A CRITICAL EVALUATION OF THE CONSENT REQUIREMENT FOR CHILD PARTICIPATION IN HEALTH RESEARCH

by

FREDERICK JACOBUS VOGEL
(98000200)

Submitted in partial fulfilment of the requirements for the degree

LEGUM MAGISTER
(CHILD LAW)

in the Faculty of Law
University of Pretoria

APRIL 2014

SUPERVISOR: Dr. M. Buchner-Eveleigh

A CRITICAL EVALUATION OF THE CONSENT REQUIREMENT FOR CHILD PARTICIPATION IN HEALTH RESEARCH

TABLE OF CONTENTS

CHAPTER 3: THE SOUTH AFRICAN REGULATORY FRAMEWORK

CHAPTER 4: INFORMED CONSENT AND THE ABILITY OF ADOLESCENTS TO PROVIDE CONSENT TO RESEARCH

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

UNIVERSITY OF PRETORIA
DECLARATION OF ORIGINALITY

Full names of student:

FREDERICK JACOBUS

Student number: **98000200**

Topic of work:

A CRITICAL EVALUATION OF THE CONSENT REQUIREMENT FOR CHILD PARTICIPATION IN HEALTH RESEARCH

Declaration –

1. I understand what plagiarism is and am aware of the University's policy in this regard.

2. I declare that this mini-dissertation is my own original work. Where other people's work has been used (either from a printed source, Internet or any other source), this has been properly acknowledged and referenced in accordance with departmental requirements.

3. I have not used work previously produced by another student or any other person to hand in as my own.

4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

SIGNATURE OF STUDENT: .....

SIGNATURE OF SUPERVISOR: .....

ACKNOWLEDGEMENTS

I wish to acknowledge the valuable contribution made by the following persons during the course of this study –

1. First and foremost I wish to thank my supervisor, Dr. M. Buchner-Eveleigh for her guidance. I appreciate her patience, constructive criticism and very helpful ideas during the course of finalising my dissertation.

2. A special word of thanks to my wife and daughter for their motivation and encouragement. Your words of encouragement inspired and motivated me throughout.

ABSTRACT

In the context of medical research, children are especially vulnerable to exploitation. As a result several codes of research ethics emphasise the need for special protection. Prior to the implementation of the National Health Act children participating in medical research enjoyed limited legal protection. Instead, research and ethical committees relied on non-research law and ethical guidelines to identify protective measures for children.

The National Health Act establishes a platform for developing a wide range of legal norms for research on human subjects and supplements and strengthens the already existing principles related to informed consent.

The Act deals specifically with consent for child participation in research. Section 71 requires written consent from a parent or legal guardian for a child to participate in all research conducted with minors, irrespective of age. In addition, minors with sufficient understanding must consent alongside their parents or legal guardians.

While the purpose of the Act is to provide legal protection to participants, it fails to take into account the emerging autonomy of the adolescent sufficiently and ignores the fact that many children do not have parents or legal guardians and are cared for by alternative caregivers. These stricter controls are in contravention with other legislation such as the Children's Act and Choice on Termination of Pregnancy Act, and may also undermine the constitutional rights of children.

The study critically evaluates the consent requirements of the National Health Act with reference to the evolving capabilities of children and the exercise of their parents' or caregivers' parental or similar responsibilities and rights, and relevant suggestions are made.

The study discusses the conceptual framework related to medical research on children and the applicable international and national regulatory framework. The position before and after the Act came into operation is also assessed. An evaluation of the requirements for consent to be informed is made and a description of the current legal framework related to the acquisition and exercise of parental responsibilities and rights is considered. Specific reference is made to situations where children do not reside with parents or guardians but with alternative caregivers. In conclusion, a comparative study is undertaken and relevant suggestions are made.

CHAPTER 1: GENERAL INTRODUCTION

1.1 Problem statement

Children are regarded as especially vulnerable to exploitation in health research. Several codes of research ethics and related conduct, such as the Declaration of Helsinki, emphasise the need of children to be provided with special protection.

The need for such protection is especially acute in South Africa where there exists a mixture of developed country skills, expertise and infrastructure on the one hand, and a developing country burden of disease on the other. This unique situation has led to an influx of researchers. The resulting increase in research activity and competition, as well as the relatively attractive research environment may sometimes result in dishonest and fraudulent practices.[1]

Prior to the implementation of the National Health Act[2] there was limited legal protection for children who form the subjects of medical research.[3] No specific South African legislation addressed health research with children. Instead, research and ethical committees relied on non-research law (e.g. principles of health law relating to medical treatment of minors) in order to identify protective measures for children.[4] This was supported by ethical guidelines which provided that adolescents[5] could consent unassisted to research if certain requirements were met.

---

1 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004), Introduction.

2 61 of 2003.

3 See National Health Research Ethics Council *Ethical-legal protection for vulnerable research participants in South-Africa: An audit of relevant laws and ethical guidelines* (2011).

4 For example, s39 of the Child Care Act (74 of 1983) determined that any person over the age of 14 could consent independently to medical treatment without the assistance of a parent or guardian. The provisions of the Child Care Act have since been repealed by the Children's Act, 2005, which determines, in s129(2) that a child may consent to his or her own medical treatment if the child is over the age of 12 and is of sufficient maturity and mental capacity to understand the implications of the treatment.

5 Defined as persons who have reached puberty.

The National Health Act is the first effort made by government to protect health research participants, including children, under law. The Act establishes a platform for developing a wide range of legal norms for research on human subjects. It supplements and strengthens the already existing general legal principles related to informed consent and introduces the concept of the 'best interests' of the child pertaining to research for therapeutic purposes. It also creates additional safeguards for children participating in research conducted for non-therapeutic purposes.[6] The Act deals specifically with consent for child participation in research. Section 71, enacted on 1 March 2012, requires written consent from a parent or legal guardian for all research conducted with minors, irrespective of age. In addition to this, minors must consent alongside their parents or legal guardians if they have sufficient understanding. While the Act does not define what exactly a minor is, the Children's Act[7] and Constitution[8] define a minor as any person under the age of 18 years.

Section 71 requires consent from a parent or legal guardian as a legal requirement for a minor child to participate in health research. While the purpose of the National Health Act is to provide legal protection to participants, it is not without criticism. It does not sufficiently take into account the emerging autonomy of the adolescent and ignores the fact that many children in South Africa do not have parents or legal guardians and are cared for by caregivers.

By addressing these two issues it will become clear that the Act, by placing stricter control on research of children under 18 years, is in contravention of other legislation such as the Children's Act and Choice on Termination of Pregnancy Act,[9] and may also be undermining the constitutional rights of children.

---

6 Strode (et al) "How well does South Africa's National Health Act regulate research involving children?" 2005 *SAMJ* 266.

7 38 of 2005.

8 Constitution of the Republic of South Africa, 1996.

9 92 of 1996.

1.2 Aim of research

The purpose of this study is to critically evaluate the consent requirements of the National Health Act, with reference to the evolving capabilities of children and the exercise of their parents' or caregivers' parental or similar responsibilities and rights, and to make relevant suggestions in this regard.

In order to achieve this, the conceptual framework related to medical research on children and the applicable international and national regulatory framework will be discussed. The position before and after the implementation of section 71 of the National Health Act will be assessed and an evaluation of the requirements for consent to be informed will be made. A description of the current legal framework related to the acquisition and exercise of parental responsibilities and rights will also be considered to identify who should give consent where children do not reside with either a parent or guardian.

