical principles such as autonomy. It is a step away from the physician- centered model of medical decision making in which the doctor knows best and the information given to the patient is limited to what the doctor deems necessary.[222] The existing models by which decisions are made in medically related encounters may be arranged on a continuum which ranges from paternalism as the one extreme and informed consent as the other. In a paternalistic model of decision making, the physician makes and imposes all decisions and in the informed model the patient decides on the treatment based on information with which they have been provided. In

[221] Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 686 & 687 for a discussion of certain steps which a physician may use in order to establish a shared decision making process such as creating an environment which is conducive to shared medical decision making. The patients obligations are discussed in this article *inter alia* include taking responsibility for and being honest about any preferences which should be disclosed.
[222] Karnieli- Miller & Eisikovits (2009) *Soc Sci Med* 1 at 1.

the middle of the continuum enhanced autonomy, shared decision making and the hybrid intermediate models may be found.[223] Each model differs in the degree of participation, involvement and responsibility of each of the parties involved in the decision making process, be that the physician, patient or family member. Underlying each model of decision making is mutual respect and a joint interest in achieving a beneficial outcome. The informed model,[224] or informed consent, has been discussed at length above. It is however necessary to briefly discuss paternalism in order to understand how it differs from the informed model and from shared decision making.

6.3.1.1 Paternalism as model for medical decision making

Paternalism explicitly assumes a passive role for the patient in decision making regarding treatment.[225] It may be said that the paternalistic model of medical decision making stems from the *Hippocratic Oath*.[226] Parsons created one of the earliest formulations of this model in the conceptualized role of a sick person and argued that the sick role entailed certain rights and obligations for the patient.[227] In other words, while a person is sick they are excused from certain activities such a work, but they are also obligated to get well by seeking expert advice and complying with the prescribed

[223] *Idem* 1 at 2.
[224] The informed model of decision making increases the patients information of possible benefits, risks and alternative treatments as well as the effectiveness of treatments which then allows the patient to make a decision which reflects their preferences. See in general Hurley J, Birch S & Eyles J (1992) *Information, efficiency and decentralization within health care systems (Centre for Higher Education Policy Analysis working paper 92- 21)*. A model which also recognizes the informational asymmetry between a patient and a physician is the physician- as- agent model which, in short, requires the physician to "sell" a procedure by explaining such treatment to the patient and the patient may then bring his or her preferences to the equation, thereby improving the quality of information and ultimately obtaining consent. See in general Levine MN, Gafni A & Markham B (1992) "A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer" *Annals of Internal Medicine* 5 at 29. This model does however not allow for participation to the extent in which the informed model does. See also Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 684 for more on the physician- as- agent model.
[225] Charles, Gafni & Whelan (1997) 681 at 682.
[226] Ogunbanjo GA (2009) "The Hippocratic Oath revisited" *South African Family Practice* January/ February 51(1): 30-31.
[227] See in general Parsons T (1951) *The social system*.

medical regime. The patient must thus comply with the doctor's orders. A more modern paternalistic view of medical treatment sees the physician as dominating the medical encounter by virtue of their skill to diagnose an illness and recommend a course of action to the patient. In certain extreme cases the physician thus authoritatively informs the patient of the course of treatment. In less extreme scenarios, the physician gives selective information to the patient and encourages the patient to consent to what the physician has proposed.[228] The role of the physician may therefore be summarised as one of the guardian of the patient's best medical interests. The patient's participation only comes into play when consent to the physician- proposed treatment option is obtained.[229] The paternalistic model of decision making is however no longer viable in practice due to two major developments. First, the standard of informed consent has changed. Treatments may occur only after the patient has been properly informed of the options, consequences and implications of their choices and agree thereto. Secondly, the public has become more educated and skeptical of physicians and there is less confidence in the medical world than before.[230] Furthermore, patients' rights movements have given value to the interests and choices of patients.[231] A shared decision making process could thus be advantageous as it allows for better collection of information and it forces the physician to present and consider all the available treatment alternatives. The quality of the treatment is improved as well as patient compliance therewith since the patient feels that and appreciates that they have participated in this choice which affects them.[232] Shared decision making is increasingly being advocated as informed consent implies a patient's interest to participate in

[228] Emanuel EJ & Emanuel LL (1992) "Four models of the physician- patient relationship" *Journal of the American Medical Association* 267: 2221.
[229] Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 683.
[230] See in general Brody DS (1980) "The patients role in clinical decision making" *Annals of Internal Medicine* 93: 718- 722.
[231] Frosch & Kaplan (1999) *Am J Prev Med* 285 at 286.
[232] *Idem* 287. See also Brody (1980) *Ann Intern* 718-722.

decisions regarding their health and also due to the fact that informed choice is being recognised in medical encounters.[233]

Shared decision making must however not be confused with obtaining informed consent. While ethical guidelines mandate informed consent, shared decision making takes the process of patient self- determination further as it does not simply present the facts and information to the patient, but allows for a consideration of the available information which then includes the treatments which may be applied. It then also allows an assessment of the patient's preferences. After each option is considered, using the knowledge of the physician and the preferences of the patient, a treatment decision is made.[234] However, for shared decision making to occur, certain conditions must be met. Firstly, the atmosphere must be conducive to active patient participation. Secondly, the physician must ensure that the patient feels that their contributions are a valued element to the process, thirdly patients must be honest about their preferences and health goals and lastly, the physician must help to determine how each such a health goal and preference fits with the available treatment options.[235] Shared decision making is thus a mechanism which decreases the inequality in the physician- patient relationship by increasing the patients' information, sense of autonomy and control over the treatment decisions which will affect their well- being.[236]

6.3.1.2 Conclusion

The informed model of medical decision making incorporates the sharing of information but does not necessarily lead to a shared decision making process. Theoretically, the patient is now in a position where the physician is no longer needed in the decision making as the information deficit has been overcome. Both the required components or

[233] Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 681. It may also be argued that SDM has roots in consumer rights. See also Karnieli- Miller & Eisikovits (2009) *Soc Sci Med* 1 at 1.
[234] Frosch & Kaplan (1999) *Am J Prev Med* 285 at 285.
[235] Frosch & Kaplan (1999) *Am J Prev Med* 285 at 285.
[236] Charles, Gafni & Whelan (1997) 681 at 682.

forms of knowledge, information and preference, are now vested in one person.[237] Treatment decision making control is now vested in the patient.[238] This model is however not free of critique as it must be kept in mind that physicians do possess knowledge and skills which fall beyond the comprehension of the lay patient. This model may lead to physicians becoming weary of prescribing a certain treatment in fear of imposing their will upon the patient and thus competing for decision making control.[239]

The relationship between a physician and a patient is personal and often based on trust and perhaps it is time to consider a new form of medical decision making and to agree on fundamental principles which should include the patients preference and participation which must be elicited and then acknowledges, that patients be given choices surrounding the process of decision making and the treatment options and lastly, that the choices made by the patient must be respected and adhered to. Shared decision making may offer an intermediate alternative to both the physician and the patient as it offers the patient a voice in their treatment without total responsibility and the physician is given a chance to transfer information and to participate in decision making without dominating the medical encounter.[240]

6.4 SECTION 11: HEALTH SERVICES FOR EXPERIMENTAL OR RESEARCH PURPOSES

Before a health establishment may provide a health service for experimental or research purposes to a user, the health establishment must inform the user, in the prescribed manner,[241] that the specified health service is partly or as a whole intended for experimental or research purposes or projects.[242] This is however subject thereto that a health establishment may not provide any health service to a user unless the user, the health care provider who is primarily responsible for the user's treatment, the head of

[237] Levine, Gafni & Markham (1992) *Annals Inter Med* 5 at 7.
[238] Eddy DM (1990) "Anatomy of a decision" *Journal of the American Medical Association* 263: 441.
[239] Emanuel & Emanuel (1992) *JAMA* 2221 at 2225.
[240] Charles, Gafni & Whelan (1997) *Soc Sci Med* 681 at 690.
[241] As provided for by section 6 of the NHA.
[242] Section 11(1) of the NHA.

the health establishment as well as the relevant health research ethics committee have given prior written authorisation for the provision of the specific health service.[243]

The NHA does not define "experimental or research purposes" and the assumption could thus be made that this must be understood as experimentation and research regarding health and health care. The NHA does provide a definition of "health research" and states that it includes any research which contributes to knowledge of the following:[244]

(a) The biological, clinical, psychological or social processes in human beings;

(b) Improved methods for the provision of health services;

(c) Human pathology;

(d) The 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.

Stem cell research may thus qualify as health research under the provisions of the NHA. In context of stem cell research, this means that where a person wishes to participate in a research study which is intended to further knowledge regarding medicine,[245] such a person must be informed of all relevant information as provided for by sections 6 and 11 of the NHA.

[243] Section 11(2) of the NHA.
[244] Section 1 of the NHA.
[245] "Medicine" is used here as a broad term which must be understood as encompassing the elements of health research, namely 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.

Chapter 1 of the Human Subjects Regulations,[246] which also supplement section 71 of the NHA, deals with general research principles including the principles of health research,[247] the obligations of researchers,[248] participation of special groups of people[249] and research which requires additional consideration and consent. This chapter may then also be used to supplement the provisions of section 11 of the NHA.

Regulation 2 states that any health research within South Africa which involves human subjects, must be relevant both to the overall health and developmental needs of the people of South Africa and the needs of individuals suffering from disease.[250] It is safe to assume that the health care priorities of South Africa must be kept in mind. Such research must be practiced according to valid scientific methodology and possess a high probability of answering the posed research question.[251] It must further be managed and conducted by a suitably qualified principal investigator who is a South African resident and who possesses extensive experience in health research.[252] Regarding the research participants, regulation 2 requires that research participants be well informed in order to make informed decisions,[253] as is also required by section 6 of the NHA and also the rights to privacy and confidentiality of research participants must be protected.[254] The participants are further protected as it must be ensured that the selection and recruitment of participants is just and fair.[255] Any research must be preceded by an analysis of the risks and benefits[256] and is subject to independent review

[246] Regulations Relating to Research on Human Subjects No. R135 in Government Gazette No. 29637 of 23 February 2007.
[247] Regulation 2 of the Human Subjects Regulations.
[248] Section 3 of the Human Subjects Regulations.
[249] This includes: regulation 4(1) children, regulation 4(2) persons with intellectual or mental impairment, regulation 4(3) vulnerable groups and regulation 4(4) women.
[250] Regulation 2(1)(a) of the Human Subjects Regulations.
[251] Regulation 2(1)(b) of the Human Subjects Regulations.
[252] Regulation 2(1)(c) of the Human Subjects Regulations.
[253] Regulation 2(1)(d) of the Human Subjects Regulations.
[254] Regulation 2(1)(e) of the Human Subjects Regulations. See also section 14 of the NHA.
[255] Regulation 2(1)(f) of the Human Subjects Regulations.
[256] Regulation 2(1)(g) of the Human Subjects Regulations.

by an accredited registered health research ethics committee.[257] Clinical research is also required to be registered on the South African National Clinical Trials Register.[258]

Regulation 3 states that additionally to the provisions of regulation 2, in the conducting of research which involves human subjects, a health researcher must submit research proposals to research ethics committees for approval,[259] report on positive or negative research results in a timely fashion,[260] disclose the sources and extent of funding,[261] ensure safety monitoring of research[262] and refer research participants for professional assistance if it is necessary.[263]

Regulation 6 of the Human Subjects Regulations is of great importance to this discussion regarding consent as it stipulates the aspects of which a person must be informed. It is submitted that section 6 of the NHA must be used in conjunction to regulation 6 of the Human Subjects Regulations as it is more detailed and precise in what is required. The topic of obtaining consent and informed consent specifically in the processes of stem cell research and stem cell treatments is one which holds many difficult and complex issues. It is submitted that these issues can only be overcome by the use of a detailed informed consent document and that generic consent will not and should not be deemed valid in this context. Regulation 6 of the Human Subjects Regulations must therefore be used as the guiding provision in obtaining informed consent for research which is connected to, or is intended to relate to, health and health care.

The research participant must thus be informed of the following:[264]

(a) The purpose of the research;

[257] Regulation 2(1)(h) of the Human Subjects Regulations.
[258] Regulation 2(1)(i) of the Human Subjects Regulations.
[259] Regulation 3(1)(b) of the Human Subjects Regulations.
[260] Regulation 3(1)(c) of the Human Subjects Regulations.
[261] Regulation 3(1)(d) of the Human Subjects Regulations.
[262] Regulation 3(1)(e) of the Human Subjects Regulations.
[263] Regulation 3(1)(f) of the Human Subjects Regulations.
[264] Regulation 6(1)(a)- (m) of the Human Subjects Regulations.

(b) Treatments and possibilities of random assignment of each such treatment should the research involve treatment;

(c) Methods and procedures to be followed or used in the course of the research;

(d) Alternatives apart from participating in the research;

(e) The potential or real harm and risks which are or could be associated with participating in such research;

(f) The expected benefits to the participant themselves and to others persons;

(g) The extent of the protection and maintenance of confidentiality and privacy;

(h) Insurance availabilities in the case of injury or damage due to participation;

(i) Contact details of the contact person in the case of such injury or damage;

(j) Incentives;

(k) The option and availability of treatment beyond the duration of the trail in the case of clinical trials;

(l) Details of the sponsor of such research and any potential conflicts of interest; and

(m) Proof of the relevant ethics committees approval of the research.

6.5 SPECIFIC PROVISIONS REGARDING CONSENT

Chapter 2 of the NHA deals with consent in general and the focus now falls on the specific provisions regarding consent as provided for by the NHA. The regulations which were made in terms of the NHA will also be discussed shortly. This discussion attempts to illustrate the magnitude of the influence of consent on the regulation of stem cells and especially stem cell research.

6.5.1 The National Health Act

Section 55[265] of the NHA states that a person may not remove any products from the body of another living person for the purpose referred to in section 56[266] unless it is done with the written consent of the person from whom the products are being removed and then under the prescribed conditions. Where such products include stem cells and zygotes which are more than 14 days old, the Minister may only permit research thereon where the donor has given prior consent thereto and the researcher undertakes to properly document such research.[267] The Act will be discussed in greater detail in the following chapter of this dissertation.

6.5.2 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[268]

Informed consent was defined here for the first time in regulation 1 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." [269] Regulation 3 is of great importance as it deals with removal or withdrawal of biological material from living persons and is connected to the previous discussion of who may give consent to certain procedures and must thus be discussed in some detail.[270] Sub- regulation (1)(a) states that a person may not remove any biological

[265] Removal of tissue, blood, blood products or gametes from living persons.
[266] See chapter 6 paragraph 2.2.4 *infra*.
[267] Prohibition of reproductive cloning of human beings. See section 57(4) of the NHA.
[268] 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 No. R7 in Government Gazette No. 29526 of 5 January 2007 3. Hereafter referred to as the Regulations Regarding Use.
[269] This definition is also provided for in the Regulations Regarding Artificial Fertilisation and Related Matters.
[270] See paragraph 5.3 *supra*.

material from the body of another living person unless it is done with the informed consent of the person from whom such biological material is removed. Sub- regulation (1)(b) then deals with the consent of a minor person and provides for the following:

> "Where the person is younger than 18 years for the medical treatment of such person -
>
> (i) an informed consent by a child over the age of 12 years, provided the child is of sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the procedure;
>
> (ii) an informed consent of a parent, guardian or care giver where the child is younger than 12 years or the child is over 12 years but has no sufficient maturity or the mental capacity to understand the benefits, risks, social and other implications of the procedure;
>
> (iii) consent by head of the health establishment in the case of an emergency;
>
> (iv) consent by the Minister if the parent, guardian or caregiver of the child-
>
> > (aa) unreasonably refuses to give consent or assist the child in giving consent;
> >
> > (bb) is incapable of giving consent or cannot assist the child in giving consent;
> >
> > (cc) cannot be readily traceable;
> >
> > (dd) or is deceased."