1.3 Limitations of the study

Medical research and participation therein may take several forms and range from research involving only minimal risk to research involving increased risk. This study will deal exclusively with research on children that entails only a minimal risk or a slight increase over minimal risk. It is accepted that for children wishing to participate in research with an increased risk, additional safeguards are required such as the consent of a parent or guardian.

1.4 Methodology

Use will be made of literary sources. References to all the sources that have been used will appear in the bibliography. A comparative study will also be undertaken.

1.5 Outline

Chapter 2 deals with the conceptual and international regulatory framework related to medical research on human subjects.

Chapter 3 sets out the South African regulatory framework relating to child participation in research. The position before and after the implementation of section 71 of the National Health Act will be examined.

In Chapter 4 the requirement of informed consent and the ability of adolescents to provide such consent will be discussed. The Chapter deals especially with the evolving nature of children's capabilities and their increasing autonomy and gives an overview of certain aspects of social theory relevant to the issue. Legislation giving effect to children's autonomy will also be discussed.

Chapter 5 addresses the issue of parental consent and identifies the bearers of parental responsibilities and rights. Specific reference will be made to persons who do not possess parental responsibilities and rights but who, nonetheless, are burdened with the care of children who are not their own. The importance of these alternative caregivers and the role they can plan in consenting to participation in medical research will also be discussed.

Chapter 6 consists of a comparative study and broadly examines the current position related to children and the issue of medical research in Australia and the United Kingdom.

Chapter 7 concludes the study and contains several applicable recommendations.

CHAPTER 2: CONCEPTUAL AND INTERNATIONAL FRAMEWORK

2.1 Introduction

The participation of children in medical research projects is of extreme importance, not only because participation could benefit them directly, but also for purposes of acquiring generalisable medical knowledge. However, history has shown that participants in medical research have far too often been the subjects of human rights abuses. Children have been especially vulnerable in this regard.

In order to curtail these abuses, medical research has developed into a highly regulated field. Research and ethical committees make substantial use of international and national principles, guidelines and legislation in order to lay down the parameters of what would be acceptable research behaviour, both legally and ethically.

What follows is a brief discussion of the concepts and definitions inherent to the field of medical research, as well as an overview of the international regulatory framework and how that has impacted domestically.

2.2 Conceptual Framework

Medical research "is a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalisable knowledge."[10] The National Health Act elaborates and defines health research as, *inter alia*, research "which contributes to knowledge of the biological, clinical, psychological or social processes in human beings."[11]

---

[10] South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles* (2002) par 2.1.2.

[11] s 1.

For a more detailed definition of what is meant by health research and research projects, the following description, as provided by the United States National Commission for the Protection of Human Subjects, is appropriate:[12]

> "A research project generally is described in a protocol that sets forth explicit objectives and formal procedures designed to reach those objectives. The protocol may include therapeutic and other activities intended to benefit the subjects, as well as procedures to evaluate such activities. Research objectives range from understanding normal and abnormal physiological or psychological functions or social phenomena, to evaluating diagnostic, therapeutic or preventive interventions and variations in services or practices. The activities or procedures involved in research may be invasive or non-invasive and include surgical interventions; removal of body tissues or fluids; administration of chemical substances or forms of energy; modifications of diet; daily routine or service delivery; alteration of environment; observation; administration of questions or tests; randomisation; review of records etc."

A broad distinction is generally made in many national and international codes and legislation between therapeutic research (clinical) and non-therapeutic research (non-clinical).

Therapeutic research envisages research that holds out the prospect of direct benefit to the participant, whereas non-therapeutic research refers to research that only holds out the prospect of generalisable knowledge.[13] Whereas the aim of therapeutic research is to benefit the individual research participant directly, the aim of non-therapeutic research is to benefit persons other than the research participant. Consequently, the acquisition of knowledge through non-therapeutic research may be of no immediate or direct benefit to the research participant.[14]

---

12 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) par 1.3.

13 National Health Act *Regulations Relating to Research on Human Subjects* (29 May 2013) Reg 1.

14 South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles* (2002) paras 2.1.2.1 ("Therapeutic research") & 2.1.2.2 ("Non-therapeutic research").

In addition to the distinction between therapeutic and non-therapeutic research, participation in medical research may incur risks ranging from minimal to increased risk. Minimal risks would be those encountered in daily life or during routine medical or psychological examinations, whereas minor increases over minimal risks are consistent with those in a child's medical, dental, psychological, social or educational setting.[15] Increased risk would, for example, entail participation in clinical trials where the risks would not be encountered in daily life or during routine examinations.

Whatever the type of research or the risks involved, the participation of children and adolescents is very important, not only because of possible direct benefits to the participant, but also because of the possible acquisition of generalisable knowledge.

Despite the noble aims of medical research, history has shown that research participants, especially those regarded as vulnerable such as children, have often been abused physically and psychologically. Consequently, medical research has developed into a discipline that is highly regulated by means of international and national principles, guidelines and legislation.

2.3 International Regulatory Framework

2.3.1 Nuremberg Code

After the atrocities committed before and during World War II, the allied powers convened the International Military Tribunal in Nuremberg to try Germany's main war criminals. In addition to the main trial, the United States conducted twelve additional trials of representative Nazis from various sectors of the Third Reich. The first of these trials was the so-called 'Doctors' Trial' in which the majority of defendants were physicians accused of murder and torture during the conduct of medical experiments on concentration camp inmates.[16]

---

15 Strode (et al) 2011 "Using the concept of parental responsibilities and rights to identify adults able to provide proxy consent to child research in South Africa" *SAJBL* 71.

16 Shuster "Fifty Years Later: The Significance of the Nuremberg Code" 1997 *N Engl J Med* 1437.

In their judgement, the judges at Nuremberg confirmed the importance of Hippocratic ethics and the maxim *primum non nocere*,[17] but recognised that more was needed to protect human research subjects. Accordingly, the judges developed a sophisticated set of ten research principles centred not on the physician but on the research subject.[18] These principles became known as the Nuremberg Code.

The most important contribution of Nuremberg was to merge Hippocratic ethics and the protection of human rights into a single code. In the traditional Hippocratic doctor-patient relationship, the patient is silent and dutifully obedient to the beneficent and trusted physician. In medical research, such trust may be misplaced since the physician's primary goal is not treatment but rather the testing of a scientific hypothesis. The research participant's best interest is not always of relevance.[19]

In terms of the Nuremberg Code, specifically Principle 1, the voluntary consent of the human subject is absolutely essential. For consent to be voluntary, the person involved should have legal capacity to give consent, and should be so situated as to be able to exercise free power of choice. Shuster[20] states that -

> "[B]efore the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment."

---

17 First, do no harm.

18 Shuster 1997 *N Engl J Med* 1439.

19 *Ibid*.

20 Shuster 1997 *N Engl J Med* 1436.

The Nuremberg Code not only requires of physicians to protect the best interests of their research subjects, but proclaims that the research subjects can actively protect themselves. The Code gives the research subject as much authority as the physician to end an experiment even before its conclusion.[21]

Although the Nuremberg Code has never officially been adopted in its entirety as law by any nation or as a code of ethics by any major medical association, its central tenet of informed consent has been universally accepted and articulated in international law.[22]

The Nuremberg Code is the most important document in the history of medical research ethics and has served as a blueprint for today's principles that aim to ensure the rights of medical research subjects.[23]

2.3.2 Declaration of Helsinki

The World Medical Association develops ethical standards for the medical profession involved in medical research. In 1964 the Association produced a clinical research ethics code as a further measure to the Nuremberg Code. This ethics code, which is known as the Declaration of Helsinki, has been revised on various occasions since its inception, most recently in October 2013.[24]

The Declaration of Helsinki is addressed primarily to physicians and is a "statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data."[25] The Declaration confirms the standard set out in the International Code of Medical Ethics that a physician is obliged to act in a patient's best interest when he or she provides medical care.[26]

---

21 *Ibid*.

22 Shuster 1997 *N Engl J Med* 1439.

23 Shuster 1997 *N Engl J Med* 1436.

24 Davidson (et al) "Ethics and Medical Research in Children" 2009 *Pediatric Anesthesia* 995.

25 World Medical Association *Declaration of Helsinki* (1964) Preamble.

26 World Medical Association *Declaration of Helsinki* (1964) Principle 3.

The Declaration confirms that some groups and individuals are particularly vulnerable.[27] Medical research with a vulnerable group is, accordingly, only justified if the research is responsive to the needs or priorities of that group and only if the research cannot be carried out on a non-vulnerable group. In addition to this, the group should stand to benefit from the resulting knowledge, practices or interventions.[28]

Of particular significance to this study is the Declaration's prohibition on the enrolling of individuals in a research study unless that individual is able to give informed consent.[29] Human subjects capable of giving informed consent must be adequately informed of, *inter alia*, the aims and methods of the study as well as the anticipated benefits and potential risks inherent to the research.[30] If a potential research subject is incapable of giving informed consent the physician must seek informed consent from a legally authorised representative.[31] Research subjects must also be informed of their right to refuse to participate in the study or to withdraw consent at any time without reprisal.[32]

2.3.3 Other International and Regional Instruments

2.3.3.1 Introduction

The Council for International Organisations of Medical Sciences and the World Health Organisation also published guidelines for biomedical research on human subjects in 1993.[33] Guideline 14 deals specifically with research on children and states that the participation of children is "indispensable for research into diseases of childhood and conditions to which children are particularly susceptible." The Guideline assumes that children over the age of 12 or 13 are usually capable of understanding what is required of them to give adequately informed consent but their

---

27 World Medical Association *Declaration of Helsinki* (1964) Principle 19.

28 World Medical Association *Declaration of Helsinki* (1964) Principle 20.

29 World Medical Association *Declaration of Helsinki* (1964) Principle 25.

30 World Medical Association *Declaration of Helsinki* (1964) Principle 26.

31 World Medical Association *Declaration of Helsinki* (1964) Principle 28.

32 World Medical Association *Declaration of Helsinki* (1964) Principle 26.

33 Davidson 2009 *Pediatric Anesthesia* 995.

consent should normally be complemented by the permission of a parent or guardian.

In 1997 the Council of Europe produced the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. It was enacted into law in 1999.[34]

In addition to these international instruments many countries have their own regulations and codes of ethics.

2.3.3.2 Belmont Report[35]

Between 1932 and 1972 several black men suffering from syphilis in Alabama in the United States were recruited into the so-called Tuskegee Syphilis experiments. This was made possible through extensive collaboration between government agencies and community based organisations ranging from Boards of Health to churches.[36]

Although penicillin was administered to syphilis sufferers as an effective treatment in selected clinics across the United States, the men forming part of the Tuskegee experiments were excluded from treatment with the aim of studying the effects of syphilis. The research subjects were furthermore not educated about syphilis and, in many instances they died merely because they did not receive the treatment that was already available.[37]

---

34 *Ibid*.

35 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979).

36 Thomas (et al) "The Tuskegee Syphilis Study, 1932 to 1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community" 1991 *American Journal of Public Health* 1500.

37 Thomas (et al) 1991 *American Journal of Public Health* 1501.

Prompted in part by problems arising from this study, the United States Department of Health, Education and Welfare revised and expanded its regulations pertaining to medical research on humans. The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research was charged with identifying basic ethical principles related to medical research on humans and to develop applicable guidelines. The resulting document was the so-called Belmont Report which summarises the basic ethical principles identified by the Commission during its deliberations.[38]

Three fundamental ethical principles were identified for using any human subjects for research purposes: (i) respect for persons and their autonomy, fostering informed consent whilst shunning deception; (ii) beneficence by adhering to the principle of doing no harm; and (iii) justice by ensuring all relevant procedures are reasonable, well-considered, non-exploitative, and fairly administered.[39]

2.4 Summary

The field of medical research is highly regulated through international and national principles, guidelines and legislation. In this respect, the Nuremberg Code is the most important historical document. Its provisions have formed the blueprint for most of the ethical principles and guidelines in use today. The most important contribution made by the Nuremberg Code was to merge Hippocratic ethics and the protection of human rights.

In furtherance of the principles laid down in the Nuremberg Code, the Declaration of Helsinki was adopted to primarily address physicians. The Declaration is basically a statement of ethical principles which acknowledges the fact that some groups and individuals, such as children, are particularly vulnerable. The Declaration confirms the importance of informed consent in the context of medical research.

---

38 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979).

39 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979) Principle B.

In addition to the international measures, most countries also have their own legal and ethical instruments in place through which research on human subjects is regulated. Although the contents of these instruments vary from country to country and from state to state, their underlying principles remain the same.

CHAPTER 3: THE SOUTH AFRICAN REGULATORY FRAMEWORK

3.1 Introduction

Prior to the implementation of section 71 of the National Health Act, children enjoyed very limited legal protection in the context of medical research. South African legislation failed to address the issue of child participation and research ethics committees had to rely on principles of non-research law instead.[40] Their reliance on these principles was supported by several ethical guidelines.

The medical research landscape, particularly as it relates to child participation, has changed significantly since the implementation of section 71 which came into operation in March 2012. The section requires consent from a parent or legal guardian as a legal requirement for a child, irrespective of age, to participate in research. Despite this welcome intervention, the National Health Act fails to take into consideration the evolving nature of children's autonomy and seems oblivious to the fact that many children are not under the care of and do not reside with parents or guardians.

In this Chapter, relevant provisions of the Constitution will be stated and its impact on the National Health Act assessed. The National Health Act as it relates to medical research will then be discussed and critiqued.

[40] Zuch (et al) "Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research" 2012 *BMC International Health and Human Rights* 1.

3.2 Constitution of the Republic of South Africa, 1996

3.2.1 Introduction

Even as far back as 1923, in the matter of *Stoffberg v Elliott*,[41] our courts considered the issue of patient autonomy and security of the person. The court held that "every person has certain absolute rights ... and one of those rights is the right of absolute security of the person."[42]

Today, any and all legislation has to comply with the provisions of the South African Constitution. In many instances the Constitution states human rights only in general terms and has left the interpretation of these rights in the hands of the courts.

With regards to medical and health related questions, our courts have interpreted the right to dignity, as contained in section 10 of the Constitution, to include autonomy or the right and ability to regulate one's own affairs.[43] The Constitution also specifically addresses the right to bodily and psychological integrity and acknowledges that failure to respect the autonomy of individuals may be an infringement of a person's constitutionally held rights.

Since the provisions of the Constitution are not only applicable to adults, the relevant sections need to be discussed in the light of children's participation in medical research.

3.2.2 Right to dignity

In terms of section 10 of the Constitution, "[e]veryone has inherent dignity and the right to have their dignity respected and protected." Human dignity should be distinguished from the concept of dignity in general. *Human dignity* denotes a very

41 1923 CPD 148.