A child may thus consent to stem cell research provided that the required additional consent is provided. Provision is also made for mentally- ill persons in sub- regulation (1)(e) which provides that consent must be obtained from the mentally- ill where he or

she is capable of giving consent,[271]also the consent of certain named persons[272] must be obtained and the consent of the head of the specific health establishment.[273]

Further, any competent person who wishes to use adult, foetal and umbilical cord stem cells, for therapeutic cloning must obtain informed consent from the donor of such stem cells[274] and subject to regulation 16,[275] spare embryos obtained from *in vitro* fertilisation may be used to derive embryonic stem cell lines for the purpose of research as long as informed consent from embryo donor has been obtained.[276]

6.5.3 The Regulations Regarding Artificial Fertilisation and Related Matters[277]

Regulation 7 makes for the provision for the prerequisites for removal or withdrawal of gametes and states *inter alia* the informed written consent of the donor as one such prerequisite.[278] According to regulation 8(e) this consent must then be kept on record. Regulation 11 regulates the requisites for artificial fertilisation and embryo transfer and consent is then also required therefore.[279]

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[271] Regulation 3(1)(e)(i) of the Regulations Regarding Use.
[272] A court appointed curator, a spouse, next of kin, a parent or guardian, major child, brother or sister, partner or associate. See regulation 3(1)(e)(ii) of the Regulations Regarding Use.
[273] Regulation 3(1)(e)(iii) of the Regulations Regarding Use.
[274] Regulation 11(1)(c) of the Regulations Regarding Use.
[275] Regulation 16: **Research findings on stem cells**
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 shall apply to all other forms of genetic research, as appropriate.
[276] Regulation 12(1)(a) of the Regulations Regarding Use.
[277] The Regulations Regarding Artificial Fertilisation and Related Matters No. R8 in Government Gazette No. 29527 of 5 January 2007 3.
[278] Regulation 7(1)(e) further elaborates that consent must be obtained for the following: (i) to a physical examination and questioning by a competent person; (ii) that a competent person may remove or withdraw a gamete, or cause a gamete to be removed or withdrawn, from the body of the gamete donor for the purpose of such testing, analysing or other processing of that gamete as the competent person may deem necessary; (iii) to the particulars contemplated in regulation 8(l)(a)(ii), (iii) and (iv).
[279] See regulation 11(1)(b) of the Regulations Regarding Artificial Fertilisation and Related Matters.

6.5.4 The Regulations Relating to Human Stem Cells[280]

Regulation 2 of the regulations deal with the use of stem cells and provide therefore that no person shall release any stem cell products for *therapeutic use*, unless it has been authorised in terms of section 54 of the Act and laboratory tests which are in accordance to the newest scientific information regarding infectious agents and diseases which may be transmitted have been performed with the informed consent of the donor thereof and the results are available.[281] Regulation 2 additionally requires the consent of the donor where stem cells are to be used for research or educational purposes.[282] A record of the informed consent obtained from the donor must then be kept.[283]

7 CONCLUSION

Informed consent is a process whereby an agreement to partake in a specified medical or scientific activity is reached and is a prerequisite for participation in any such intervention as mandated by the Constitution. It remains a complex and controversial subject in South African medical law in spite of cases such as *Castell v De Greef* and *Stoffberg v Elliott*. The nature, scope, application and boundaries of this doctrine are especially controversial and this is no less true in context of stem cells. Although the common law regarding this subject must be developed, attention must be paid to shared decision making models as well, since it strives to remove conflict between the

[280] The Regulations Relating to Human stem Cells No. R376 in Government Gazette No. 29840 of 4 May 2007 5.
[281] Regulation 2(1)(c)(ii) of the Regulations Relating to Human Stem Cells.
[282] Regulation 2(1)(d)(iii) of the Regulations Relating to Human Stem Cells.
[283] Regulation 5(1)(a)(viii) of the Regulations Relating to Human Stem Cells. Regulation 5 deals with the keeping of records and the reporting obligations of an establishment dealing with stem cells and subsection (1) lists the details of the donor which must be kept on record as the following: (i) the surname, first name and initials or the other names, (ii) the gender, (iii) the date of birth or approximate age if the former is not available, (iv) identity number, (v) the address, (vi) the nature and quantity of the stem cells concerned, (vii) reason for acquiring the stem cells, and (viii) a record of the written informed consent.

physician and patient and promotes trust and confidence between the parties involved by opening the channels of communication and co- operation.

The Constitution distinguishes between treatment or therapy and research. Treatment is an activity which has the sole purpose of benefiting the patient where there exists a reasonable chance of success, while research is a systematic search or inquiry of knowledge. This is not directly of benefit to the person who is subjected to the research but is generalised and may be transferred to others or presented at a scientific meeting, submitted for publication or for higher qualification. Research may then also be subdivided into therapeutic research which is characterised thereby that it is of direct benefit to the person undergoing or participating in the research and non- therapeutic research which may be of benefit to general scientific knowledge and thus does not directly promote the health of the participant.

The requirement of consent protects autonomy. It was submitted that this freedom includes free will which alludes to the exercise of some mental power or function. An embryo or cell of any kind cannot exercise this power and it was submitted, has no sense of autonomy. Autonomy issues in context of stem cells therefore relate to the donor of the material. A strict interpretation of section 12(2)(c) the Constitution must not lead to the use of the word “their” as prohibition on research or experimentation. It was thus submitted that the consent which must be sought is that of the donor of the material which will be used in experimentation. This must be kept in mind especially during the second stage of interpretation where a balancing of competing rights takes place and the rights of other persons must also be considered. 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. It may however be difficult to balance these rights as they are incommensurable and a choice may have to be made between competing visions of the world and the manner in which society should be arranged.

Informed consent is a keyword in research as the right to self- determination and autonomy lay at the basis of consent. Originally derived from the common law and entrenched in the Constitution, it is further based on various rights which include dignity, privacy as well as freedom and security of the person. It should by now be clear that consent is a prerequisite for interventions which may take the form of donation, removal or withdrawal of the material. Specific consent must be obtained for the chosen or indicated method. A capacitated adult person, a person over the age of 18 years, may consent to the activity in which they will partake and where such a person is unable to make decisions the NHA provides for proxy consent. Section 71(1) of the NHA confirms the need for informed consent and provides therefore by stating that "research or experimentation on a living person may only be conducted with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences for his or her health." This is applicable to mentally- ill persons as well, because a person is not *per se* unable to consent when they are classified as mentally- ill according to the Mental Health Care Act. In such circumstances additional consent from a named person is however required. The information required for research is wider than that which is required for medical treatment seeing that the patient need only be informed of benefits, risks and the consequences generally associated with their treatment option during the consent process for medical treatment. Additional consent is further required where the proposed participants is a minor. The minor may then consent to the intervention as long as the additionally required consent as provided for in section 7(2) and (3) of the NHA is adhered to. In the case of non- therapeutic research on a minor the NHA provides for situations where the Minister may not consent to such non-therapeutic research. A child may thus consent to therapeutic and non- therapeutic research provided that such consent is accompanied by the required consent of a third party as well as that all other requirements are met.

Informed consent deals with the process whereby a patient is given information in order to establish knowledge, appreciation and acquiescence on the part of the patient. Discussions regarding consent for the donation of material for embryo research must occur only after infertility treatment has been completed and a decision has been made to discard of any spare frozen embryos. Some however argue that it is wise to discuss embryo donation at the onset of fertility treatment and two motivations are offered for these arguments. It is submitted that discussions regarding consent should be done as soon as possible.

It is further recommended that the consent process cover the explanation of pertinent aspects of stem cell research which includes the objects or the proposed research topic and the methods or techniques which will be employed. Section 6 of the NHA provides for certain aspects of which the potential donor or patient must be informed. In circumstances where embryos will be frozen and used at a later stage in research protocols which have not been designed the donors or participants should consent to general categories of research or research methods rather than specific protocols. It is suggested that different research categories should be identified.

Donors must also be informed of matters regarding confidentiality and privacy. Issues of confidentiality must be discussed during the process of obtaining consent and informed thereof that in certain cases an identifying code will be required which links the material to the donor. The donor must here be further informed of anyone who may have access to the code and the extent to which confidentiality and privacy will be protected. Participants must therefore also consent to the retention of a link between themselves and the donated material.

Where consent has not been obtained for the donation of embryos such embryos may not be used for research as this would be a gross violation of autonomy and will result in liability and it is submitted that where other material is donated to stem cell research, such as umbilical cord blood, consent must be obtained prior to the removal or withdrawal thereof. The persons who should obtain consent may be the attending

physician or other care giver but such a person should have no interest in the research which will be performed on the donated material or where such a person has interests, such interests must be disclosed to the donor or patient. This is important as the donor or patient has a right according to section 8 of the NHA to participate in decision making and should thus be fully informed in order to make decisions.

As the participant or donor has a right to partake in decisions, a model of shared decision making was proposed. Shared decision making may offer an alternative method of decision making to both the physician and the patient as it offers the patient a voice during their treatment without taking all the responsibility and the physician may then transfer information and to participate in decision making without dominating the encounter. Shared decision making is strongly propagated in cases of medical uncertainty and is therefore an ideal model to be considered in context of stem cell research. Lastly, specific provisions pertaining to consent were discussed and the magnitude of the consent issue was thus illustrated.

7.1 RECOMMENDATIONS

Due to the extreme scope of issues related to informed consent in context of stem cell research it is strongly suggested that the process whereby consent must be obtained should be clarified by legislation or guidelines. Keeping in mind the above discussion it is submitted that the research protocol should follow the following format. Firstly, the research protocol should contain the title of the research, person or institution undertaking the research or performing the treatment, background information and explanation of the research or treatment, methods which will be employed, a statement of the purpose and benefits of the research or treatment as well as a statement of the risks of the research or treatment, duration of approval of the applicable ethics committee and finally the required consent form. Secondly, the consent form must comply with the general requirements of informed consent such as capacity. The requirements as set by the NHA must also be complied with.

The consent section of the research protocol will have to contain, at the very least the following:

1. An explanation of what specifically is being consented to: removal, withdrawal or donation of the embryo, fetus or somatic cells;
2. Purpose of the proposed removal, withdrawal or donation;
3. Alternative options of use: research, therapy or education;
4. Methods and procedures of removal, withdrawal or donation;
5. Potential for real harm or risks;
6. Expected benefits;
7. Options regarding storage and time limits thereof;
8. The manner in which removed, withdrawn or donated material may be destroyed or disposed of;
9. The option to renew or revoke consent for any of the above;
10. Extent to which privacy and confidentiality will be protected;
11. Incentives to participate; and
12. Proof of Ethics Committee approval.

In conclusion, consent and the process of obtaining consent remains a complicated subject which is loaded with difficult issues and questions. To fully examine these issues and problems requires an investigation which goes beyond the scope of this dissertation. It is therefore submitted that the subject of consent in context of stem cell technology requires further study. The basic concept of informed consent as it pertains to stem cells has now however been discussed and thus we move to the final chapter of this dissertation which deals solely with chapter 8 of the NHA.

CHAPTER 6
THE PROPOSED LEGISLATION: CHAPTER 8 OF THE NATIONAL HEALTH ACT, ACT 61 OF 2003

1 INTRODUCTION

The purpose of this dissertation is an analysis of the proposed regulatory framework for the procurement and distribution of stem cells in South Africa. In order to fully understand the status of regulation of stem cell technology a layered approach has been followed in the course of this dissertation which entailed an explanation of stem cells and stem cell technology, an examination of the Constitutional impact on stem cells and stem cell banking, a discussion of the numerous ethical principles and guidelines which currently act as hard law and in the previous chapter, the law of obligations as it manifests in the doctrine of informed consent was examined. This has lead to the final layer which is an analysis of the National Health Act, Act 61 of 2003.[1] The reasons for this is that all the above layers will have to be incorporated to the point of overlapping in any proposed legislation regulating stem cells and chapter 8 of the NHA is the supposed regulatory tool for stem cells in South Africa. It is thus pertinent to this dissertation to analyse whether or not chapter 8 of the NHA sufficiently regulates stem cells with reference to the science thereof, in a constitutionally valid manner which does not conflict with ethics and which is not in violation with medical law principles.

Ideally the NHA would contain and address the above yet unfortunately it is not yet in force. This is however the least of the concerns regarding chapter 8. All in all, chapter 8 of the NHA is not satisfactory enough to regulate stem cells in future and this will be illustrated in the course of this chapter.[2] The purpose of this chapter is thus to illustrate the problems encountered with chapter 8 and to make recommendations in order to correct this situation. This will be done via a discussion of chapter 8 wherein critique will be offered against the provisions contained in the chapter. This is followed by a discussion of certain

[1] Hereafter referred to as the NHA.
[2] It appears as though the quality of South African legislation has drastically decreased and the National Health Act is no exception. See in general Naidoo P (2010) "Flawed fundamental: The quality of SA's legislation is declining. What is going on?" *Financial Mail* October 44-45.

Regulations which were made in terms of the NHA and lastly a comparative, or guiding, examination will be undertaken of the regulatory measures in the United Kingdom.

It must however be stated that any previous reference to sections contained in chapter 8 in the course of this dissertation have been references of such sections as they currently appear in the NHA. The reason for this is that although there is currently a revised chapter 8 being presented to the Department of Health, this is only the first draft of the revisions and it is certain to undergo various further amendments. Also, and due to this, the revisionary document is confidential and it would be a violation of academic integrity to publish such revisions in this dissertation as it would not constitute a proper and truthful source. A further motivation behind the previous references to the sections as is, is the fact that it will still be some time before any amended regulatory tools are published or signed into law and thus the current position must be studied. This mention, however, excludes the sections relating the Ethics Council and Committee as found in chapter 9 of the NHA and discussed in chapter 4 of this dissertation and also as relating to consent as discussed in chapter 5 of this dissertation and found in chapter 2 of the NHA as these sections are not subject to revision.

2 CHAPTER 8 OF THE NHA

2.1 A SHORT HISTORY OF THE NHA

On the 19th of August 2004 the then Minister of Health, Manto Tshabalala-Msimang delivered a briefing on the NHA. The Minster stated that the NHA replaced "the last vestige of apartheid in health policy," referring to the Health Act, Act 63 of 1977, and that the NHA now also provides a framework for a structured and uniform health system in order to unite the various elements of the South African national health system in one common goal which is the improvement of universal access to quality health services. This is done by taking into account the obligations imposed by the Constitution.[3]

[3] Briefing by the Minister of Health on the National Health Act, 19 August 2004 available at http://www.doh.gov.za/docs/pr/2004/pr0819.html accessed 6/ 8/ 2010. The preamble to the NHA further eludes to the reformative spirit of the Act and reads as follows: **Preamble**

Recognising-

- the socio-economic injustices, imbalances and inequities of health services of the past;

The NHA was said to rely heavily on the Constitution in that some 50 sections of the Constitution directly relate to the content of the NHA.[4] The NHA further covers constitutional issues such as the right of children to basic health services,[5] the right of everyone to an environment that is not harmful to a person's health or well-being[6] and the right to emergency medical treatment.[7] Other Constitutional rights which are relevant to health care services and are directly involved in the NHA are:

1. The right to dignity;[8]
2. The right to equality;[9]
3. The right to life;[10]
4. The right to bodily and psychological integrity;[11]

- 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."

[4] The Minister stated "You will recall that 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."
[5] Section 28(1)(c) of the Constitution. See chapter 3 paragraph 11 *supra*.
[6] Section 29 of the Constitution.
[7] Section 27(3) of the Constitution. See chapter 3 paragraph 10 *supra*.
[8] Section 10 of the Constitution. See chapter 3 paragraph 4 *supra*.
[9] Section 9 of the Constitution. See chapter 3 paragraph 3 *supra*.
[10] Section 11 of the Constitution. See chapter 3 paragraph 5 *supra*.

5. The right to privacy;[12]
6. The right to freedom of conscience, religion, thought, belief and opinion;[13] and
7. The right to choose one's trade, occupation or profession freely.[14]

According to the Minister's briefing, the inclusion of such constitutional provisions is what makes the NHA the single, most important piece of legislation in the health sector. The Minster then stated that the NHA had, at that time not come into operation and would be proclaimed into operation by the President once it had completed certain processes. The NHA is currently[15] still not fully in force and this is one of the main problems regarding the NHA.