42 148.

43 See discussion in par 3.2.2.

specific and objective value inherent to all human beings.[44] The Constitutional Court has remarked that human dignity "is a difficult concept to capture in precise terms".[45] Generally speaking, however, it refers to the intrinsic value of all human beings.[46]

In *Barkhuizen v Napier*[47] the Constitutional Court confirmed that "[s]elf-autonomy, or the ability to regulate one's own affairs, even to one's own detriment, is the very essence of freedom and a vital part of dignity."[48]

Although the connection between autonomy (autonomous decision-making) and human dignity is not always logically apparent, its causality depends on the following two values: (i) recognition of a person's inherent value would mean that such person's own good is of great value; and (ii) a person's own good is best provided for by empowering such person his or her own means of pursuing it.[49]

3.2.3 Right to bodily and psychological integrity

In South Africa, health related autonomy interests are protected by section 12(2) of the Constitution which reads as follows –

> *"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."*

---

44 Jordaan "Autonomy as an Element of Human Dignity in South African Case Law" 2009 *The Journal of Philosophy, Science and Law* 2.

45 *National Coalition for Gay and Lesbian Equality and Another v Minister of Justice and Others* (CCT11/98) [1998] ZACC 15 at par. 28.

46 Jordaan 2009 *The Journal of Philosophy, Science and Law* 3.

47 2007 (5) SA 323 (CC).

48 [57].

49 Jordaan 2009 *The Journal of Philosophy, Science and Law* 9.

The right to bodily integrity underlies the autonomous pursuit of health through lifestyle-related choices.[50] In accordance with the common law understanding of physical integrity, paragraphs (b) and (c) also seem to enshrine rights of meaningful participation in health-related decision-making.[51]

Consequently, failure to respect autonomy-related elements of the right to health may amount to an infringement of the constitutional right to bodily and psychological integrity. Since section 12(2) does not contain an internal limitation, any such infringement would have to satisfy the criteria laid down in section 36 of the Constitution.[52]

3.2.4 Other Constitutional Provisions

In addition to the constitutional rights referred to above, section 28 of the Constitution deals specifically with the rights of children.

Section 28(1)(b) holds that every child has the right "to family care or parental care, or appropriate alternative care when removed from the family environment." In *Government of the Republic of South Africa and Others v Grootboom and Others*[53] the Constitutional Court considered the issue of who is responsible for the realisation of a child's socio-economic rights, including the right to basic health care services. The Court found that the obligation to fulfil children's socio-economic rights is "imposed primarily on the parents or family and only alternatively on the State."[54]

---

50 Pieterse "The Interdependence of Rights to Health and Autonomy in South Africa" 2008 *South African Law Journal* 558.

51 Pieterse 2008 *South African Law Journal* 559.

52 Pieterse 2008 *South African Law Journal* 560.

53 2001 (1) SA 46 (CC).

54 [77].

Furthermore, section 28(2) stipulates that "a child's best interests are of paramount importance in every matter concerning the child." The Constitutional Court has held that this section creates both a self-standing right and a guiding principle in all matters affecting children.[55] This right, however, is not absolute.[56]

3.3 The National Health Act

3.3.1 Introduction

As already alluded to above, section 71 of the National Health Act came into operation in March 2012. In order to highlight the differences in approach before and since March 2012 and the ways in which the National Health Act has actually regressed with regards to the protection of children's autonomy, the position pre- and post-March 2012 will be discussed briefly.

3.3.2 Position before March 2012

3.3.2.1 Guidelines on Ethics in Health Research (2004)[57]

The purpose of the Guidelines is to "identify good, desirable and acceptable conduct, to protect the welfare and rights of research participants, and to reflect the basic ethical values of beneficence, justice and respect for persons."[58]

The Guidelines determine that informed consent is a vital requirement in ethical conduct and indicates that consent can only be valid if obtained without deceit or misrepresentation. According to the Guidelines, informed consent means "that a participant has been informed about the risks and benefits of the research, understands such risks and benefits and is able to give consent to participation, without coercion, undue influence or inappropriate incentives." Participants should

---

55 *Minister of Welfare and Population Development v Fitzpatrick and Others* 2000 (3) SA 422 (CC) [17].

56 *S v M* 2008 (3) SA 232 (CC).

57 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004).

58 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 2.

also be free to withdraw consent to further involvement in the research at any stage without the threat of adverse consequences. The Guidelines require consent to be given by an appropriate other person where the participant lacks the capacity to exercise an informed decision.[59]

The Guidelines identify children and adolescents as persons who should receive special attention when it comes to the protection of their welfare. According to the Guidelines, minors can only participate where their participation is indispensable to the research and not contrary to their best interests. The research also has to investigate a problem of relevance to children.[60]

Research involving children can only be approved if it places the child at no more than minimal risk. If the research involves more than minimal risk, the possible benefit has to justify the degree of risk. In cases where there is more than minimal risk and no prospect of direct benefit, but a high probability of significant generalisable knowledge, the risk has to be justified by the risk-knowledge ratio.[61]

Although the Guidelines require consent by the parent or legal guardian in all but exceptional circumstances (such as emergencies),[62] reference is made to section 39(4) of the Child Care Act which determined that a minor over the age of 14 could consent independently to medical treatment. This was considered by the Guidelines to be analogous to research.[63]

---

59 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 2.6.

60 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 5.1.

61 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 5.2.

62 *Ibid*.

63 Nienaber "Consent to research by mentally ill children and adolescents: the implications of Chapter 9 of the National Health Act" 2013 *S Afr J Psych* 21.

The Guidelines recognise that adolescents[64] may be capable of consenting themselves to certain types of research participation and even went so far as to state that unassisted participation may be desirable in certain circumstances.[65] For example, the Guidelines state that research ethical committees may approve research involving adolescents who may consent unassisted only if the following conditions are met:[66]

- The research, including observational research, entails no more than minimal risk for the adolescent; and
- The nature of the research is such that, in the opinion of the research ethics committee, the parents or legal guardians or community at large are unlikely to object to the adolescent giving independent consent. The opinion of the research ethics committee must be informed by the gathering of information from the relevant community and from contributions by lay members of the committee.
- In all cases, the protocol must provide sufficient information to justify clearly why adolescents should be included as participants.
- In all cases, the protocol must justify clearly why the adolescent participants should consent unassisted.

3.3.2.2 Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa

The Guidelines for Good Practice in Clinical Trials determine that all medical research involving human subjects must undergo independent ethical review by autonomous accredited ethics committees that must assure accordance with international standards and guidelines.[67]

---

64 Defined as persons who have reached puberty.

65 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 5.3.

66 Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004) Guideline 5.3.1.

67 Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2006) Guideline 2.2.

The requirements for children participating in research are similar to those contained in the Guidelines on Ethics in Health Research but a minor is defined as a person under the age of 21.[68] Very importantly, the Guidelines for Good Practice in Clinical Trials determine that, in all cases, assent[69] from the minor is required where he or she is capable of understanding.[70] In addition to the minor's assent, the consent of a parent or legal guardian or caregiver should also be obtained in all but exceptional circumstances (such as emergencies).[71] 'Caregivers' include custodians or persons providing long-term day-to-day care for a child.[72]

As in the general guidelines referred to above, it is the responsibility of the Principal Investigator to ensure that the necessary informed consent is obtained.[73]

3.3.3 Position since March 2012: Section 71 of the National Health Act

The reliance by research ethics committees on general guidelines and principles for guidance in medical research or experimentation has now been curtailed by the provisions of the National Health Act which aim, *inter alia*, to unite the various elements of South Africa's national health system into a common goal and to promote and improve its functionality.[74]

---

68 Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2006) Guideline 2.3.1.