The NHA is very complex in both scope and objects and entrenches many principles of health policy which has been developed over the years. It is furthermore framework-legislation which means it prescribes a broad legal and operational system of principles which must be "fleshed out" in regulations. These are then also discussed in the course of this chapter of the dissertation.[16]

The NHA contains the following 12 chapters and the intended implementation thereof is also discussed here. It was recommended that certain chapters be implemented as soon as the NHA was proclaimed and certain chapters which require supplementation by regulations. The NHA thus contains the following chapters:[17]

1. Chapter 1 which establishes the National Health System;
2. Chapter 2 begins to incorporate some transformative elements and aims to restore the dignity of every citizen. This chapter emphasises the right to emergency medical treatment, the right to have full knowledge of one's condition, the right to exercise one's informed consent, the right to participate in decisions regarding one's health, the right to be informed when one is participating in research, the right to

[11] Section 12 of the Constitution. See chapter 3 paragraph 6 *supra*.
[12] Section 14 of the Constitution. See chapter 3 paragraph 7 *supra*.
[13] Section 15 of the Constitution. See chapter 3 paragraph 8 *supra*.
[14] Section 22 of the Constitution. See chapter 3 paragraph 12.5 *supra*.
[15] This is the time of publication of this dissertation: November 2010.
[16] Briefing by the Minister of Health on the National Health Act, 19 August 2004 available at http://www.doh.gov.za/docs/pr/2004/pr0819.html accessed 6/ 8/ 2010.
[17] For the purpose of this dissertation only the chapters which have been discussed in the course of this study will be addressed in some detail here.

confidentiality and access to health records, the rights of users to lay complaints related to the service and the rights of health workers to be treated with respect. This chapter was implemented immediately, except for section 11 (1)[18] as regulations and guidelines as well as set parameters and criteria had to be created and published;[19]

3. Chapter 3 describes the general functions of the national Department of Health and the Director General;
4. Chapter 4 establishes provincial health services and outlines the general functions of provincial health departments;
5. Chapter 5 establishes the District Health System;
6. Chapter 6 provides some of the more interesting and innovative elements of the NHA such as the classification of health establishments, the certificate of need, the establishment of hospital boards, clinics and community health centres as well as the relationship between the public and private health establishments;
7. Chapter 7 deals with Human Resources Planning and Academic Health Complexes;
8. Chapter 8 provides for complex issues such as the control of use of blood, blood products, tissue and gametes in humans. The Minster stated in the briefing that this was a chapter of particular importance. She further stated that the body of a human being should not be exploited as a commodity as this would be a contradiction to human dignity. Human dignity must be protected while the importance of human tissue is acknowledged;[20]
9. Chapter 9 stipulates provisions regarding the establishment of a National Health Research Ethics Council and Health Research Ethics Committees. Research in South Africa must be done in accordance to the health priorities of the country and Reproductive health care is a critical aspect of health services due to the "prevalence of sexually transmitted infections in South Africa, the challenges of gender imbalances and the major problem of violence against women and children." Major

[18] This section deals with health services for experimental or research purposes and states that prior to the provision of services by a health establishment for experimental or research purposes, the health establishment must inform the user that the service is for experimental or research purposes or part of such a project.
[19] Chapter 2 was discussed in chapter 5 of this dissertation.
[20] Chapter 8 is the focal point of this chapter of the dissertation. At the time that the Ministers briefing was made she stated that this chapter would hopefully be in force in a year's time. This was not the case.

advances are being made in medical science using new technologies and it is thus important to ensure that the public has access thereto. It must still however be utilised in a responsible manner and for the benefit of all patients;[21]

10. Chapter 10 also deals with inspections of health establishments and compliance with basic norms and standards;
11. Chapter 11 came into effect immediately after proclamation as it empowered the Minister to make regulations on various mentioned issues;[22] and
12. Chapter 12 which also came into immediate effect in order to empower the Minister to appoint advisory and technical committees.

As mention above, the NHA is however still not fully operational.

2.2 CHAPTER 8

Chapter 8 is the proposed legislation for stem cell regulation in South Africa and yet there are various problems found in this piece of legislation. This is holding the development of stem cell technology back as South Africa is currently in a legislative vacuum. To date, only sections 53, 56, 68 and 93(1) are operational as proclaimed by notice in the Government Gazette.[23] Not only the lack of force of law is problematic as chapter 8 furthermore does not reflect international trends in stem cell research and is of a very low quality of legislation. Scientists and ethicists have often pointed out the factual errors contained within this chapter. In 2009, a working group was therefore established in order to attempt to rewrite and amend chapter 8.[24] The culmination of their efforts is a revised chapter 8. This document will greatly amend the published chapter 8 and also broaden the scope thereof. It will further bring scientific accuracy to the NHA. The revised chapter 8 in draft form is currently with the Department of Health. This document is confidential and not intended for

[21] Chapter 9 was discussed in chapter 4 of this dissertation.
[22] Numerous of these regulations made under the Act have been discussed in the course of this dissertation.
[23] Section 53 was proclaimed in Notice 22 of 2008 and sections 56, 68 and 93(1) were proclamation by the President of the Republic of South Africa in Notice 20 of 2010 in the Government Gazette No. 33187 of 14 May 2010.
[24] The working group was established after a mandate from the Department of Health on the 14th of July 2009 and is comprised out of seven expert groups. One such group is dedicated to cell- based therapy. The group has consulted with the stakeholders and their representatives and have considered the policy documents under which such entities function in order to amend or rewrite chapter 8. Some of the documents taken into consideration include *inter alia* the *World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation* and the *Istanbul Declaration of 2008*.

public comment as it may lead to even greater confusion regarding the regulation of stem cells. Many changes and amendments will still be made to chapter 8 and hopefully the new chapter 8 will be published by next year.

Chapter 8 was published with the title "Control of Use of Blood, Blood Products, Tissue and Gametes in Humans." It is submitted that the title be amended in some way, either directly or under an umbrella term, to include stem cells.

2.2.1 Section 53: The Establishment of a National blood Transfusion Service

Section 53 was the first section of chapter 8 to come into force and was proclaimed to commence on the 30th of June 2008.[25] Until recently it was also the only enacted section of chapter 8.[26] The original text of section 53 states that the Minister[27] must establish a blood transfusion service for the Republic of South Africa by granting a license to non-profit organisations, which are able to provide this service throughout the territory of the South Africa.[28] An organisation with such a license must then comply with the prescribed[29] norms and standards of such a service and has to provide the prescribed blood transfusion and related services.[30] A license holder further has the sole right to provide a blood transfusion service in South Africa.[31] "Blood transfusion service" was not defined in the NHA as published and it is submitted that a definition thereof should be included in the NHA in order to clarify the ambit of section 53.

[25] Section 53 was enacted by the President of South Africa in Notice No. 22 of 2008.
[26] Sections 55, 56 and 58 came into force on the 17th of May 2010 as well as section 93(1) to the extent in which it repeals section 23(b) of the Human Tissue Act, Act 65 of 1983. 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." See paragraphs 2.2.3, 2.2.4 and 2.2.5 *infra*.
[27] This is "the Cabinet member responsible for health" according to section 1.
[28] Section 53(1).
[29] This means it is prescribed by the regulations which were made under section 90.
[30] Section 53(2)(a).
[31] Section 53(2)(b). Sub- section (3) states that any person other than the holder of the license which is granted in terms of sub- section (1) who provides a blood transfusion service is 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.

2.2.2 Section 54: Designation of Authorised Institution[32]

The Minister may by way of a notice in the Gazette,[33] according to section 54(1)[34] designate any institution other than an institution as contemplated in section 63 of the NHA as an authorised institution.[35] Such institution may then undertake the following:[36]

(a) Acquire, use or supply the body of a deceased person for any of the purposes referred to in section 64.[37] It is submitted that this sub- section (2)(a) be elaborated on to allow such institution to also store, process or anaylse such deceased's body. In this manner one central institution may regulate the activities surrounding the body of a deceased person.[38]

(b) Acquire or use any tissue[39] 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. It is submitted that the ambit of this sub- section should be broadened by the addition of blood and gametes.[40] Also cells in general or stem cells in particular should be added to the ambit of section 54(2)(b). It is also submitted that a definition of cells and stem cells must be included in the NHA. Currently no such definition exists. At the very least an umbrella term must be defined under which cells and stem cells, embryonic as well as adult stem cells where appropriate, as well as other human genetic material such as DNA and RNA may be grouped. As previously used in this dissertation, "biological material" is suggested as umbrella term. This would mean that not only tissue may be imported or removed from the body of a living or deceased person, but also blood, gametes and biological material such as DNA.

[32] An authorised institution is defined as "any institution designated as an authorised institution in terms of section 54" according to section 1.
[33] This is the Government Gazette.
[34] Section 54(1).
[35] See paragraph 2.2.10 *infra*.
[36] Section 54(2)(a)- (d).
[37] See paragraph 2.2.11 *infra*.
[38] This would then closely resemble the position of the Human Tissue Authority in the United Kingdom. See paragraph 4.1.2 *infra*.
[39] According to section 1 this means "human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or gametes." Perhaps a new definition must be created which adds embryos as falling under tissue.
[40] Gametes are "either of the two generative cells essential for human reproduction."

(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. This section must then also include blood, gametes and biological material as submitted above.

(d) Acquire, use and supply blood products for any of the purposes referred to in sections 56 or 64. As mentioned above, it is submitted that this section should be expanded on to include the storage, processing and analysis of such materials.

Lastly, according to section 54(3) the Minister may impose conditions in respect of the exercise of a power referred to in sub- section (2). The suggestions related to section 54 thus also broaden the ambit of the section. The actions which institutions are allowed to undertake are more inclusive and the variety of biological material which may be involved in such actions are diversified. This thus leads to a more comprehensive and inclusive regulation of human biological material.

2.2.3 Section 55: Removal of Tissue, Blood, Blood Products or Gametes from Living Persons

Section 55 reads that a person may not remove tissue, blood, a blood product or gametes from another living person's body for the purposes referred to in section 56 unless the person from whom the tissue, blood, blood product or gametes are removed has granted permission therefore in the prescribed manner[41] and such removal is done in accordance with the prescribed conditions.[42] The permission which must be obtained is consent. Some clarity must be given regarding the conditions however. It is submitted that biological material, which then includes stem cells, or stem cells expressly should be added to the ambit of section 55 in order to protect the person from whom such material is removed as they must then also consent to such removal or withdrawal and it will only be permitted under the prescribed conditions.

[41] Section 55(1)(a).
[42] Section 55(1)(b).

2.2.4 Section 56: Use of Tissue, Blood, Blood Products or Gametes Removed or Withdrawn from Living Persons

Due to the content of section 56, the prescription of what action is permissible, it is a very important section to be taken into regard in any attempt to regulate stem cells in South Africa. Section 56 states the following:

> **"**(1) 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.
>
> (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):
>
> (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[43] 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."

It is submitted that section 56(1) should be amended so that it holds that the Minister may permit a health care professional or an authorised institution to use tissue, gametes or biological materials which have been removed or blood which has been withdrawn from a

[43] It is important to note that this is the first time that stem cells are mentioned in chapter 8. Stem cells are not defined in the NHA and it is submitted that a definition thereof should be provided as chapter 8 is after all the proposed regulatory tool for stem cells.

living person only for medical, dental or research purposes. The ambit of sub- section (1) must however not only been broadened but also narrowed. The removal of biological material must now be allowed as well as the removal of tissue and gametes and then for research purposes as well as medical or dental purposes. This would constitute a huge development in context of stem cell research. This would allow for research to be conducted on embryos[44] as it could then be argued that an embryo is the product of fertilisation and fertilisation is the union of the male and female gametes.[45] Research on the gametes may lead to fertilisation and thus an embryo which may be utilized in stem cell research. If biological material were to be included under the regulatory scope of section 56 however, the above argument will not even have to be made as it is submitted that the definition of biological material would be wide enough to include stem cells. Naturally the inclusion of stem cells would be preferred as no interpretive arguments such as this would then be necessary and it would be expressly regulated. In effect this would then further permit the use of embryonic and adult stem cell research.

The ambit of this section should then also be narrowed by the removal of "blood products." Blood products are considered an indication of the legislators' lack of knowledge surrounding human biology. The NHA defines blood products as "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."[46] 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 thus submitted that separate provisions must be made for an institution where blood products may be generated.[47] 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.

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[44] Section 1 of the NHA defines an embryo as "a human offspring in the first eight weeks from conception." The definition of "embryo" may perhaps be amended to read that it is "human offspring in the first fourteen days from conception." This would be done to bring the South African definition in line with internationally used definitions of embryos.

[45] See chapter 2 footnote 19 *supra*.

[46] The Free Medical dictionary available at http://medical-dictionary.thefreedictionary.com/blood+products accessed 15/ 11/ 2010.

[47] Such as a blood fractionation service.

Sub- section (2) reads that, unless permitted by the Minister, certain materials may in certain cases not be removed or withdrawn from a living human body, even for the purposes as described in section 56(1). These materials and circumstances are as follows:[48]

(i) Tissue, blood, a blood product or gametes from a person who is mentally ill as contemplated in the Mental Health Care Act, Act 17 of 2002. It is submitted that this should include stem cells or biological material;

(ii) Tissue which cannot be replaced by natural processes from a minor;[49]

(iii) Gametes from a minor. Concerning sub- sections (ii) and (iii) it must be mentioned that stem cells may be removed or withdrawn from a minor as they do not technically constitute gametes, especially in the case of adult stem cells, and stem cells are replaceable by natural processes as stem cells proliferate indefinitely. The required consent, as described in the previous chapter, must however be obtained; and

(iv) Placenta, embryonic or fetal tissue, stem cells and umbilical cord. This sub-section thus actually prohibits stem cell removal or withdrawal. Section 56(2)(b) states that the Minister may approve such removal but only of tissue, blood and blood product or gametes. No mention is made of stem cells and it could therefore be thought that stem cell removal is not permitted. Once again the NHA results in more uncertainty than in clarity regarding what is permitted regarding stem cells. It is strongly suggested that this sub- section be revised to include stem cells. It is further submitted that this sub- section functions as an internal limitation to chapter 8 of the NHA due to the prohibition on removal or withdrawal of material from certain persons and also due to the additional ministerial regulation.[50]

[48] Section 56(5)(a)(i)- (iv).
[49] A minor is a person under the age of 18 years.
[50] It is submitted that ministerial approval is not the ideal as the Minister or the delegated person acting on his or her behalf often lack full knowledge regarding stem cell research and related matter. This inhibits their decision making and ultimately has negative repercussions on the development of this science in South Africa. It is thus submitted that an independent authority be established to deal with such matters. See paragraph 3.7 *infra*.

Some further recommendations for the expansion of section 56 may be summarised as follows:

1. This section may be greatly simplified, instead of repeating itself as it does in section 56(1)(a) and (1)(a)(i) with "tissue, blood, blood products and gametes." It is submitted that it may merely state that the following activities are prohibited and then continue to list such activities in individual sections. It is submitted that this would lend more certainty to the section and what it attempts to regulate. "Biological material" may be added into the ambit of this sub- section and "blood product" may be removed.
2. Section 56 should be broadened to include genetic testing. Genetic testing, also known as gene testing, involves an examination of a person's DNA which is taken from cells in a blood sample or sometimes from other bodily fluids or tissues. This is done to detect any anomaly or abnormality which flags a disease or disorder such as birth defects or thalassemia.[51] The change in the DNA can be relatively large like a missing or added part of a or an entire chromosome for example and this can be seen under a microscope. The change may also be small such as one extra, missing, or altered chemical base. Genes can further be overexpressed,[52] inactivated or altogether lost. In some cases sections of chromosomes become switched or transposed which leads to the gene ending up in a location in which it is then permanently expressed or repressed.[53] Genetic testing when seen in a broader light may include biochemical tests for the presence or absence of certain key proteins used to signal aberrant genes.[54]
3. Specific provision should be made for consent in context of embryo research or the derivation of embryonic cells such as stem cells. The Minister should permit research on cells derived from embryos on written application only if such research is undertaken according to the prescribed conditions and with the prior written

[51] See in general Holtzman NA, Murphy PD, Watson MS & Barr PA (1997) "Predictive genetic testing: From basic research to clinical practice" *Science* 278(5338) 24 October, 602– 605.
[52] There are then too many copies of said gene.
[53] This means that the gene is permanently switched on or off. See chapter 2 paragraph 2 *supra* or footnote 15.
[54] "Understanding gene therapy: What is gene testing?" available at http://www.accessexcellence.org/AE/AEPC/NIH/gene09.php accessed 2/11/2010. See in general "Understanding gene testing" available at http://www.accessexcellence.org/AE/AEPC/NIH/ accessed 2/11/2010 and "Genetic testing" available at http://kidshealth.org/parent/system/medical/genetics.html# accessed 2/ 11/ 2010.

consent from the donor of such embryo. Should this amendment be made to section 56, embryonic stem cell research would be permitted.

4. Finally, some provision must be made for situations wherein chimeras are used for therapeutic purposes. The use of human- animal hybrid embryos is an ethically difficult subject and therefore some regulation is needed.