69 Assent means a minor's affirmative agreement to participate in research.

70 Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2006) Guideline 2.3.1.1.

71 *Ibid*. Also see Guideline 2.3.9 which refers to emergency care research and states that this includes instances where it is not possible to obtain consent without delaying the initiation of treatment, and so risking a reduction of possible benefits. Because of participants' vulnerability under such circumstances, they should be excluded from all but minimally invasive observational research.

72 *Ibid*.

73 Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2006) Guideline 3.5.

74 National Health Act, 2003, Preamble.

The rules generally applicable to all research subjects, both children and adults, came into operation in March 2012. Section 71(1) provides as follows:

> *'research or experimentation on a living person may only be conducted in the prescribed manner; and 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 on his or her health'*

It is clear from this subsection that consent to participation in research must be in writing and the research participant needs to be informed of the objects of the research or experimentation as well as any possible positive or negative consequences to his or her health.

Subsections (2) and (3) deal with consent by children and adolescents who wish to participate in research. Because the two subsections are important to this discussion, they are quoted in full:

> *"71(2) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-*
>
> *a) if it is in the best interests of the minor;*
>
> *b) in such manner and on such conditions as may be prescribed;*
>
> *c) with the consent of the parent or guardian of the child; and*
>
> *d) if the minor is capable of understanding, with the consent of the minor.*
>
> *71(3)*
>
> *a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted-*
>
> *i) in such manner and on such conditions as may be prescribed;*
>
> *ii) with the consent of the Minister;*
>
> *iii) with the consent of the parent or guardian of the minor; and*

iv) if the minor is capable of understanding, the consent of the minor.

b) The Minister may not give consent in circumstances where-

i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;

ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;

iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;

iv) the research or experimentation poses a significant risk to the health of the minor; or

v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

All health research studies involving human subjects must also be reviewed by a Research Ethics Committee registered with the National Health Research Ethics Council and must satisfy their requirements and adhere to their recommendations.[75]

Subsections (2) and (3) require written consent from a parent or legal guardian for all research (therapeutic and non-therapeutic) conducted with children (note that these subsections make no distinction between children and adolescents), irrespective of age. In addition, children must consent alongside their parents or legal guardians if they have sufficient understanding. Health research ethical committees no longer have discretion to permit unassisted consent for an adolescent's participation in any kind of research.[76] Written consent from a parent or guardian is a legal requirement for their inclusion. No other caregiver will be able to give consent for a child's

[75] National Health Act *Regulations Relating to Research on Human Subjects* (29 May 2013) Reg 7.

[76] Zuch (et al) 2012 *BMC International Health and Human Rights* 2.

participation in research.[77] Where research will be conducted for non-therapeutic reasons, the additional consent of the Minister is required.[78]

The National Health Act fails to take into account the emerging autonomy of adolescents and merely seems to ignore the fact that many children do not have parents or legal guardians and are cared for by alternative caregivers. In South Africa approximately 26% of all children would fall into the latter category. Of these children, 80% live with their grandparents or other relatives.[79] Many children also reside in households that are headed by other children, usually a brother or sister. The provisions of the Act would make it impossible for children residing with these caregivers to participate in any medical research.

Due to poverty or other socio-economic reasons many of these children do not have access to formal court processes and are left without recourse in this respect. To institute High Court applications every time may prove costly, prohibitive, impractical and inconvenient.[80]

Section 71's failure to take cognisance of children's evolving capabilities and autonomy is inconsistent with the Constitution and other legislation such as the Children's Act[81] which allows for adolescents to consent to certain forms of medical intervention without being assisted by a parent or guardian.[82]

It should, furthermore, be noted that subsection (2) uses the term 'therapeutic research' (usually taken to mean that the participant benefits directly from the research) and subsection (3) the term 'non-therapeutic research' (usually taken to mean that it confers no personal benefit on the participant). It has been submitted that the use of these terms may be problematic. Apart from the lack of a clear definition it is often difficult to distinguish between them.[83]

---

77 *Ibid*.

78 S 71(3)(a).

79 Strode (et al) 2011 *SAJBL* 71.

80 Mahery *South African Health Review* 2006 171.

81 38 of 2005.

82 See discussion in ch 4 par 4.3.2.2.

83 Nienaber 2013 *S Afr J Psych* 22.

The distinction between the two types of research also fails to take into account different risk standards. Some therapeutic research may have more substantial risks than non-therapeutic research,[84] and *vice versa*, which would make ministerial consent either unnecessary or lacking. It might have been more prudent for the legislature to have used different categories of risk or to have defined the research permissible on minors in terms of well-defined risk standards.[85] It is suggested that, as is the case in local and international guidelines, the legislator should rather have used the different categories of risk or defined the research permissible in minors in terms of well-defined risk standards such as research which involves minimal risk or a minor increment over minimal risk.

As already discussed in Chapter 2, minimal risks would be those encountered in daily life or during routine medical or psychological examinations, whereas minor increases over minimal risks are linked to risks consistent with those in a child's medical, dental, psychological, social or educational setting.[86] Research that involves minimal risk generally takes the form of surveys which address sensitive topics including questions about illicit drug use, physical or sexual abuse, experiences in receiving treatment for sexually transmitted infections and perceptions of school counselling services. This research is important to understand the needs of children and to develop and evaluate effective programmes or interventions and deliver adequate services promoting their welfare. The benefits of participation in research should not be underestimated and may even be in the best interests of the child participant.[87]

84 Nienaber 2013 *S Afr J Psych* 22.

85 *Ibid*.

86 Strode (et al) 2011 *SAJBL* 71.

87 Zuch (et al) 2012 *BMC International Health and Human Rights* 2.

3.4 Summary

Before March 2012 children enjoyed very little legal protection in the context of medical research. Research ethics committees had to rely on the provisions of non-research law and other ethical guidelines. The framework governing research permitted adolescents to consent independently to research and, in the case of clinical trials, provided for a broader range of adults eligible to provide proxy consent.

Section 71 of the National Health Act, which came into operation in March 2012, is the first effort made by government to protect health research participants, including children. Section 71 of the National Health Act requires written consent by a parent or guardian in all instances where children wish to participate in medical research. No distinction is made between children in general and adolescents and alternative caregivers will not be able to consent under any circumstances. This ignores firstly the emerging autonomy of children.[88] It seems also that the relevant constitutional provisions have been ignored or not considered.

With regards to medical and health related issues our courts have interpreted the right to dignity, as contained in the Constitution, to include autonomy. Section 71 of the National Health Act may indeed be contravening children's right to dignity as well as their constitutionally held right to bodily and psychological integrity.[89] Secondly, it fails to acknowledge the very real reality that many South African children are cared for by caregivers other than their parents or guardians.[90]

88 See discussion in ch 4.

89 See discussion in ch 3 par 3.2.

90 See discussion in ch 5.

CHAPTER 4: INFORMED CONSENT AND THE ABILITY OF ADOLESCENTS TO PROVIDE CONSENT TO RESEARCH

4.1 Introduction

The doctrine of informed consent is very closely related to patient autonomy and self-determination and was first introduced in South Africa, in 1976, in the case of *Richter and another v Estate Hammann*.[91] [92] Seventeen years later, in *Castell v De Greef,*[93] the doctrine was entrenched in medical and health law jurisprudence.[94]

The doctrine of informed consent is codified in sections 6, 7 and 8 of the National Health Act, which sets out the nature and scope of information that has to be disclosed to a patient. In compliance with informed consent, the 'best interests of the patient' is secondary to patient autonomy and self-determination.[95]

In the following chapter the doctrine of informed consent will be explained and elaborated upon with specific reference to the protection of medical research participants, particularly children.