2.2.5 Section 57: Prohibition of Reproductive Cloning of Human Beings

Section 57 deals with reproductive cloning of human beings and more specifically, with the prohibition thereof. This section states that no person may manipulate genetic material such as gametes, zygotes[55] or embryos[56] and further that no person may partake in any activity with the purpose of reproductive cloning and this includes nuclear transfer and embryo splitting.[57] This is, it is submitted, utterly unnecessary and should be regarded as a waste of legislative space. The reason for this is that reproductive cloning of humans is internationally and nationally prohibited and almost goes without saying. It was uncalled for to dedicate an entire section to this subject matter and could have simply been prohibited in a sub- section under prohibitions and offences for example. What is even more vexing about this section is that it conflicts within itself as sub- section (2) allows for therapeutic cloning using adult or umbilical cord cells. Therapeutic cloning and reproductive cloning are done by the exact same process, that of nuclear transfer.[58] Sub- section (1) however prohibits such activity. It is submitted that this clearly indicates a lack of knowledge on the part of the legislator and reiterates that regulatory control should not vets in a governmental branch but in an independent authority.[59] This section of chapter 8 should thus be completely scrapped or totally amended.

[55] A zygote is "the product of the union of a male and female gamete" as defined in section 1 of the NHA.
[56] Section 57(1)(a).
[57] Section 57(1)(b).
[58] See chapter 2 paragraph 3.6.1 *supra*.
[59] See footnote 50 *supra* wherein it is submitted that the Minster should nor have such ultimate power.

Section 57 then continues by stating that ministerial approval is required for the importation or exportation of human zygotes or embryos[60] and that a contravention of these provisions could lead to a fine or imprisonment.[61] Also, the definitions for reproductive and therapeutic cloning are provided for in the section itself.[62] A further anomaly exists in that the section 57 allows for research on stem cells and zygotes not older than 14 days.[63] Nowhere however has it been mentioned that a stem cell must be under 14 days old. In fact, one of the wondrous characteristics of a stem cell is that it is seen as immortal and thus this leads to the conclusion that a stem cell's age is irrelevant. This once again illustrates a lack of technical knowledge on the part of the legislator regarding stem cells. It is once again strongly recommended that a knowledgeable, independent authority must be established to regulate stem cells and related processes in South Africa.

2.2.6 Section 58: Removal and Transplantation of Human Tissue in Hospital[64] or Authorised Institution

Section 58 states that "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 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." Sub- section (2) then continues to state that the medical practitioner contemplated in sub- section (1)(b) may not participate in any transplant for which they themselves granted authorisation. It is important to note that section 58 should

[60] Section 57(3).
[61] Section 57(5).
[62] Section 57(6) holds that (a) 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" and (b) therapeutic cloning is "the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues."
[63] Section 57(4) states that "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."
[64] A hospital for purposes of this chapter is "a health establishment which is classified as a hospital by the Minister in terms of section 35."

be read together with section 56(1).[65] It is submitted that "gametes" and "stem cells" or "biological material" must be added to sub- section (1) so that it reads that tissue, gametes and biological material may be removed only in a hospital or institution and with the proper authorisation.

Section 58 thus has a strong undercurrent of consumer, or then patient protection in that any such procedure must be undertaken in a prescribed location which will then have to adhere to certain standards of *inter alia* treatment or hygiene and a knowledgeable person is placed in an authoritative position in order to monitor that the patient is not unnecessarily subjected to a procedure of removal or transplantation. In a society such as South Africa with both first and third world elements, the proper regulation of such a sensitive and ethically concerning technology is of immense importance and thus the legislator's time and work should rather be spent on actual issues and problems than jaded and tired ones such as the prohibition of reproductive cloning of humans.

2.2.7 Section 59: Removal, Use or Transplantation of Tissue, and Administering of Blood and Blood Products by Medical Practitioner or Dentist

Section 59 in a nutshell deals with who may undertake the permitted activities. Sub- section (1) reads that only a registered medical practitioner or dentist may remove tissue from a living person, use said tissue or transplant it into another living person.[66] Sub- section (2) provides therefore that only a medical practitioner or dentist or a person under their instruction or supervision may administer blood or a blood product to a living person.[67] It is submitted that this section should be amended to include that a competent persons may act within their field of competency and may then remove any tissue, blood, gametes or biological material from a living person or use the tissue, blood, or biological materials which have been removed for any of the purposes contemplated, or transplant the tissues or gametes into another living person. It is further submitted that "researcher" must be included under this section as a competent person in order to facilitate stem cell research.

[65] 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."
[66] Section 59(1).
[67] Section 59(2).

This would then correspond with the suggested amendment to section 56 of adding research as a permissible use of biological material or stem cells.

2.2.8 Section 60: Payment in Connection with the Importation, Acquisition or Supply of Tissue, Blood, Blood Products or Gametes

Section 60(1) provides therefore that not only an authorised institution but also a hospital and a prescribed person,[68] and in the case of tissue or gametes, the exporter or importer may receive payment for the import, acquisition or supply of materials. Sub-section (2) then stipulates that a person or institution as prescribed could then also receive payment for the importation, export or supply of blood or blood products. It is submitted that this section may be greatly simplified by merely stating that an authorised institution may receive payment for the acquisition, supply, import or export of tissue, blood, blood products, gametes or biological material. Hospitals should only apply or use such material and should have no part in the "trade" aspect thereof.[69] This will help ensure that there are no conflicts of interest. The amount of payment should then not exceed an amount which is reasonably required to cover the costs involved in any importation, export, acquisition or supply of the tissue, blood, blood product, gamete or biological samples.[70] This does however not prevent the health care provider from receiving remuneration for any professional service rendered by him or her according to section 60(3).[71]

[68] As was contemplated in section 63.
[69] This is also in accordance to the previous discussion of whom should obtain consent wherein it was stated that the attending physician, who will naturally be employed by a hospital, should obtain consent but only where there are no conflicts of interest. See chapter 5 paragraph 4.1 *supra*.
[70] Section 60(2). See also chapter 4 paragraph 4.4.4 *supra*.
[71] Section 60(3). Section 60(4) continues by stating that it is an offence for a person who has donated material to receive any other financial reward for said donation except for the reimbursement of reasonable costs or to sell or trade such material in contravention to chapter 8 of the NHA. This is in line with the ethical position on the matter of payment. See footnote 70 *supra* in this regard. Sub- section (5) provides for punishment in the case of contravention and states that any person convicted of an offence will be liable on conviction to a fine, imprisonment for a period no longer than five years or to both.

2.2.9 Provisions Regarding Deceased Persons: Sections 61, 62 and 64- 67

Stem cells, as was mentioned in chapter 2 of this dissertation, may be removed or withdrawn from cadaveric fetal tissue. Considering that this is being phased out by the development of adult stem cells however, the provisions regarding organs,[72] tissue and other materials from human bodies fall outside the scope of this dissertation as they are not pertinent to this discussion in context of stem cells. For completion sake it is only necessary to briefly mention these sections of chapter 8 of the NHA.

Section 61[73] provides for the allocation and use of human organs. Although little attention has been given to the fact that stem cells may be obtained from a deceased person in the course of this dissertation, it is possible and thus it is submitted that section 61 should be amended to broaden the scope thereof in order to regulated the transplantation of stem cells removed or withdrawn from the body of a deceased person. This may be done by renaming this section so it does not only deal with organs but also tissue and biological material. Any material which is removed or withdrawn from a deceased person must be used in the prescribed manner, be the material removed for transplantation, treatment, education or research.[74] Section 62 is not relevant to this dissertation and it is only necessary to take cognisance thereof as it in effect permits the donation of human bodies and tissues.[75] Such a donation may be made for purposes of education,[76] for health

[72] 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" as stated in section 1 of the NHA. This definition is quite boorish and it should perhaps be amended to state something along the lines thereof that an organ is various tissues which are joined in a structural unit and adapted to perform specific functions.

[73] 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.

[74] Section 61(2).

[75] Section 62: **Donation of Human Bodies and Tissue of Deceased Persons**

(1) (a) A person who is competent to make a will may—

research,[77] the advancement of health sciences,[78] therapeutic purposes[79] or for the production of therapeutic or diagnostic or prophylactic substances.[80]

Any such donation may then be revoked according to section 65 which reads that "a donor may, prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document." As mentioned during the discussion regarding consent in this dissertation, it was suggested that the possibility must exist to revoke consent and thus in effect participation. Section 65 then legally provides for revocation and in this case, the revocation of a donation. This section is not of great importance to this dissertation and must only briefly be discussed as it reiterates the fact that consent should be revocable. Section 65 states that a donor of an organ may revoke a donation in the same manner as it was made, be that by document or will, prior to the transplantation or then the use of such donated material.[81] It is submitted that certainty should be provided regarding the "cut- off" time for revocation. Although

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(i) in the will;
(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 sub- section (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 sub- section (2).

[76] The training of students in health sciences according to section 64(1)(a).

[77] 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.

[78] Section 64(1)(c).

[79] Section 64(1)(d) and this includes the use thereof in living persons.

[80] Section 64(1)(e).

[81] Section 65 as published.

section 65 currently provides therefore that a donation may be revoked prior to transplantation there is a difference between revoking a donation a week before transplantation of an organ and revocation at a time where the donee is already on the operating table. In such a situation, the revocation is prior to transplantation but still does not appease a legal or medical sense of what is fair and potentially fatal.

Section 66 deals with post mortem examination of human bodies and section 67 with the removal of tissue at a post mortem examination as well as the obtainment of tissue by persons or institutions.

2.2.10 Section 63: Human Bodies, Tissue, Blood, Blood Products or Gametes May Be Donated To Prescribed Institutions or Persons

"A human body, tissue, blood, blood products or gametes may be donated by any person contemplated in section 55 (a) or 62 or to any prescribed institution or person for any purpose contemplated in section 56 or 64 (1)," according to section 63. Section 63, it is submitted, should be broadened to include stem cells. Currently only the bodies of deceased persons, tissue, blood or blood products and gametes may be donated to the prescribed persons or institution. Some might argue that by using the interpretation-method of reading in stem cells may be included under this section. Van Wyk for example stated that the definition of blood product is wide enough to include stem cells.[82] It is however submitted that when taking into account that chapter 8 is the proposed regulatory device for the regulation of stem cells in South Africa, this is insufficient and stem cells, or at least an umbrella term therefore should be expressly mentioned in order to regulate this matter in a black on white manner. Should this not be done a strong case may be made against the donation of stem cells as it may easily be argued that had the legislator intended the possibility of stem cell donation under this section, it would have been included along with the named material. The inclusion of "stem cells" or an umbrella term would thus ensure legal certainty.

[82] 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.

2.2.11 Section 68: Regulations Relating to Tissue, Cells, Organs, Blood, Blood Products and Gametes

Under section 68(1)(c) the Minister may make regulations regarding the removal, procurement,[83] processing, storage and allocation of human cells. Also the Minister may make regulations regarding the supply of human stem cells,[84] the unification of human gametes outside of the body and artificial fertilisation[85] and also regarding the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes[86] or human stem cells for any purpose.[87] In the course of this dissertation certain regulations have been discussed. There are however still two regulations from 2007 which are of importance and will be discussed below.

2.2.12 Prohibitions and Offences

It is submitted that a wholly new section dealing only with prohibitions and offences under chapter 8 must be created as opposed to the scattered prohibitions and offences being stated in individual sections of chapter 8. Such a section may then include *inter alia* the prohibition of reproductive cloning, improper financial incentives or the trafficking of stem cells. The prescribed punishment may then be imprisonment for no more than 5 years or a fine or both.

2.2.13 Summary of Recommendations:

The following recommendations have been made in the course of this chapter concerning chapter 8 of the NHA:

[83] For the purposes of the Regulation procurement is defined as "a process by which tissue or cells are made available" in regulation 1 in the Regulations Relating to Human Stem Cells.
[84] Section 68(1)(f).
[85] Sections 68(1)(k) and (l) respectively. Regulations regarding artificial insemination have been made but are still in draft form.
[86] Section 1 of the NHA defines an oocyte as "a developing g human egg cell."
[87] Section 68(1)(p).

1. No mention is made whatsoever of the creation of embryos outside of the body. Some provision must be made in this regard for embryos created for IVF purposes which were not used, otherwise only ethical guidelines will regulate this.[88] It is submitted that embryos should not be created for research purposes only but that the use of spare embryos should be permitted.

2. "Stem cells" must be defined as the NHA is the proposed regulatory tool in the pursuit of regulating stem cell technology is South Africa. In order to provide the NHA some flexibility, an umbrella term such as biological material may possibly provide a good option as various materials may be included under such a term and this would not limit the provisions of chapter 8 to embryonic stem cells only but would leave space for the application thereof to adult stem cells;

3. A definition of "Blood transfusion service" must be provided in context of section 53;

4. Authorised institutions should be able to not only acquire, use or supply biological material as is provided for by section 54 but also store, process and analyse such material. This would allow for a centralised regulating body which may then be in control of all activities concerning stem cells. Also the range of material which may be subjected to these activities must be added to in order to be more inclusive and thus afford better protection to the patient, research participant and public;

5. The ambit of section 55 must be broadened to include stem cells or at least an umbrella term under which it may be grouped, in order to facilitate the removal or withdrawal thereof. This would also result in better protection of the patient or research participant and public;

6. Research should be recognised as a permitted activity under section 56 of the NHA. Also, the format of section 56 may be simplified to aid understanding of the provisions thereof, genetic testing ought to be included as a further permissible activity under section 56, consent should be specifically addressed here as consent may differ according to what the material could be used for and some provision

[88] See chapter 4 paragraph 4.1 *supra*.

must be made for circumstances wherein human and animal genetic material or cells are combined as this is currently unregulated;[89]

7. The prohibition of reproductive cloning is unnecessary and could merely have been mentioned in a section devote exclusively to prohibitions and offences. It indicates a lack of understanding as to what must be regulated and what is jaded by the legislator. It further reiterates the fact that an independent body of regulatory authority is needed;

8. The ambit of section 58 must be broadened to include stem cells or at least biological material to provide for an environment or place wherein such material may be removed and monitored and is subject to strict regulation;

9. "Competent person" must be elaborated on to include a researcher and "research" must be added to the scope of section 59 in order to allow for the lawful removal and use of stem cells in a scientific context as this is currently not provided for;

10. Only authorised institutions should deal with the trade and financial implications involved in stem cells;

11. Stem cells should be included under the material which may be donated; and lastly

12. A separate section should be brought into chapter 8 which deals exclusively with prohibitions and offences under this chapter.

This list illustrates that, and makes it blatantly clear that the NHA is very much lacking when it comes to the regulation of stem cell technology in South Africa. An attempt was however made to rectify or at least supplement the NHA by way of two sets of regulations which have not yet been properly discussed in the course of this dissertation. The first is 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 of 5 January 2007 and the second is the Regulations relating to Human Stem Cells of 4 May 2007. The regulations will thus be examined in an attempt to find solutions to the problems found in chapter 8 of the NHA.

[89] See chapter 2 paragraph 3.3 *supra* for a discussion regarding chimeric embryos.

3 THE REGULATIONS

The above recommendations could be seen as a list of problems or shortcomings found in the NHA. Regulations however, are tools which may be used to supplement legislation and thus it now becomes necessary to search for solutions and additions to the NHA in two sets of regulations made under the NHA. The first is 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 and the second is the Regulations Relating to Human Stem Cells. These Regulations will be discussed in context of the recommendations and are therefore not numerically discussed. Where the Regulations do however not provide a satisfactory solution to the problem areas, the United Kingdom's position will be used as comparative guideline.

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[90] were made under section 90(1) of the NHA read with section 68(1)[91] by the Minister of Health. The Regulations are divided into three chapters which will be discussed here in an attempt to resolve some of the problems found in the NHA. Chapter 1 deals with harvesting and use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic genetic testing, health research and therapeutics. Chapter 2 holds the provisions regarding research relating to the use of gametes, embryos, fetuses, cultured cells and stem cells and chapter 3 lastly deals with genetic, stem cell registers and research findings, which involve long term storage. The Regulations Relating to Human Stem Cells[92] were made in terms of section 68 of the NHA and according to regulation 22 was to come into operation six months after the publication thereof. It is interesting to note that

[90] 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 No. R7 in Government Gazette No. 29526 of 5 January 2007 3. Hereafter referred to as the Regulations Regarding Use.
[91] Section 68(1).
[92] Regulations Relating to Human Stem Cells No. R375 in Government Gazette No. 29840 of 4 May 2007 5.

regulation 1 of the Regulations Relating to Human Stem Cells provide definitions of "multipotent,"[93] "pluripotent"[94] and "totipotent."[95]

3.1 THE CREATION OF EMBRYOS OUTSIDE OF THE BODY AND SPARE IVF EMBRYOS[96]

A major problem which was identified in the NHA and which was mentioned in the recommendations above is the fact that no mention was made of spare embryos from IVF treatment. Regulation 12 now regulates this by stating that, subject to regulation 16, excess embryos obtained from IVF may be used to derive embryonic stem cell lines for the purpose of research. The prerequisites therefore are however:[97]

(a) Informed consent from the donor of the embryo;
(b) Ministerial approval; and
(c) An undertaking by the applicant of such research to document the research.

3.2 DEFINITION OF "STEM CELLS"

The Regulations Regarding Use are immediately helpful in the regulation of stem cells technology in South Africa as, for the first time a definition of stem cell is provided and thus this development was an immense step forward, even if it was only provided four years after the original publications of the NHA. According to regulation 1 a stem cells is "any embryonic stem cell,[98] circulating progenitor cell, bone marrow progenitor cell, umbilical cord progenitor cell, hematopoietic progenitor cell or any cell that is capable of replicating (proliferating) and giving rise to a different cell." This definition also appears in the Regulations Relating to Human Stem Cells. Although this definition constitutes a great improvement in the legislation, it is limiting as it names certain cells such as circulating progenitor cells for example and this may narrow the scope of the definition. It is submitted

[93] This is "a cell that is specialized for specific tissue."
[94] "A cell that is able to develop into most tissues of an organism."
[95] This means "a cell that is able to form an entire organism."
[96] For a discussion on the use of such embryos, see chapter 4 paragraph 2.4 *supra*.
[97] Regulation 16(a)- (c) of the Regulations Regarding Use.
[98] Embryonic stem cells are defined in the Regulations Regarding Use as "any cell from the 30- 200 inner cell mass of the blastocyst."

that any future definition of stem cells should be more open ended and rather state that it is a cell which is capable of indefinite replication and gives rise to any of the different cells found in the human body.

Regulation 2 states that only a medical practitioner or dentist may harvest biological material. "Biological material" is defined as "any material from a human being including blood, cells,[99] tissues, DNA, RNA polar bodies,[100] blastomeres,[101] embryos and gametes." This definition is thus simply a more detailed definition than the umbrella term suggested in the previous discussion of chapter 8.

3.3 DEFINITION OF "BLOOD TRANSFUSION SERVICE

The Regulations Regarding Use do not offer a definition of "Blood transfusion services." Nor do the Regulations Relating to Human Stem Cells. It is submitted that a definition of blood transfusion service will have to be included in any future legislation dealing with this subject matter.

3.4 BROADENING OF ACTIVITIES OF AUTHORISED INSTITUTIONS

Regulations 15, 16 and 17 of the Regulations Regarding Use deal with the activities which an authorised institution is permitted to undertake or should undertake as recommended above. Previously it was submitted that authorised institutions should be able to acquire, use or supply biological material and also store, process and analyse such material. Regulation 15 requires an authorised institution to keep a register of any genetic material

[99] Cell is defined by the Regulations Regarding Use as "the basic structural and functional unit in people and all living things. Each cell is a small container of chemical [*sic*] and water wrapped in a membrane."
[100] Polar bodies may, according to regulation 1 of the Regulations Regarding Use, be defined as "a product that is formed during the development of the female gamete (during meiosis), which contains [a] little cytoplasm and a haploid number of chromosomes." Chromosomes are then defined as "a thread- like structure and made up of DNA found in the nucleus of all cells with the nuclei of human cells normally contain [*sic*] 46 chromosomes, arranged in 23 pairs."
[101] Blastomeres, or apparently also a "blastocyte" is defined as "an undifferentiated embryonic cell, derived from the blastocyst" according to regulation 1 of the Regulations Regarding Use. A blastocyst is "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."

which has been tested and stem cells lines which have been generated.[102] The stem cells which are derived in this manner and any information from this research will, according to regulation 16, not be subject to intellectual property and regulation 17 is of great importance as it provides for the regulation of storage and flow of genetic information. Such information must be treated with confidentiality and this should be explained to patients and their consent must be obtained before any such information may be released. Patients must also have access to their records and the records must be destroyed once they are of no further use.[103] Regulation 11 of the Regulations Relating to Human Stem Cells provides for data protection and confidentiality and these provisions must be strictly adhered to.[104]

Regulation 5 of the Regulations Relating to Human Stem Cells provides for the keeping of records and reporting of obligations. A stem cell establishment must keep a registered of stem cells donors and stem cell donations.[105] Also, a record of statistics regarding stem cells must be kept,[106] a system must be in place to "receive, investigate, register and transmit" information to the Director General regarding any serious or adverse events or reactions[107] which could have an impact on the safety and quality of stem cells.[108] Lastly, a recall procedure must be in place in the case of such serious or adverse events or reactions.[109]

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[102] Only the National Human Genetics Stem Cell Research and Ethics Committee shall have access to such registers according to regulation 15(3). See also regulation 5(6) of the Regulations Relating to Human Stem Cells.

[103] Regulation 17(a)- (g) of the Regulations regarding Use.

[104] Regulation 11: **Data protection and confidentiality**

1) A stem cell establishment shall ensure that all data, including genetic information, collated within the scope of these regulations and to which third parties have access remain confidential at all times.

2) For the purposes of sub- regulation (1), stem cell establishment shall ensure that:
   a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or referral records and transfer of information;
   b) procedures are in place to resolve data discrepancies: and
   c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations.

[105] Regulation 5(a) and (b) of the Regulations Relating to Human Stem Cells.

[106] Regulation 5(c) of the Regulations Relating to Human Stem Cells.

[107] This is "any 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 results in, or prolong, hospitalisation or morbidity" according to regulation 1 of the Regulations Relating to Human Stem Cells.

[108] Regulation 5(d) of the Regulations Relating to Human Stem Cells.

[109] Regulation 5(e) of the Regulations Relating to Human Stem Cells.

Stem cell establishments must additionally ensure the quality and safety of stem cells as provided for in Regulations Relating to Human Stem Cells regulation 12 which requires an updated quality system which is based on the principle of good practice[110] and this must include at least the following documents:[111]

(i) Standard operating procedures (SOP);

(ii) Guidelines;

(iii) Training and reference manuals;

(iv) Reporting forms;

(v) Donor records; and

(vi) Information on the final destination of stem cells.

As was recommended above, the scope of activities which an authorised institution may conduct should include the processing,[112] storage[113] and distribution[114] of stem cells. Regulations 15 to 19 of the Regulations Relating to Human Stem Cells deal with this and deserve some in depth discussion.

Stem cells must be kept in quarantine until the requirements relating to donor information and test results have been met.[115] Regarding the processing of stem cells, a stem cell establishment must include all processes that affect the quality and safety of stem cells and ensure that these are carried out under controlled conditions[116] and special provision for the handling of stem cells which are to be discarded, in order to prevent the contamination of other cells, processing environment or personnel in its standard operating procedures

[110] Regulation 12(a) of the Regulations Relating to Human Stem Cells.
[111] Regulation 12(d)(i)- (vi) of the Regulations Relating to Human Stem Cells.
[112] This is "all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications."
[113] Storage is defined as "maintaining the product under appropriate controlled conditions until distributed" in regulation 1 of the Regulations Relating to Human Stem Cells.
[114] This is defined as "transportation and delivery of tissue and cells intended for human applications" by regulation 1 of the Regulations Relating to Human Stem Cells.
[115] Regulation 15 of the Regulations Relating to Human Stem Cells.
[116] Regulation 16(1)(a) of the Regulations Relating to Human Stem Cells.

and guidelines.[117] A stem cell establishment must also ensure that the equipment used, the working environment and process design, the validation and control conditions are in accordance with the establishment's standard operating procedures.[118]

A stem cell establishment must further ensure that all procedures associated with the storage of stem cells are documented in the standard operating procedures and guidelines and that the conditions of storage comply with the requirements referred to therein.[119] The establishment should have agreements and procedures in place to ensure that stored stem cells are transferred to other authorised stem cell establishments should that establishment seize to function.[120] Labelling, documentation and packaging must also conform to any standard operating procedures.

Lastly, a stem cell establishment must, according to regulation 19, ensure that the quality of stem cells during distribution is not compromised. From the length of the discussion here on the elaboration of the activities in which a institution or establishment working with stem cells may partake, it is brought to attention that this is an undeniably important aspect of the regulation of stem cell technology is South Africa. The position of the United Kingdom regarding a regulatory body will thus be discussed in the course of this chapter as an example of what South Africa should aim to achieve.

3.5 THE PROVISION FOR THE REMOVAL OR WITHDRAWAL OF STEM CELLS

Regulation 4 of the Regulations Regarding Use is relevant in as far as it provides for research which may be conducted on single cells from developing blastocysts. Embryonic stem cells are removed from a blastocyst at the 8 cell stage thereof which is otherwise known as the Morula stage.[121] Regulation 4(b) provides for health research as referred to in section 69(3) of the NHA on such cells

[117] Regulation 16(1)(b) of the Regulations Relating to Human Stem Cells.
[118] Regulation 16(3) of the Regulations Relating to Human Stem Cells.
[119] Regulation 17(1)(a) of the Regulations Relating to Human Stem Cells.
[120] Regulation 17(1)(b) of the Regulations Relating to Human Stem Cells.
[121] See chapter 2 paragraph 3.4 *supra*.

3.6 RECOGNITION OF RESEARCH, GENETIC TESTING, CONSENT AND HUMAN- ANIMAL HYBRID EMBRYOS

The Regulations Regarding Use state that only a medical practitioner or dentist may harvest biological material for genetic testing, health research or therapeutic purposes.[122] It is further stated that biological material for such purposes my only be harvested in a hospital or authorised institution, a prescribed institution or a research institute.[123] Regulation 2 supplements the NHA in two ways. Firstly, research is permitted on biological material, even if it is only for the purpose of ancestry analysis, and secondly genetic testing is provided for as a legitimate activity which involves biological material. Regulation 3 of the Regulations Regarding Use are also further important in context of providing for genetic testing as it requires informed consent prior to any removal of biological material.[124] Unfortunately genetic testing is not defined in the Regulations.

3.7 THE NEED FOR AN INDEPENDENT BODY OF REGULATORY AUTHORITY

As mentioned in the recommendations above it is necessary to have clarity regarding the environment wherein stem cell research may take place. Regulation 7 of the Regulations Regarding Use supplements the NHA is this regard and relates to the establishment of a central data bank which will contain all information regarding human DNA, RNA, cultured stem cells,[125] stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue bioposies which have been donated and stored. This regulation supports the recommendation that an independent authority must be established in order to regulate stem cell technology in South Africa. Such a data bank will have to be strictly supervised and controlled and thus the need for a regulatory body is once again made obvious.

[122] Regulation 2(a) of the Regulations Regarding Use.
[123] A research institution is an museum for example and this is done only for the purpose of ancestry analysis according to section 2(b)(iii) of the Regulations Regarding Use.
[124] Section 3(1)(a) of the Regulations Regarding Use. Sub- section (b) provides for circumstances involving a minor.
[125] Cultured cells are “cells that have been grown outside the body.” This definition may be found in regulation 1 of the Regulations Regarding Use.

3.8 PROVISION OF AN ENVIRONMENT OR PLACE FOR THE REMOVAL OF MATERIAL

Regulation 2 not only deals with the harvesting of biological material for genetic testing, health research or therapeutic purposes but also states that biological material may only be harvested in a hospital or authorised institution, a prescribed institution or a research institute.[126] Also an environment wherein such harvesting may take place is specified. Regulation 2(b) reads as follows:

> "Biological material for genetic testing, health research or therapeutic purposes may only be harvested in-
>
> (i) A hospital or an authorised institution;
>
> (ii) Prescribed institution; or
>
> (iii) For ancestry analysis, a research institution such as a museum."

In order to become an authorised institution, an application therefore must be made to the Minister and this is regulated by regulation 3 of the Regulations Relating to Human Stem Cells.[127] It must be noted that regulation 4 deals with the suspension or withdrawal of such authorisation in circumstances where institutions do not meet the requirements of such status for whatever reason. From this regulation the overly excessive powers of the Minster are apparent.

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[126] Sub- regulation 2(b) of the Regulations Regarding Use.

[127] Regulation 3: **Application for authorization**

1) A person desiring to be designated as an authorised institution shall apply for such authorisation to the Minister.
2) The application referred to in sub- regulation (1) shall contain the following information:
   a) the name and nature of the applicant (whether an organization, institution, medical scientist, etc);
   b) location of the premises where business is to be conducted;
   c) an indication of how records and data shall be kept;
   d) the quality system to be used;
   e) details of the responsible person;
   f) qualifications and training for personnel;
   g) standing operating procedures of the applicant; and
   h) any other information the Minister may consider necessary for the consideration of the application.
3) The Minister may, on application in tens of sub- regulation (1) authorize the applicant concerned as a stem cell establishment, subject to such conditions as the Minister may determine.
4) An authorised stem cell establishment shall operate as a non-profit making entity.
5) Only a health organisation, health institution, medical scientist or human biological scientist can apply for authorisation in terms of this regulation.

3.9 A RESEARCHER MUST BE INCLUDED UNDER THE MEANING OF "COMPETENT PERSON" AND PROVISION MUST BE MADE FOR THE LAWFUL REMOVAL AND USE OF STEM CELLS IN RESEARCH

The definition of competent person as provided for in the Regulations Regarding Use does not include a research as a competent person who may remove stem cells for research purposes. Provision is only made for a medical scientist in the Regulations Regarding Use and this is described as a person registered as a medical scientist with the HPCSA. It is nowhere clarified whether or not a researcher may be seen as a medical scientist.

The Regulations Relating to Human Stem Cells define a competent person as a medical practitioner or suitably qualified person in the case of stem cell retrieval. This is the case for retrieval from both deceased and living persons.[128]

3.10 TRADE ASPECTS SHOULD EXCLUSIVELY BE DEALT WITH BY AUTHORISED INSTITUTIONS

Regulation 5(4) of the Regulations Relating to Human Stem Cells deals with matters related to payments made in terms of section 60 of the NHA. It requires a stem cell establishment to record such payments, the person to whom payment was made, the reasons therefore and who made the payment.

3.11 ABILITY TO DONATE STEM CELLS

It was recommended previously that stem cells should be included under the list of material which may be donated and this is indirectly done by regulations 9 and 10 of the Regulation Regarding Use. Regulation 9[129] deals with the ownership of material before harvesting of

[128] Regulation 1 of the Regulations Relating to Human Stem Cells.
[129] Regulation 9 reads that "ownership of (a) excess embryos from in vitro fertilisation, for the purpose of research, is vested with the donor; (b) umbilical cord blood for the purpose of research, is vested with the donor; (c) umbilical cord blood for the purpose of using the cord blood to harvest stem cells for the benefit of the child's or sibling's benefit in the future, is vested with the parents; and (d) aborted foetuses for the purpose of research are vested with the donor."

stem cells and regulation 10[130] with the ownership thereof after the donor has given consent therefore. The use of the word donor denotes that stem cells are harvested for the purpose of donation. This is a welcome addition to the NHA.

Regulation 5 of the Regulations Relating to Human Stem Cells refers to donors of stem cells and thus it may be concluded that the Regulations Relating to Human Stem Cells provide for the donation of stem cell in a direct manner. The definition as provided by the Regulations Relating to Human Stem Cells define a donor as "a person who has donated tissue in terms of the Act."[131]

3.12 A SEPARATE PROVISION DEALING WITH PROHIBITIONS AND OFFENCES

Regulation 18 of the Regulations Regarding Use provides for the same punishment of offences as is mentioned in the NHA.[132] Regulation21 of the Regulations Relating to Human Stem Cells states the same as regulation 18. Neither regulation specifies any contraventions which are punishable.

In conclusion it may be stated that the Regulations supplement the NHA to the extent that it may be useable, at least for the time being. It is however nowhere near sufficient and will have to be subjected to great amendment or possibly, a complete repeal and rewrite. A main concern as is illustrated from the above, is the need for an independent regulatory body. In order to establish such a body in South Africa, it is submitted that the United Kingdom's model should be followed. The following section of this dissertation will thus focus on the Human Fertilisation and Embryology Authority and the Human Tissue Authority as found in England.[133]

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[130] Regulation 10 states that "ownership of stem cells derived from (a)excess embryos for the purpose of research, is vested with the State; (b)umbilical cord blood for the purpose of research, is vested with the State; (c) umbilical cord blood for the purpose of harvesting stem cells to use for the benefit of the child's or sibling's benefit in the future, is vested with the parents; (d)aborted foetuses for the purpose of research is vested with the State; and (e) other adult progenitor cells for the purpose of research are vested with the State."

[131] Regulation 1 of the Regulations Relating to Human Stem Cells.

[132] This is imprisonment of no more than 5 years and or a fine according to regulation 18 of the Regulations Regarding Use.