Focus will be placed on the evolving autonomy of children and a summary will be given of the instances in which adolescents are able to consent independently to various medical interventions. The apparent contradiction between the provisions of the National Health Act and other pieces of legislation, as it pertains to the evolving capabilities of children, will also be dealt with.

---

91 1967 3 SA 226 (C).

92 Britz (et al) "Voluntary Informed Consent and Good Clinical Practice for Clinical Research in South Africa: Ethical and Legal Perspectives" 2012 *S Afr Med J* 746.

93 1994 4 SA 408 (C).

94 Britz (et al) 2012 *S Afr Med J* 746.

95 *Ibid*.

4.2 Nature of 'consent'

Respect for the decision-making capabilities of autonomous persons, is one of the four pillars of biomedical ethics as identified by philosophers Beauchamp and Childress. In addition to respect, they also identified beneficence (acting in a way that benefits the patient), non-maleficence (avoiding the causation of harm), and justice (the notion that patients in similar positions should be treated similarly).[96]

Of specific importance to this study is the notion of consent which can be defined as "the legal and ethical expression of the human right to have one's autonomy respected." For consent to be proper it has to be valid, and for it to be valid certain common law requirements need to be complied with: (i) the consent must be given by a person capable in law to give consent; (ii) the consent must be free, clear and unequivocal; (iii) the consent must be comprehensive and, of particular importance to this study; (iv) the consent must be informed.[97]

The concept of informed consent forms the basis of the common law doctrine of *volenti non fit iniuria* in terms of which conduct is justified which would otherwise have constituted a delict or crime had it occurred without the "victim's" consent. This includes invasive medical treatment which, without the informed consent of the patient, would violate a patient's rights to privacy and personal integrity.[98] Consent by a patient to medical treatment is thus regarded as falling under the defence of *volenti non fit iniuria*.[99]

---

96 Beauchamp TL & Childress JF *Principles of Biomedical Ethics* (2009) 191 & Carstens P & Pearmain D *Foundational principles of South African medical law* (2007) 879-883.

97 Mahery "Consent Laws Influencing Children's Access to Health Care Services" in Ijumba & Padarath (eds) *South African Health Review* 2006 169.

98 *Christian Lawyers' Association v Minister of Health and Others (Reproductive Health Alliance as amicus curiae)* 2005 (1) SA 509 (T) 510D-E.

99 *Castell v De Greef* 1994 (4) SA 408 (C) 420 H. The Court also held that a doctor is obliged to warn a patient of a material risk inherent in the proposed treatment. The risk will be material if a reasonable person in the patient's position, if he or she was warned about it, would likely attach significance to it, or if the medical practitioner is or should reasonably be aware of this likelihood. [426F].

Informed consent is regarded as "the cardinal principle for judging the propriety of research with human beings"[100] and requires that the person giving his or her consent should be in a position to "understand the information supplied, comprehend the consequences of acting on that information, be able to assess the relative benefits and dangers of the proposed action, and be able to provide a meaningful response to the question of what should be done."[101]

The requirement of informed consent is one of the primary ways of ensuring that research participants are protected. The rationale behind the requirement is to give effect to a patient's fundamental right to self-determination as encapsulated in the Constitution.[102]

Section 71 of the National Health Act gives substance to the Constitutional imperatives and sets informed consent as a prerequisite for medical research to be conducted. The Regulations further deal with this issue and determine that the participants of medical research or their legally authorised representatives (parents or guardians in this case), have the right to be informed of, *inter alia*, the purpose of the research, its potential harms and risks, its expected benefits, the methods and procedures to be followed or used during the research, alternatives apart from participating in the research, and their right to decline or withdraw from the research without prejudice.[103]

Children, because of their youth, may not be able to make autonomous decisions and therefore need special protection. Subsections 71(2) and (3) specifically pertain to research on children. These subsections mandate, *inter alia*, written consent from a parent or legal guardian for research conducted with minors, irrespective of age.

---

100 Nienaber 2013 *S Afr J Psych* 20.

101 Mahery 2006 *South African Health Review* 170.

102 Kruger "Traces of Gillick in South African jurisprudence: Two variations on a theme" 2005 *Codicillus* 11.

103 National Health Act *Regulations Relating to Research on Human Subjects* (29 May 2013) Reg. 6.

It is my submission that the National Health Act, in protecting children from harmful and exploitive research, excessively regulates the matter so much so that it negates the autonomy of adolescents.

4.3 Independent adolescent consent

4.3.1 Evolving capacity and autonomy

Childhood is a unique concept and has been described as a 'process' rather than a 'state'.[104] This 'process' entails continuous change which takes place as the child matures from new born to adolescent. This maturation leads to the gradual development of a child's capacity for rational thought and action.[105]

Article 5 of the Convention on the Rights of the Child ("CRC"),[106] to which South Africa is a signatory, obligates state parties "to provide, in a manner consistent with the evolving capacities of the child, appropriate direction and guidance in the exercise by the child of the rights recognized in the present Convention." This principle has profound implications for children's human rights and implies that, as children acquire enhanced competencies, the need for direction reduces whilst their capacity to take responsibility for their decisions increases.[107]

In addition to the provisions of Article 5, Article 12 requires recognition of children as active agents who are able to participate[108] in decisions that affect their lives. The greater the age and capacity of the child, the more seriously their views should be considered.[109]

---

104 Kruger 2005 *Codicillus* 5.

105 *Ibid*.

106 United Nations Convention on the Rights of the Child, 1989.

107 UNICEF *The Evolving Capabilities of the Child* (2005) ix.

108 There is, of course, a difference between participation in decision-making and autonomous decision-making. Autonomous decision-making implies not only the freedom to make the decision but also the responsibility for the decision and its consequences. See Donnelly (et al) "Child-Friendly Healthcare: Delivering on the Right to be Heard" 2011 Med Law Rev 4.

109 UNICEF *The Evolving Capabilities of the Child* (2005) 4.

Various levels of involvement have been identified in children's decision-making processes: (i) to be informed, (ii) to express an informed view, (iii) to have that view taken into account, and (iv) to be the main or joint decision-maker.[110]

Although the CRC does not reverse the presumption of incompetence in children, it places an onus on state parties to ensure that children's capacities are respected, and offers potential that the principle of autonomy can be extended more fully to children.[111]

It should be acknowledged that the law generally regards young children as being incapable of rational thought. The aim of this is to protect children against the negative consequences of their own immaturity and lack of judgment.[112] Despite this noble aim, the overwhelming findings of developmental psychologists that children reach adult decision-making capacities around mid-adolescence cannot be ignored.[113] Adolescents may be as competent as adults in their ability to make decisions and provide informed consent. These findings call for a re-evaluation of the many restrictions that have historically been placed on children's capacities.[114]

Although not all adolescents mature at the same rate, the question of adolescent self-consent can be resolved by determining legal capacity on a case-by-case basis by assessing the actual capacity of a specific adolescent for specific activities.[115]

The so-called maturation factor, as eluded to above, was recognised by the British House of Lords in *Gillick v West Norfolk and Wisbech Area Health Authority and the DHSS*.[116] In *Gillick* the Court held that children under the age of 16 did not lack capacity to make their own decisions by virtue of age alone, but acquired it when "he [sic] reaches a sufficient understanding and intelligence to be capable of making up his own mind on the matter requiring decision." According to the Court, parental

110 *Ibid*.