[133] See in general Swanepoel M *Embryonic Stem Cell Research and Cloning: A Proposed Legal Framework in Context of Legal Status and Personhood* (LLM thesis, unpublished, University of Pretoria 2006) 218- 279.

4 STEM CELL REGULATION IN THE UNITED KINGDOM

The above discussion clearly illustrates that South Africa has many shortcomings in the regulation of stem cell technology. In order to change this, attention must be paid to what is being done globally. The United Kingdom offers much insight into the regulation of this technology and is thus of great comparative use. South African medical law is founded on English medical law and thus certain principles are the same which then motivates the use of English law as example of where South Africa should be heading. Also, stem cell technology or related technology at least has been regulated in the UK for a substantial amount of time.[134] Due to this, most of the issues which are new to the South African regulation of stem cells have already been dealt with by the English. This section of this dissertation will now focus on the English position on and regulation of stem cells, specifically the Human Fertilisation and Embryology Authority and the Human Tissue Authority will be discussed. This is due to the fact that the Regulations supplement the NHA but the establishment of an independent authority remains difficult issue and could benefit from the example found in the UK. The Human Embryology and Fertilisation Authority and Human Tissue Authority will be discussed as well as the Human Fertilisation and Embryology Act of 1990 as amended by the Human Fertilisation and Embryology Act of 2008 and the Human Tissue Act of 2004 under which the authorities were established. In the course of this discussion recommendations will also be made regarding certain provisions of features which should be "copied" in South Africa.

4.1 REGULATORY AUTHORITIES

In a joint statement by the Human Fertilisation and Embryology Authority[135] and the Human Tissue Authority,[136] it was stated that the aim of regulating embryonic stem cells is to ensure the highest standards in the derivation of stem cells in a laboratory through to the

[134] Regulation of such technology was started in 1982 with the establishment of the Warnock Committee. The committee was established in response to the 1978 birth of Louise Brown, the ever IVF baby. For more on the Warnock Committee and report see The HFEA (2009) "Warnock Report" available at http://www.hefa.gov.uk/2068.html accessed 7/ 8/ 2010.
[135] Hereafter referred to as the HFEA.
[136] Hereafter referred to as the HTA.

clinical application thereof.[137] The HFEA is responsible for regulating the procurement of gametes and any related processing which is involved in the creation of an embryo. The HFEA's scope of functions includes the use of embryos but excludes the regulation of stem cell lines themselves. This is where the HTA steps in and it is thus responsible for the regulation of processing, storage and distribution of stem cell lines intended for human therapeutic application.[138] The HTA's regulatory role thus starts or takes over from the HFEA when the embryo is dissociated during the derivation of a stem cell line.[139] It is thus important to discuss the HFEA and HTA separately.

4.1.1 The HFEA

The HFEA was established in August 1991 as part of the Human Embryology and Fertilisation Act of 1990 as has the primary goal of licensing[140] and monitoring institutions such as clinics which carry out *in vitro* fertilisation,[141] donor insemination and human embryo research as well as the regulation of storage of gametes and embryos. The HFEA is the independent regulator of IVF treatment and embryo research. This then makes the HFEA responsible for the protection of patients and the public, the promotion of improvement in treatment and research and to educate and inform the public and policymakers in this regard.[142] As mentioned above the HFEA was established under the Human Fertilisation and Embryology

[137] HTA (2008) "Position statement on regulating human embryonic stem cell lines for human application" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/positionstatementonregulatinghumanembryonicstemcelllinesforhumanapplication.cfm accessed 8/ 7/ 2010.
[138] Under the Human Tissue (Quality and Safety for Human Application) Regulations of 2007.
[139] Once fully characterised and cultured the stem cells are deposited in a stem cell bank within the UK and from here fall under the regulatory power of the Medicines and Healthcare Products Regulatory Agency.
[140] The HFEA licences procurement and processing, storage and treatments. Procurement and processing includes the procurement, processing and distribution of gametes and embryos. Storage is the storage of eggs, sperm and embryos. The treatments which are licensed by the HFEA include insemination, IVF, intra-cytoplasmic sperm injection, treatment with donor gametes or donor embryos, preimplantation genetic diagnosis, preimplantation genetic screening for aneuploidy, assisted hatching, zona drilling, gamete intra fallopian transfer, zygote intra-fallopian transfer, subzonal insemination and non- medical fertility services. See in general HFEA (2009) "What we license" available at http://www.hfea.gov.uk/139.html accessed 7/ 8/ 2010.
[141] Hereafter referred to as IVF.
[142] HTA (2008) "Position statement on regulating human embryonic stem cell lines for human application" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/positionstatementonregulatinghumanembryonicstemcelllinesforhumanapplication.cfm accessed 8/ 7/ 2010.

Act of 1990. This Act has since been amended by the Human Fertilisation and Embryology Act of 2008.

It could be said that the HFEA plays two important roles. Firstly, as regulator and secondly as provider of information which could be divided into their role to provide guidance and advice and also as provider of improved information. As the HFEA is the independent regulator of eggs and sperm in the UK, it acts according to the following principles in the exercise of its responsibilities:[143]

1. Sensitive, respectful and confidential treatment of persons and their information;
2. Observance of the highest standards of integrity and professionalism in putting into effect the law which governs the HFEA;
3. Wide consultation with the intent of learning from and listening to those with an interest in the field of human fertilisation and embryology;
4. Keeping abreast of current scientific and clinical advances; and
5. To consistently, proportionally, openly and fairly exercise their allocated functions.

Additionally to the above mentioned responsibilities, the HFEA is responsible for the licensing and monitoring of institutions undertaking IVF, donor insemination and human embryo research, the maintenance of a record of clinics, research establishments and storage centres and the implementation of the requirements of the European Union Tissue and Cells Directive.[144]

The advisory role of the HFEA involves numerous aspects and is of importance as the HFEA may determine the policy framework for fertility issues and seeks to guide and advise the public is such matters. The HFEA must therefore investigate serious and adverse incidents and reactions to treatments and keep a register of such incidents or reactions, produce and maintain a Code of Practice which provides guidelines for clinics and research establishments regarding the proper conduct of licensed activities, [145] to maintain a formal register of information about donors, licensed treatments and children conceived and born

[143] HFEA (2009) "Our role as regulator" available at http://www.hfea.gov.uk/135.html accessed 8/7/ 2010.
[144] Hereafter referred to as the EUTCD.
[145] The Code of Practice is available at http://cop.hfea.gov.uk/cop/ accessed 9/ 10/ 2010.

as a result of such treatments, provide relevant advice and information to donor-conceived persons, donors, clinics, research establishments and patients, to review information regarding human embryos and any developments in research which involves human embryos, or the provision of treatment services and activities governed by the Human Fertilisation and Embryology Acts of 1990 and 2008 and lastly to advise the Secretary of State for Health on developments in the relevant fields.[146] The HFEA's role as provider of improved information concerns the keeping of a register and confidentiality issues and the improvement of clinical practice.

The HFEA holds a great quantity of information regarding fertility treatment in the UK and this information is held in a register which is the largest database in the world for information on IVF, donor treatments and the storage of embryos and gametes. This register contains information dating back to 1991 and whenever a patient starts with a treatment and at various periods during such treatment information must, by law, be provided to the HFEA. The register further contains information regarding all children born from infertility treatments and provides donor information to such children born from donated material. Confidentiality is however strictly protected and under the Human Fertilisation and Embryology Act of 1990 this information could not be shared for research purposes. The 2008 Act has however made information more accessible but only certain parts of information and only under strictly defined conditions.[147] The HFEA also strives to improve clinical practice, strengthening patient choice and serving persons affected by donation. This is also done via the register and the HFEA has *inter alia* improved the manner of publication and created a supportive and accessible framework for donors in order to fulfil this role.[148]

[146] HFEA (2009) "Our role to provide guidance and advice" available at http://www.hfea.gov.uk/136.html accessed 7/ 8/ 2010. See in general the List of HFEA publications at http://www.hfea.gov.uk/120.html. These publications serve as the practical implementation of this role of the HFEA.

[147] See in Jones C (2009) "Human Fertilisation and Embryology Act 2008: Promoting wider access to information about genetic origins" available at http://www.bionews.org.uk/page_48473.asp accessed 1/ 11/ 2010.

[148] HFEA (2009) "Our role as an improved information provider" available at http://www.hfea.gov.uk/5443.html accessed 7/ 8/ 2010. For the goals of the HFEA see "Our goals" available at http://www.hfea.gov.uk/137.html accessed 7/ 8/ 2010.

4.1.2 The HTA

The HTA was established in April 2005 under the Human Tissue Act of 2004[149] in order to regulate the removal, storage, use and disposal of human bodies, organs and tissues for the purposes of research, transplantation, education and training.[150] When the EUTCD were transported in UK law on the 5th of July 2007 via the Quality and Safety Regulations of 2007[151] the remit of the HTA's regulatory powers were changed and the HTA is now responsible for the procurement, testing, processing, storage, distribution as well as importation or exportation of tissues and cells intended for human application. The HTA may also approve transplantation of organs and bone marrow from living donors.

The HTA is a watchdog that supports public confidence by licensing the organisations that store and use human tissue for purposes which include research, the treatment of patients, post-mortem examinations of human bodies, teaching, and public exhibitions. The HTA also approves organ and bone marrow donations from living persons. The aim of the HTA is to set the standards which are clear and reasonable, and wherein both the public and professionals can have confidence.[152]

The HTA provides advice and guidance regarding two laws. Firstly, the HT Act of 2004 and the European Union's Tissue and Cells Directives. These are European laws which have been implemented in the UK by the Quality and Safety Regulations. These laws then ensure that human tissue is used in a safe and ethical manner with the proper consent. Consent is specifically provided for in sections 2, 3 and 6 of the HT Act. A further goal of the HTA is to ensure that these laws are followed by setting clear and reasonable standards. The HTA helps people to understand the requirements of the HT Act by providing codes of practice and by giving advice, guidance and support to persons contemplating donation of material

[149] Hereafter referred to as the HT Act.
[150] These purposes are known as "scheduled purposes" as provided for in the Human Tissue Act of 2004. The Human Tissue Act covers the territory of England, Wales and Northern Ireland. Scotland has separate legislation in the form of the Human Tissue (Scotland) Act of 2006. The HTA does however perform certain tasks on behalf of the Scottish Executive.
[151] See footnote 150 *supra*. The regulations cover England, Wales, Northern Ireland and Scotland.
[152] HTA "About us" available at http://www.hta.gov.uk/aboutus.cfm accessed 7/ 8/ 2010.

such as stem cells.[153] As the focus of this dissertation falls on stem cells, it is important to discuss the HTA's statements regarding stem cells and cord blood.

Human stem cells and cord blood, which is very rich in stem cells, are used to undertake research into the causes of and treatments of illnesses and diseases. Stem cells may be used in treatment of patients through such research. Human stem cells may be applied in the treatment of cancer, blood diseases such as leukemia and have the potential to be applied in future in the treatment of brain disorders and those of the nervous system such as Parkinson's disease. The HTA licenses establishments which remove, store, test, process, use or distribute human cells for the purpose of patient treatment and includes the use of cell lines which have been grown outside the human body.[154] The HTA is extremely user-friendly in the provision of information in this regard. The UK Stem Cell Toolkit is an example of this and constitutes an electronic "questionnaire" which may be used by persons or institutions who wish to develop a program for stem cell research. The ToolKit constitutes a consolidation of existing regulatory resources and aids the clarification of the remit regulators.[155]

Umbilical cord blood may be collected at the time of birth and may then be stored, so that it is available for the potential future treatment of the child or other person. Since the 5th of July 2008 any person who collects cord blood must act in accordance with and under the authority of an HTA license. Additionally, those persons who collect cord blood must be appropriately trained to ensure that the collection of cord blood takes place safely and that any such collected samples are not contaminated and are safe to use.[156]

The HTA further regulates research utilising human tissue. Scientists study human tissue in an attempt to improve their understanding of how disease starts and progresses and

[153] HTA "Legislation, policies and codes of practice" available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice.cfm accessed 7/ 8/ 2010.
[154] HTA "Stem cells and cord blood: Stem cells" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/stemcellsandcordblood.cfm accessed 7/ 8/ 2010.
[155] The Toolkit is available at http://www.sc-toolkit.ac.uk/home.cfm accessed 7/ 8/ 2010. The ToolKit has been developed with the support of the Gene Therapy Advisory Committee, and regulators including the HTA and MHRA. It is a demonstration of the regulators, government and funders commitment to working together to help stem cell scientists in the United Kingdom.
[156] HTA "Stem cells and cord blood: Cord blood" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/stemcellsandcordblood.cfm accessed 7/ 8/ 2010.

also what keeps humans healthy. Research often leads to different manners to diagnose disease and may be helpful in the development of new treatments. Examples of types of research involving human tissue include *inter alia* development of screening tests for different types of cancer, the testing of new treatments for conditions such as heart disease and researching the manners wherein stem cells could be used to treat conditions such as multiple sclerosis. The HTA licenses organisations which store human tissue for research and ensures that tissue is removed and stored under appropriate and well managed conditions.

4,2 RELEVANT UK LEGISLATION

4.2.1 The Human Fertilisation and Embryology Act[157]

The Human Fertilisation and Embryology Act of 1990[158] was amended by the 2008 Act after the British parliament announced in January 2004 that the 1990 Act should be reviewed.[159] This was due to the fact that it was deemed necessary to update the law in response to the technological developments which had occurred since 1990. For this reason the 2008 HFE Act will mainly be discussed here but reference will be made to the 1990 Act where appropriate.

The 1990 Act was drafted after a 1987 White Paper was published titled Human *Fertilisation and Embryology: A Framework for Legislation*. On 1 November 1990 this cornerstone piece of legislation received Royal Assent. The key features to the 1990 Act were that it established the HFEA which was the first ever statutory body of its kind and thus the regulation and licensing of the creation of embryos outside of the body for treatment and research purposes, the use of donated gametes and embryos as well as the storage thereof

[157] Hereafter referred to as the 2008 HFE Act.

[158] Hereafter referred to as the 1990 Act. HFEA (2009) "HFE Act 1990" available at http://www.hfea.gov.uk/2070.html accessed 7/ 8/ 2010. See in general Morgan D & Lee RG (1991) *Blackstone's guide to the Human Fertilisation and Embryology Act, 1990: Abortion and embryo research, the new law* Blackstone: London.

[159] This happened after the House of Commons Science and Technology Select committee published a report on human reproductive technologies and the law. This lead to an investigation of the legislative framework as provided for by the 1990 Act. See in general HFEA (2009) "Development of the HFE Act 2008" available at http://www.hfea.gov.uk/134.html accessed 7/ 8/ 2010. For the Report on human Reproductive Technologies and the Law see http://www.publications.parliament.uk/pa/cm200405/cmselect/cmsctech/7/702.htm.

was regulated. Various changes occurred during the years that followed and thus the 1990 Act was eventually amended. The following timeline illustrates the changes to legislation which ultimately lead to the 2008 HFE Act:[160]

1. 1991: the Human Fertilisation and Embryology (Statutory Storage) Regulations[161] allowed for storage periods for sperm and eggs to be extendable in certain situations. In the same year the Human Fertilisation and Embryology (Special Exemptions) Regulations[162] were created which set out the license committee and appeals structure of the HFEA;
2. 1996: the Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations[163] permitted extended storage periods for embryos in prescribed circumstances;
3. 2001: the purposes for which embryo research was permitted was extended to include "increasing knowledge about the development of embryos", "increasing knowledge about serious disease" and "enabling any such knowledge to be applied in developing treatments for serious disease" by the Human Fertilisation and Embryology (Research Purposes) Regulations.[164] This resulted in embryonic stem cell research; and
4. 2004: donor- conceived children were given access to the identity of the sperm, egg or embryo donor at the age of 18 by the Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations.[165]

The Human Fertilisation and Embryology Bill was in Parliament for a year before receiving Royal Assent on 13 November 2008.[166] Although the main goal of the 2008 HFE Act is to

[160] HFEA (2009) "Changes to legislation" available at http://www.hfea.gov.uk/2221/html accessed 7/8/2010.
[161] Human Fertilisation and Embryology (Statutory Storage) Regulations 1991/1540.
[162] Human Fertilisation and Embryology (Special Exemptions) Regulations 1991/1588.
[163] Human Fertilisation and Embryology (Statutory Storage Period for Embryos) Regulations 1996/375.
[164] Human Fertilisation and Embryology (Research Purposes) Regulations 2001/188.
[165] Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004/1511.
[166] The 2008 HFE Act was implemented in stages. On 6 April 2009 the revised definition of "parent" took effect. The amendments to the 1990 Act took effect in October 2009 and in April 2010 persons of the same sex in partnerships and unmarried couples were allowed to apply for recognition as parents of children born as result of surrogacy. Department of Health (2010) "Human fertilisation and embryology act 2008" available at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211 accessed 7/ 8/ 2010. The regulations made under the 2008 HFE Act have also come into force as of the 1st of October 2009 and offer greater clarity regarding certain provisions of the 2008 HFE Act. The regulations are: The Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations, the Human Fertilisation and

amend the 1990 Act, the following are also key provisions, which are relevant to this dissertation, of this Act:[167]

1. To ensure that all human embryos outside of the body are subject to regulation;
2. Ensure the regulation of chimera- embryos created from human and animal genetic material for research;[168]
3. To prohibit sex selection of offspring for non-medical reasons;[169]
4. Recognition of same-sex couples as legal parents of children conceived by way of donated sperm, eggs or embryos;[170] and
5. To alter the restrictions on the use of data collected by the HFEA to help enable follow-up research related to infertility treatment.

The 2008 HFE Act has been divided into three parts. Firstly the amendments to the 1990 Act,[171] secondly the 2008 HFE Act deals with parenthood and lastly, part 3 deals with miscellaneous and general provisions.[172]

It is submitted that a separate body which controls and regulates embryos in South Africa must be established and that such body must function alongside a body which deals with stem cells and stem cell lines. The disclosure of donor information as allowed by the 2008 HFE Act is however excluded from this submission as it would grossly violate privacy and dignity as is protected by the Constitution. The HFEA and the HTA work together to regulate

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Embryology (Procedures for Revocation, Variation or Refusal of Licences) Regulations, the Human Fertilisation and Embryology (Appeals) Regulations and the Human Fertilisation and Embryology (Disclosure of information for research purposes) regulations.

[167] Department of Health (2010) "Human fertilisation and embryology act 2008" available at http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211 accessed 7/ 8/ 2010. See also HFEA (2009) "The HFE act (and other legislation)" available at http://www.hfea.gov.uk/134.html accessed 7/ 8/ 2010.

[168] It is submitted that South Africa should follow this model.

[169] Sex selection is only permitted for medical reasons such as to avoid a serious disease that only affects boys.

[170] This enables the civil partner of a woman who carries a child via IVF to be recognised as the child's legal parent for example.

[171] Part 1 of the 2008 HFE Act, including Schedules 1 to 5 amend the 1990 Act in order to take account of scientific developments, to reflect the changes which have occurred in social attitudes towards this technology and to update the HFEA's ability to regulate and monitor. See the explanatory notes on the 2004 Act at http://www.legislation.gov.uk/ukpga/2008/22/notes/division/4/1?type=en which was accessed 7/8/2010.

[172] See in general McCandless J & Sheldon S (2010) "The human fertilisation and embryology act (2008) and the tenacity of the sexual family form" *The Modern Law Review* March 73(2): 175- 207.

this technology in the UK and it is thus important to examine the Human Tissue Act of 2004 in order to understand the competencies and the role of the HTA.

4.2.2 The Human Tissue Act[173]

The Human Tissue Act[174] was passed by Parliament on the 15th of November 2004 and repealed the Human Tissue Act of 1961, [175] the Anatomy Act of 1984,[176] the Corneal Tissue Act[177] and the Human Organ Transplants Act of 1989.[178] The HT Act however only came into force on the 1st of September 2006 as subordinate legislation first had to be passed and the HTA had to be established.[179] The HT Act covers the removal, storage[180] and use of "relevant material"[181] from deceased persons and organs intended for transplantation. The Act also only regulates the storage and use of relevant material in the case of living persons while the removal of tissue from a living person is regulated by common law principles and thus informed consent is required. Practically speaking, the HT Act sets two fundamental requirements to be met by researchers. Firstly, consent must be obtained for storage and use of relevant material and secondly, a license must be obtained for such storage or use.[182]

According the HT Act it is unlawful to undertake activities using relevant material if such activities are not sanctioned under the Act. Lawful activities are thus the activities which

[173] It is interesting to note the following key aspects of the HT Act: 1. The HT Act regulates the removal, storage and use of human tissue. This is defined as material which originates from a human body and consists of or includes human cells; 2.It creates the new offence of DNA 'theft'. It is therefore unlawful to posses human tissue with the intention of analysing the DNA thereof without the consent of the person from whom the tissue was obtained; and 3. The HT Act provides for lawful minimum steps to preserve organs of a deceased person for use in transplantation. See HTA "Human Tissue Act 2004" available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm accessed 7/8/2010.
[174] The Human Tissue Act, Act 30 of 2004. Hereafter referred to as the HT Act.
[175] The Human Tissue Act, Act 54 of 1961.
[176] The Anatomy Act, Act 14 of 1984.
[177] The Corneal Tissue Act, Act 18 of 1986.
[178] The Human Organ Transplants Act, Act 31 of 1989.
[179] Cooke E (2007) "Unpacking the Human Tissue Act 2004" *Research Ethics Review* 3(1): 61 at 61.
[180] "Storage" is not defined in the HT Act but in the HTA Code of Good Practice as "maintaining the tissue under appropriate controlled conditions."
[181] "Relevant material" is defined in section 53(1) of the HT Act as "material other than gametes, which consists of or includes human cells." Section 53(2) excludes embryos outside of the human body, hair and nails from the definition. Blood and tissue samples are thus regulated by the HT Act as they comprise of cells but DNA falls outside of the scope of this definition as it does not consist of cells. According to Cooke this definition is derived from the purpose of the Act. See Cooke (2007) *Research Ethics Review* 61 at 61.
[182] Cooke (2007) *Research Ethics Review* 61 at 61.

may be undertaken for a specific purpose as listed in schedule 1 of the Act. The appropriate consent is required and as not all activities may be carried out for all purposes, four categories have been identified. Firstly activities allowed for all lawful purposes specified in the Act under all parts of Schedule 1. These activities include the storage of a deceased body and removal of relevant material from such body[183] and then for the purposes of *inter alia* anatomical examination, public display and transplantation.[184] Secondly activities allowed only for the purposes specified in Part 1 of Schedule 1 may be identified. These activities are the storage of relevant material and the use thereof[185] and the permitted activities are far fewer than in the previous category.[186] The third category deals with activities allowed only for the purposes specified in Part 2 of Schedule 1 which is thus the storage and use of relevant material from deceased persons.[187] Finally the fourth category relates to activities which are specified in the Act. This is the use of a body of a deceased person for other purposes than anatomical inspection.[188]

The HT Act contains provisions regarding the appropriate informed consent.[189] Consent requirements however, subtly vary according to the person giving consent. Provision is thus made for the consent of adults,[190] children[191] and incapacitated persons.[192] The *Codes of Practice* as set up by the HTA define the consent requirements in more detail.[193] The HT Act further provides for situations wherein the HTA may dispense of the consent requirement

[183] Sections 1(1)(a) and (c) of the HT Act.
[184] There are 12 permitted purposes. They are anatomical examination, determining the cause of death, establishing after a person's death the efficacy of any drug or other treatment administered to him, obtaining scientific or medical information about a living or deceased person which may be relevant to any other person or a future person, public display, research in connection with disorders or the functioning of the human body, transplantation, Clinical Audit, education or training relating to human health, performance assessment, public health monitoring and quality assurance.
[185] Sections 1(1)(d) and (f) of the HT Act.
[186] There are 7 purposes which are allowed: aanatomical examination, determining the cause of death, establishing after a person's death the efficacy of any drug or other treatment administered to him, obtaining scientific or medical information about a living or deceased person which may be relevant to any other person, public display, research in connection to disorders or the functioning of the human body and transplants.
[187] Sections 1(1)(e) and (g) of the HT Act. Only clinical audit, education or training related to human health, performance assessment, public health monitoring and quality assurance are lawful purposes in this case.
[188] Section 1(1)(b) of the HT Act.
[189] See in general Kaye J (2004) "A guide to the Human Tissue Act: What is 'appropriate consent'?" available at http://www.ethics-network.org.uk/commentaries/a-guide-to-the-human-tissue-act-2004 accessed 6/8/2010.
[190] Section 2 of the HT Act.
[191] Section 3 of the HT Act.
[192] Section 6 of the HT Act.
[193] See in general HTA "Code of good practice 1: Consent" available at http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm accessed 6/ 8/ 2010.

such as situations with an untraceable or undecided donor.[194] Offences are also provided for under that HT Act and these include *inter alia* the failure to obtain consent[195] and false representation of consent or lawfulness of the activity.[196] Offences may be committed by individuals and by a body corporate and thus personal criminal liability is possible under section 49 of the HT Act.

Lastly, the HT Act ensures the regulation of activities using relevant material by the establishment of the HTA[197] by licensing these activities.[198] The licensing requirement is separate from the consent requirement and it is important to note that such licence need only be obtained where an institution stores relevant material for research purposes and not for the research itself.[199]

In conclusion it is submitted that a South African body which regulates stem cell technology must be established and must then control and monitor such technology and related activities by granting a license to institutions undertaking such activities.

4.2.3 The European Union Tissue and Cells Directives

The EUTCD introduced common safety and quality standards for human tissues and cells within and across the European Union and the purpose of the directives was to facilitate a safer and simpler exchange of tissue and cells between EU Member States and to improve safety standards for European citizens. Human eggs and sperm also fall within the scope of the directives. On 2 March 2004 the EUTCD were adopted by the Council of Ministers and they were published in the *Official Journal of the European Union* of the 7th of April 2004 from which date Member States of the EU were obliged to comply therewith.[200] The European Commission required Member States to bring into force, from the 7th of April 2006, the laws, regulations and administrative provisions which would be necessary to

[194] Section 7 of the HT Act.
[195] Section 5(1) of the HT Act.
[196] Section 5(2) of the HT Act.
[197] Sections 13- 15 of the HT Act.
[198] Section 16- 25 of the HT Act.
[199] Cooke (2007) *Research Ethics Review* 61 at 62.
[200] HFEA (2009) "European Union Tissue and Cells Directives" available at http://www.hfea.gov.uk/2071.html accessed 7/ 8/ 2010.

comply with the Parent Directive.[201] In order to do so, the HTA commenced licensing the storage of tissue and cells and issued Directions[202] to all licensed establishments. The Directions were a summary of the Parent Directive and had to be complied with by April 2007.

The Parent Directive as well as the first and second technical directives were formally adopted into UK law on the 5th of July 2007 and this was done via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which are discussed below. The HTA then sent out a second Direction[203] which stated the requirements of the second technical directive and supplemented and amended the Directions of 2006. On 7 October 2007 Directions 004/2007 came into force and dealt with tissue and cells from non- European Economic Area states and set requirements for the quality, safety and traceability of such tissues or cells. Directions 001/ 2006, 002/2007 and 004/2007 were however revoked by the signing into law of Direction 003/2010 on the 12th of November 2010. It clarifies and consolidates the standards as required in the Human Tissue (Quality and Safety of Tissues and Cells for Human Application) Regulations.[204]

It should be noted that the EUTCD comprises four directives. They are as follows:

1. The First Commission Technical Directive.[205] This directive deals with standards for donation, procurement and testing, processing, preservation, storage and distribution of human tissues and cells;
2. The Second Commission Technical Directive.[206] Donation, procurement and testing of tissue and cells are covered in this directive; and
3. The Third Commission Technical Directive.[207] The Third Commission Technical Directive provides the standards for traceability, notification of serious adverse reactions and events, requirements for coding processing, preservation, storage and distribution.

[201] The Parent Directive (Directive 2004/23/EC).
[202] HTA Directions 001/2006.
[203] HTA Direction 002/2007.
[204] HTA (2010) "Quality and Safety Regulations FAQs" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/qualityandsafetyregulationsfaqs.cfm accessed 15/ 11/ 2010.
[205] The First Commission technical directive (Directive 2004/23/EC).
[206] The Second Commission Technical Directive (Directive 2006/17/EC).
[207] The Third Commission Technical Directive (Directive 2006/86/EC).

The directives were absorbed into the 1990 Human Fertilisation and Embryology Act via the Quality and Safety for Human Application Regulations in 2007. The Regulations are thus discussed next.

4.2.4 Human Tissue (Quality and Safety for Human Application) Regulations 2007

The Human Tissue (Quality and Safety for Human Application) Regulations[208] is a statutory instrument whereby the EUTCD were incorporated into the law of the UK. The storing of human tissue and cells intended for human application will only be lawful where the participating establishment is licensed to do so. Some activities may however also be lawful under a third party agreement with an establishment which does carry a license. These activities are procurement, testing of donor samples, processing, import or export of tissues or cells and distribution.[209] Establishments licensed under the HT Act of 2004 are automatically considered licensed and may carry out the previously mentioned activities as well as the storage of tissues and cells. Establishments are thus licensed under the HT Act to store materials. Where cell lines are stored for the purpose of human application a license is required except if such storage is regulated by the Medicines and Healthcare Products Regulatory Agency.

Two important changes from the HT Act 2004 have been made under the Quality and Safety Regulations. Firstly, the role of the Designated Individual.[210] The designated individual must now possess a formal qualification in a biological or medical field or must be considered appropriate by the HTA on the grounds of other qualifications. Such a person must also have at least two years experience in a relevant field. The additional duties, of which the designated individual must make sure, are now as follows:[211]

1. That persons to whom the license is applicable must be a suitable persons to carry out the licensed activity;

[208] Hereafter referred to as the Quality and Safety Regulations.
[209] HTA (2010) "Quality and Safety Regulations FAQs" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/qualityandsafetyregulationsfaqs.cfm accessed 15/ 11/ 2010.
[210] Section 18 of the HT Act.
[211] Regulation 12 of the Quality and Safety Regulations.

2. That suitable practices are used during the carrying out of such activity;
3. That the conditions of the license are complied with
4. That the conditions of third party agreements are carried out; and
5. That the requirements regarding information and confidentiality which includes traceability are complied with.

The second change which was brought about by the Quality and Safety Regulations concerns the role of the license holder. The license holder must now be involved in the making of any third party agreements. Additionally the license holder must ensure compliance with Directions issued under the Regulations.[212]

What is of great importance is the fact that the Regulations may provide for a coding system. This means that a unique code is given to each donation and product and would require a link from donor to recipient. It is submitted that South Africa should employ a coding system but should this be done, it must be kept highly confidential as privacy must still be protected.

In conclusion it is recommended that two separate bodies must be established in South Africa, each with its own individual remit and function. One such body must control and regulate embryos and related matters and the other, stem cells and related matters. An important aspect of such regulation will then be licensing of institutions to lawfully carry out prescribed activities. It is submitted that the UK model as discussed in this section of the dissertation should be closely followed but that a uniquely South African approach will have to be incorporated in order to take cognisance of *inter alia* the diversity of the population, the current state of medicine and medical establishments and services and especially the Constitution.

[212] HTA (2010) "Quality and Safety Regulations FAQs" available at http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/qualityandsafetyregulationsfaqs.cfm accessed 15/ 11/ 2010.

5 CONCLUSION

In the course of this dissertation a layered approach has been followed which has resulted in the final layer being an examination of the proposed legislation regarding stem cells in the form of chapter 8 of the NHA. This final layer must thus encompass the science and manifestations of stem cells, the constitutional aspects thereof, relevant ethical principles and also the foundational principles of medical law. The purpose of this chapter was thus an examination of the proposed legislation and this was done from a critical point of view. Many anomalies were identified and the fact that chapter 8 is currently still not fully operational leads to the ultimate conclusion that this is a sub par piece of legislation. This conclusion becomes even more concerning when taken into account that it is, as supplemented by various Regulations, the only hard law which has been devised within South Africa to address this astounding new form of medicine and science known as stem cell technology.

Although a working group has attempted to revise chapter 8 as is, the recommendations and findings of the group are confidential and not intended to be published. For that reason it is simply mentioned here but not discussed in any detail. In the course of this chapter however, various recommendations were made pertaining to the issues and anomalies identified in chapter 8.

The NHA is not in force and this presents a difficult situation as South Africa is left in a legislative vacuum. It was thus recommended that some form of hard law must be brought into law as soon as possible. This should however only be done once the identified problems have been corrected in chapter 8. Firstly, the creation of embryos should be regulated in chapter 8 of the NHA. In this regard attention may be given to the Human Fertilisation and Embryology Act of 2008 and it is recommended that a statutory body must be established, based on the model of the HFEA in order to regulate and monitor the activities surrounding embryo creation, whether for reproductive purposes such as IVF treatment or for research purposes such as spare embryos or human- animal hybrid embryos.