111 *Ibid*.

112 Kruger 2005 *Codicillus* 6.

113 *Ibid*.

114 *Ibid*.

115 *Ibid*.

116 1985 3 All ER 402.

rights over children terminate when the children acquire the capacity to make their own decisions.[117] This would require an individual assessment of a child's level of maturity and intellectual ability.[118]

4.3.2 Legislation giving effect to children's autonomy

4.3.2.1 Choice on Termination of Pregnancy Act

The Choice on Termination of Pregnancy Act[119] ("The Choice Act") determines that the termination of a woman's[120] pregnancy may only take place with her informed consent.[121] No consent other than that of the pregnant woman is required for the termination of a pregnancy.[122] The Choice Act gives a pregnant minor (female under the age of eighteen), irrespective of her age, the right to terminate her pregnancy without a parent's or guardian's consent. The only requirement is that the medical practitioner or registered midwife must advise the minor child to consult with her parents, guardian, family members or friends before a pregnancy is terminated.[123] Should the girl choose not to consult with these persons, she may not be denied termination.[124]

The constitutionality of these provisions was challenged in *Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as amicus curiae).*[125] The Plaintiffs in that matter alleged that the Choice Act's allowing of abortion services to women under the age of 18 without the assistance of a parent or guardian was unconstitutional.

---

117 Kruger 2005 *Codicillus* 5.

118 Kruger 2005 *Codicillus* 6.

119 Act 92 of 1996.

120 A 'woman' is defined in s 1 as "any female person of any age."

121 S 5(1).

122 S 5(2).

123 S 5(3).

124 S 5(3).

125 2005 (1) SA 509 (T).

The court gave recognition to the autonomy of a child and held that informed consent forms the cornerstone of the Choice Act and rests on three independent legs: knowledge, appreciation and consent.[126]

'Knowledge' requires of a person giving consent to have full knowledge of the nature and extent of the harm or risk involved[127] whereas 'appreciation' implies that such person must also understand or comprehend the nature and extent of the specific harm or risk.[128] The final requirement of 'consent' means that the relevant person "must in fact subjectively consent to the harm or risk associated with [the procedure] and [his or her] consent must be comprehensive in that it must 'extend to the entire transaction, inclusive of its consequences.'"[129]

The Court also referred, with approval, to the explanation in *Castell v De Greef*[130] that the ratio for the requirement of informed consent is to give effect to a patient's fundamental right to self-determination and confirmed that it is "clearly for the patient to decide whether he or she wishes to undergo [an] operation, in the exercise of the patient's fundamental right to self-determination."[131] The Court concluded that the right of every individual to self-determination has become an imperative under the Constitution.[132]

The Court further determined that all women who have the intellectual and emotional capacity for informed consent should be allowed to terminate their pregnancies. Significantly, the Court approved of the Choice Act's failure to distinguish between women on the ground of age[133] and confirmed the rationality of the distinction between women who have the capacity for informed consent and those who do not.[134] The Plaintiff's allegation that girls or young women under the age of 18 are

126 515F.

127 515H.

128 515I.

129 515J – 516A.

130 1994 (4) SA 408.

131 517H.

132 518B.

133 528C.

134 528G – H.

incapable of giving informed consent was consequently rejected. The true position, so the Court held, will depend on the particular girl or woman and her particular circumstances, and should be determined on an individual basis.[135]

The Court concluded that it could not find that the Choice Act is unconstitutional as "the Act serves the best interests of the pregnant girl because it is flexible to recognise and accommodate the individual position of a girl child based on her intellectual, psychological and emotional make up and actual maturity. It cannot be in the interests of the pregnant minor girl to adopt a rigid age-based approach that takes no account, little or inadequate account of her individual peculiarities."[136]

It seems, therefore, that South African jurisprudence accepts that children of sound mind will have full legal capacity to make medical decisions on condition that they possess the capacity to give 'informed consent'.[137] The reduction of the parental role from parental power to voluntary consultation by the child confirms that the constitutional right of children to parental care in the context of, at least abortion is "accommodated but not imposed."[138]

Valid consent can only be given by a person who possesses the necessary intellectual and emotional capacity for the required knowledge, appreciation and consent. The legislature, instead of opting for a rigid age limit, used capacity to give informed consent as the yardstick i.e. the girl must be in fact mature enough to form an intelligent will. The Choice Act recognises such capacity irrespective of the youthfulness or age of the person involved.[139]

---

135 529B.

136 Kruger 2005 *Codicillus* 12.

137 Himonga (et al) "A Child's Autonomy with Special Reference to Reproductive Medical Decision-Making in South African law: Mere Illusion or Real Autonomy?" 2007 *Int'l J. Child. Rts*. 333.

138 Himonga (et al) 2007 *Int'l J. Child. Rts.* 334.

139 Kruger 2005 *Codicillus* 13.

The Choice Act, as interpreted in *Christian Lawyers*, indirectly introduced a test similar to that formulated by the British House of Lords in *Gillick* by providing that the 'informed consent' of a pregnant woman is required for the termination of her pregnancy.[140]

4.3.2.2 Children's Act, 2005

a. Medical treatment and surgery

In terms of section 129 the Children's Act, children who are 12 years or older may consent independently to their own medical treatment provided they have sufficient maturity and mental capacity to understand the "benefits, risks, social and other implications of the treatment.[141] The Children's Act, however, requires children to be duly assisted[142] by a parent or guardian when consenting to surgical operations.[143] Although the term 'treatment' is not defined in the Children's Act, it is generally understood to include all medical procedures save for surgical intervention,[144] but excluding the termination of a pregnancy.[145]

Where the views of the child and his or her parents diverge, the Minister of Social Development may be approached for consent. Application may also be made to either the High Court or a children's court for an order overriding parental (or other applicable) refusal.[146]

---

140 Kruger 2005 *Codicillus* 13.

141 S 129(2)(b).

142 See Regulation 49 of the General Regulations Regarding Children, 2010, which determines that assent must be in writing. Both the child and parent will sign Forms 34 and 35, annexed to the Regulations, respectively.

143 S 129(3)(c).

144 Sloth-Nielsen "Protection of Children" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 7-35.

145 S 129(1).

146 Sloth-Nielsen "Protection of Children" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 7-35.

Children younger than 12 or those older than 12 but without the requisite maturity and mental capacity need the consent of either a parent, guardian or caregiver for medical treatment[147] and the consent of either a parent or guardian for surgical intervention.[148]

b. HIV testing

Section 130 of the Children's Act determines that a child may not be tested for HIV unless it is in his or her best interests or where it is necessary to establish whether a health worker or other person may have contracted HIV after coming into contact with any relevant substance from the child's body.[149] In addition to this, the consent of the child is necessary if the child is older than 12, or younger than 12 but of sufficient maturity to understand the benefits, risks and social implications of such test.[150]

The age of 12 is fixed and not subject to the child being of sufficient maturity to understand the factors referred to previously. Any such consent, however, would still have to be 'informed' as required in terms of common law principles.