It is necessary to add a definition of “stem cell” which is biologically correct in the NHA. It must define with certainty what a stem cell is, but must be open ended enough to include embryonic and adult stem cells as well as perhaps some progenitor cells found in the human

body such as bone marrow progenitor cells. To provide the NHA some degree of flexibility, an umbrella term such as "biological material" may possibly be a valid alternative to the express mention of stem cells, as various materials may be included under such a term and it would not limit the provisions of chapter 8 to embryonic stem cells and thus leave space for the application thereof to adult stem cells. A definition of blood transfusion service must further be added to the NHA as well.

Authorised institutions should be permitted to acquire, use or supply biological material as well as store, process and analyse such material. This will result in a centralised regulating body which may then control all activities concerning stem cells. Further, the range of material which may be subjected to these prescribed activities must be elaborated on so that the NHA is more inclusive and thus afford better protection to the patient, research participant and public but also the person or institution undertaking such activity as the parameters of such activity and which material may be utilised will be certain. Research should be specifically recognised as a permitted activity. Also, consent should be specifically addressed as consent may differ according to what materials are to be used.

The prohibition of reproductive cloning is almost unnecessary and could merely have been mentioned in a section devoted exclusively to prohibitions and offences. It is thus recommended that such a section be added to chapter 8. It indicates a lack of understanding as to what must be regulated and how on the part of the legislator. It further reiterates the fact that an independent body of regulatory authority is necessary.

Misconceptions and incorrect information may then also be addressed by the establishment of an independent body or authority. Such body must be responsible for the protection of patients and the public, promote and improve treatment and research and must educate and inform the public and policymakers of issues concerning stem cells. Such authority must also be responsible for the licensing and monitoring of institutions undertaking the prescribed activities.

In conclusion it is therefore recommended that chapter 8 of the NHA will have to undergo drastic amendments or that a completely new and separate Act must be created specifically relating to stem cells. The disjointedness of the current position, wherein neither the NHA not the regulations are in force but are the regulatory legislative tools only leads to more

confusion regarding stem cells. Perhaps a completely separate and new Act must be drafted in order to provide one comprehensive regulatory document. Furthermore, two separate bodies should be established in South Africa, each possessing its own individual remit, powers and functions. One such body must control and regulate embryos and related matters and the other stem cells and related matters. Licensing will play an important role in any such attempted control and regulation of activities.

CHAPTER 7
CONCLUSION AND RECOMMENDATIONS

1 CONCLUSION

This dissertation has illustrated that there is indeed a wondrous new potential in healing to be found in stem cell technology and that the human application of stem cell therapy may in actual fact decrease human suffering. In spite of this however, stem cells and stem cell technology has caused much controversy. It is exactly this controversy and unease which has resulted in an examination of the legal position and status of stem cell technology in South Africa. The primary goal of this dissertation was thus an analysis of the proposed regulation of the procurement and distribution of stem cells within South Africa, to identify the problems encountered in the proposed legislation and regulatory instruments and to make certain recommendations for the improvement thereof.

Firstly, a lack of knowledge regarding stem cell concepts, manifestations and science was identified and addressed in this dissertation by an explanation thereof. The second problem which was identified was the constitutional status of stem cells and stem cell technology and whether or not stem cell research and therapy could be justified under the Constitution. Further issues in this regard were found in the question as to whether or not certain fundamental rights could be applied to embryos as embryos are a source of stem cells and in other cases how particular constitutional provisions would impact the person participating in stem cell research or therapy. Another problem was identified in the ethical regulation of stem cells. Ethics have had to play the role of regulator in the absence of in force law and yet, it does not carry the power of law. This means that ethics may be of advisory value in future and will further provide flexibility to stem cell legislation but it is not enforceable in the same manner as law.

Another issue which was identified in the course of this dissertation is the obtaining of consent. Specifically issues pertaining to whom may consent, what such person should be informed of and when consent should be sought were discussed. Also, a distinction must be made between consent sought for medical application of stem cells and the consent which is required for participation in stem cell research. This even further complicates this subject.

This dissertation therefore attempted to identify various legal and ethical issues which would have an impact on chapter 8 of the National Health Act in order to analyse the proposed regulatory framework for the procurement and distribution of stem cells. In pursuit of such analysis certain conclusions were arrived at and these are summarised in the following section of this dissertation.

2 OVERVIEW OF CHAPTERS

Chapter 2 dealt with the clinical aspects of stem cells and it was found that stem cells offer hope that previously considered incurable diseases, may in fact be cured in future and that damaged tissue may be replaced by regenerative medicine. In order to create an environment where in the development of stem cell technology may take place however, regulation is necessary and such regulation should be informed and have knowledge of the science and manifestations of stem cells. Chapter 2 thus explained that stem cells are cells with the ability to indefinitely renew and proliferate which results in a phenomenon of immortality on behalf of the cell. Stem cells then also have the unique ability to become any other cell as it is unspecialised.

Stem cells are however different from one another in the sense that not all stem cells are equally committed to a tissue type. The plasticity of a stem cell thus allows for a hierarchy to be identified which ranges from totipotent as the most unspecialised to the almost completely specialised unipotent stem cells.

The sources of stem cells were explained and much attention was paid to embryonic stem cells, adult stem cells and stem cells created by somatic cell nuclear transfer and induced pluripotency. The development of technologies which involve adult or created stem cells is encouraged as this would nullify the need for embryonic stem cells and would diminish most of the ethical concerns standing in the way of stem cell research and therapy. SCNT and iPS cells are however still controversial as SCNT utilises cloning procedures and iPS cells may carry cancerous genes. For this reasons an eye must be kept on the development of induction techniques which do not require retroviruses.

Chapter 3 attempted to examine the relevant constitutional provisions in context of stem cell technology and various conclusions were made in the course of this chapter. Firstly the embryo protection trend does not take away from constitutional values and stem cells debates will have to be approached differently. Section 36 must then be utilised in balancing interests and resolving conflicts between fundamental rights. Stem cell legitimacy will then be judged on this basis.

It was found that section 9 applies to women and not to the fetus and embryo in context of stem cell technology in that equality is rather sexual equality and not merely protection against discrimination. It is intrinsically linked to human dignity and dignity to life and it was also found that the embryo is not entitled to human dignity or to the right to life as the use of the word "everyone" does not intended to create a new class of rights bearers protected under the Bill of Rights. Induced pluripotency will eliminate this issue in any event. Furthermore, the embryo and fetus do not qualify as a child in terms of section 28.

Regarding freedom and security of the person and specifically bodily and physiological integrity it was submitted that the embryo can never consent and the consent requirement which is constitutionally mandated is relevant to the donor or recipient of stem cells.

Privacy is connected to stem cells by way of the shared interests in that destruction of an embryo and is protected by section 14. The privacy matter here is the interest in making private and personal decisions and it is thus also only relevant to the donor or recipient and not the embryo. The further personal matter of conscience, religion, thought, belief and opinion was examined and it was found that it may be utilsed as grounds of refusal to partake in stem cell technology in the form of therapy by health care providers. Section 36 will then be necessary to balance the rights involved in such circumstances. Section 36 will also feature in balancing certain rights and interests such as the right to freedom of scientific research. This right must be acknowledged and respected.

Socio- economic rights were discussed and it was stated that the right to reproductive health care services should include certain aspects of stem cell therapy, especially in circumstances where no alternative is available. Lastly, particular constitutional aspects were discussed relating to stem cell banking and it was found that state interference in

access to stem cell banking is unconstitutional and unjustifiable. Most importantly the need for specialised provisions regarding the regulation of stem cells was found.

The ethical aspects of stem cell technology raise various controversial and important issues and most of the issues relate to the sources of stem cells. Chapter 4 thus dealt with the ethical framework of regulation. Numerous ethical issues were discussed in this chapter and it was ultimately concluded that bioethics must play a leading role in the making of decisions which in the development and application of research. This is due largely to the fact that medical practice and the law whereby it is regulated operate in a moral. Medical law is thus also inseparable from medical ethics and can stand in the absence of an understanding of relevant ethical tensions. Ethics must however not be confused with hard law, even in a legislative vacuum such as the one we currently find ourselves in as ethics will never have the power of law. This does however not mitigate from the finding that ethics must be used in an advisory capacity as this will provide any proposed and future stem cell legislation much needed flexibility and moral credence.

It must be mentioned that issues regarding stem cell banking were briefly discussed and it was found that this constitutes a field which is in need of further study and that specialised legislation in this regard is required.

Chapter 5 dealt with informed consent and it was found that consent is a process whereby an agreement is made to partake in a specified medical or scientific activity and that is a prerequisite for participation in any medical or scientific activity. It does however remain a complex and controversial subject in South African medical law as the nature, scope, application and boundaries of this doctrine are especially controversial in context of stem cell technology. The common law must be developed and attention must perhaps be given to shared decision making.

A distinction was made between treatment or therapy and research and treatment was found to be an activity which has the sole purpose of benefiting the patient where there exists a reasonable chance of success, while research is a systematic search or inquiry of knowledge. Research does therefore not directly benefit the person who is subjected to the research but is generalised. Research may then also be subdivided into therapeutic research which is characterised by the attribute thereof that it is of direct benefit to the person

undergoing or participating in the activity and non- therapeutic research which benefits general scientific knowledge and does not directly promote the health of the participant.

Autonomy was discussed and it was found that stem cell technology is concerned with the autonomy of a born person and not with the supposed autonomy of an embryo or cell. Autonomy issues in context of stem cells therefore relate to the donor of the material. A strict interpretation of section 12(2)(c) of the Constitution, regarding the word "their" does not create a new class of rights bearers and does therefore not prohibit stem cell research. The donor or recipients consent must thus be acquired. This discussion was then followed by a discussion regarding who may and must consent according to national legislation. A capacitated adult person may consent to a proposed activity as well as a minor where such minor is capable of understanding certain aspects of the activity and the additionally required consent is provided. The provisions of the National Health Act regarding the time of obtaining consent as well as what the consent process must entail were also discussed. A proposed consent protocol was created in the course of this chapter which provides for some clarity in this regard but it is submitted that the subject of consent in context of stem cell technology requires further study.

Lastly, chapter 6 provided an analysis of chapter 8 of the National Health Act and it was ultimately concluded that the National Health Act is not a sufficient enough legislative tool to properly regulate stem cell technology. Certain shortcomings may however be addressed by a comparative study of United Kingdom legislation, the Human Tissue Act of 2004 and the Human Fertilisation and Embryology Act of 2008, and then also the establishment of a stem cell regulatory body which should be based on the model as provided for by the Human Fertilisation and Embryology Authority and the Human Tissue Authority.

In conclusion it was recommended that chapter 8 of the NHA undergo drastic amendments or even that a completely new and separate Act be created which deals specifically with stem cells in South Africa. The fractured nature of the current legislative tools, wherein neither the NHA not the regulations are in force is greatly unsatisfactory and only results in more confusion, uncertainty and controversy regarding stem cells. Perhaps a new "Stem Cell Act" must be drafted to provide for a single, comprehensive regulatory document. Also, two separate regulatory authorities should be established in South Africa, each with its own

individual remit, powers and functions. One such body must control and regulate embryos and related matters while the other authority regulates stem cells and related matters. Licensing will play an important role in any such attempted control and regulation of activities.

3 SUMMARY OF REGULATORY RECOMMENDATIONS

In the course of this dissertation two sets of recommendations were made which might resolve some of the issues in the regulation of stem cell technology. The first pertains to what should be covered in the consent process and the second concerns problems identified in chapter 8 of the National Health Act.

3.1 RECOMMENDATIONS REGARDING THE PROCESS OF OBTAINING CONSENT

The abundance of issues related to informed consent in context of stem cell technology requires clarification by legislation or guidelines. It is thus recommended that any proposed research protocol should follow the following format. Firstly, such protocol must contain the title of the research, person or institution undertaking the research or performing the treatment, background information and explanation of the research or treatment, methods which will be employed, a statement of the purpose and benefits of the research or treatment as well as a statement of the risks of the research or treatment, duration of approval of the applicable ethics committee and finally the required consent form.

Secondly, the consent section of the research protocol must contain, at the very least the following:

1. An explanation of what specifically is being consented to: removal, withdrawal or donation of the embryo, fetus or somatic cells;
2. Purpose of the proposed removal, withdrawal or donation;
3. Alternative options of use: research, therapy or education;
4. Methods and procedures of removal, withdrawal or donation;
5. Potential for real harm or risks;
6. Expected benefits;
7. Options regarding storage and time limits thereof;
8. The manner in which removed, withdrawn or donated material may be destroyed or disposed of;

9. The option to renew or revoke consent for any of the above;
10. Extent to which privacy and confidentiality will be protected;
11. Incentives to participate; and
12. Proof of Ethics Committee approval.

3.2 RECOMMENDATIONS REGARDING CHAPTER 8 OF THE NATIONAL HEALTH ACT

Concerning chapter 8, it is recommended that:

1. Provision be made for the creation of embryos outside of the human body. This must include regulation of IVF embryos which were not used. Embryos must however not be created solely for research purposes and only IVF treatment spare embryos may be utilised in research.
2. A definition of stem cells must be provided for. An umbrella term, such as "biological material", under which embryonic and adult stem cells may be included may also offer an alternative to this and should be added to section 1 of the National Health Act.
3. A definition of "Blood transfusion service" must be provided in context of section 53.
4. The remit of authorised institutions should include acquisition, use, supply, store, processing and analysis of biological material.
5. Section 55 must be broadened to include stem cells or an umbrella term in order to permit the removal or withdrawal thereof.
6. Research should be recognised as a permitted activity under section 56 of the NHA and specific consent provisions regarding consent must be made.
7. The prohibition of reproductive cloning must be grouped under a newly created section pertaining exclusively to the prohibitions and offences under chapter 8 of the National Health Act.
8. The ambit of section 58 must be broadened to provide for an environment or place wherein stem cells or biological material may be removed and monitored and is subject to strict regulation.
9. The definition of "competent person" must be broadened to include a researcher and "research" must be added to the scope of section 59.

10. Only authorised institutions should deal with the trade and financial implications involved in stem cells.
11. Stem cells should be included under the material which may be donated.

4 CONCLUDING REMARKS

Stem cell technology requires various social, ethical and legal issues to be resolved and this may be done by a specialised regulatory regime which must entail an amended chapter 8 or newly created legislation and also, an independent regulatory body. Such regulation will have to be liberal, flexible and legally sound while still scientifically correct and morally supportive. By so doing South Africa may become a world leader in stem cell technology regulation and stem cell practice. South Africa is currently the only African country in a position to pursue stem cell technology and this must be seen as a social responsibility towards those who suffer from disease and illness which may be cured by the application of stem cell therapy as regenerative medicine.

In spite of opposition on moral, ethical and religious grounds, a well structured, proper system of regulation will ensure acceptance of stem cell technology and in so doing hope may become real and the promise of stem cell technology actualised.

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1 EXPLANITORY NOTES

In the main body of this dissertation each chapter may be seen as an entity of its own regarding referencing:

1. The initials of authors are provided for in every first reference to a specific source and thereafter only the surname is used.
2. Journal articles are referred to completely in the first occurrence of reference thereto and thereafter only by the recognised abbreviation. The full names of journals have been provided in the bibliography below and thus no table of abbreviations is provided. Where different authors have published articles in the same journal and both articles are referred to in one chapter of this dissertation, the full reference of the journal name will appear in both first references to such authors.
3. Regarding books, publishers details have been provided for in the bibliography below and do no not appear in the main body of this dissertation.
4. Online sources are referred to fully in the first reference thereto which includes the URL. Thereafter only a short reference is made thereto with the URL again provided for there in the bibliography.
5. Cases appear in italics in the main body of this dissertation and the completer reference number of the case is given in the first reference thereto in each chapter. Where the case is referenced thereafter only the name is given and not the number which may be found here.
6. The figures which appear in this dissertation where created by the author and are therefore not referenced.

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6 INTERNATIONAL INSTRUMENTS

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Convention on the Rights of the Child

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European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention of Human Rights and Medicine

International Covenant on Economic, Social and Cultural Rights

The African Charter on Human and Peoples Rights

The African Charter on the Rights and Welfare of Children

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The European Convention on Human Rights

The *Harmonised Tripartite Guideline for Good Clinical Practice of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals*.

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The *International Ethical Guidelines for Biomedical Research Involving Human Subjects*

The Istanbul Declaration

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The Universal Declaration of Human Rights

World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation

7 FOREIGN LEGISLATION

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9 TABLE OF FIGURES