The consent requirements related to HIV testing seem to be in line with the obligation of states, in terms of international law, to match consent with the evolving capabilities of children younger than 12.

The requirements of section 130, read with section 129, create a somewhat peculiar situation in that a 7 year old child, for example, would be able to consent independently to an HIV test, but not to any specific treatment. To obtain life-saving anti-retroviral medication the 7 year old child in our example would still need to be 'duly assisted' by a parent, guardian or other caregiver.

147 S 129(4).

148 S 129(5).

149 S 130(1).

150 S 130(2).

c. Access to contraceptives

Section 134 of the Children's Act again uses the benchmark age of 12 and provides for access to condoms and other contraceptives without parental consent. Refusal to sell or provide condoms to a child older than 12 is a criminal offence. These provisions go further than any other in recognising children's autonomy, at least in the context of reproductive health[151] and seems to suggest that children of 12 years or older are capable of making autonomous decisions at least when it comes to their own person.

d. Male circumcision

Circumcision is widely practised on the African continent and examples of the procedure ending in tragedy abound. Section 12(8) of the Children's Act prohibits circumcision of boys under the age of 16 except for religious or medical reasons and even then only if certain requirements are met.

For circumcision of boys older than 16 to occur, section 12(9) requires the consent of the boy himself. The consent has to be given in the prescribed manner and the procedure itself has to be conducted in a prescribed manner after proper counselling is given.

Every male child has the right to refuse circumcision, taking into consideration the child's age, maturity and stage of development.[152]

---

151 Sloth-Nielsen "Protection of Children" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 7-41.

152 S 12(10).

4.4 Summary

Informed consent forms the basis of the common law doctrine of *volenti non fit iniuria* and is the primary method through which participants in medical research are protected. The requirement that consent has to be informed gives effect to a patient's right to self-determination. This right, in the context of medical research, has been given substance through the provisions of section 71 of the National Health Act, read with sections 6, 7 and 8.

The test set down in *Gillick* is probably the most appropriate way in which to answer the question as to what precisely the acceptable limits of self-determination are. Childhood is a unique concept and should be seen as a 'process' rather than a 'state'. Although the use of a specific age to determine when a child may be able to give informed consent is convenient, it is insufficient for purposes of determining whether a child has the requisite capacity to make autonomous decisions.

South African law is somewhat contradictory when it comes to determining a child's capacity to give consent. In certain instances children may make autonomous decisions as to their physical and psychological integrity if they have sufficient maturity and mental capacity. In other instances both age and capacity are determining factors.

Although the approach in the Choice Act would allow for an individual assessment of a particular child's level of maturity and intellectual ability, it is lamentable that the standards are not applied consistently.

Both the Children's Act and Choice Act acknowledge the evolving capabilities of children and give effect to their right to autonomous decision-making. The Children's Act employs a combined approach of requiring children to have attained a certain age in some circumstances and having the necessary maturity. The Choice Act, on the other hand, merely requires a female child to have the capacity to give informed consent for the termination of her pregnancy. The constitutionality of these provisions was affirmed in the *Christian Lawyers* case in which the Court held that informed consent rests on three independent legs of knowledge, appreciation and

consent. The Court shunned a rigid age-based approach and confirmed the rationality of the distinction between women who have the capacity for informed consent and those who do not.

Adolescents are in a process of becoming fully autonomous individuals. It is generally accepted that children of 12 years are old enough to make autonomous decisions. The National Health Act, which requires parental consent in all circumstances, does not take into account the emerging autonomy of the adolescent and seems to imply that all children lack the capacity to make decisions for themselves. In prohibiting children aged 12–18 from providing independent consent under certain circumstances, the enactment of section 71 may be compromising a child's right to autonomy and may be against the best interests of the minor.

If consistent standards were applied to adolescent participation in research they would have been able to consent independently to research projects which pose minimal risk. Parental consent should not be mandatory as long as the subjects are deemed able to give informed consent for him or herself and if it is in the best interests of the child. Researchers should be allowed to establish the participant's level of understanding and relevant procedures should be put in place. Assessments of a child's capabilities may include verbal or written tests with the aim of gauging the child participant's level of understanding of the consent form, knowledge of their rights as research subjects as well as their right to withdraw.

CHAPTER 5: ISSUE OF PARENTAL CONSENT

5.1 Introduction

The National Health Act requires the consent of a child's parent or guardian in all instances where a child wishes to participate in medical research, irrespective of the child's age.

In South Africa, however, the reality is that only some 32% of children reside with both biological parents. It has been estimated that South Africa has approximately 3.7 million orphans and as many as 98,000 children reside in child-headed households.[153] At least 26% of South African children reside with caregivers other than their parents or guardians. Of this group, 80% of the caregivers are grandparents or other relatives.[154]

In addition to situations where a child is voluntarily placed in the care of another person by his or her own parent or parents, a competent court may also determine that a child is in need of care and protection and that he or she should be removed from the care of a parent or caregiver. Although all children require care and protection in various degrees, there exist circumstances where a child requires additional care due to parental or family care being insufficient.[155]

Measures imposed by the state can broadly be divided into two categories. Firstly, interventions could occur while a child remains in the care of his or her caregiver or, secondly, a child may be removed from his or her current environment and placed with a new caregiver resulting in an alternative care placement.[156]

---

153 Zuch (et al) 2012 *BMC International Health and Human Rights* 3.

154 Strode (et al) 2011 *SAJBL* 71.

155 Matthias (et al) "Child in need of care and protection" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 9-3.

156 Matthias (et al) "Alternative care" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 11-2.

A child is considered to be in alternative care if he or she has been placed in foster care, the care of a child and youth care centre[157] following a court order, or in temporary safe care.[158] [159] Given the nature of the South African legal system there is a real and present danger that children may languish in temporary safe care for significant periods of time.[160]

The National Health Act prevents these children from accessing research that could be of great benefit to them. This is especially problematic given that the health of orphans and vulnerable children, precisely those without legal guardians, are at risk.

The requirement pertaining to parental consent in the National Health Act also contradicts the Children's Act. Section 129(4) of the Children's Act allows consent for medical treatment of a child to be provided by, amongst others, a parent, guardian or care-giver, if the child lacks the capacity to consent. Section 132(2), which deals with HIV testing, provides that a care-giver can give the required consent if the child does not have the capacity to consent.

What follows is a brief exposition of what is meant by parental responsibilities and rights and how the holders of these responsibilities and rights are identified. Specific reference will be made to persons without parental responsibilities and rights but who, nonetheless, are burdened with the care of children who are not their own. The importance of these alternative caregivers and the role they can plan in consenting to participation in medical research will also be discussed.

---

157 A child and youth care centre provides residential care to more than six children outside their family environment in accordance with a residential care programme suited for children in the facility [Children's Act, s. 191(1)].

158 Temporary safe care is a short-term protective measure pending a longer-term decision on a child's future care. See Matthias (et al) "Alternative care" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 11-3.

159 S 167(1).

160 Matthias (et al) "Alternative care" in Davel & Skelton (eds) *Commentary on the Children's Act* (2007) 11-4.

5.2 The concept of parental responsibilities and rights

Parental responsibilities and rights consist basically of four components and are defined as the responsibility and right to care[161] for a child, to maintain contact with a child, to contribute to the maintenance of a child, and to act as guardian of a child.[162]

If a person has the responsibility and right to do all of the aforesaid, he or she will have full parental responsibilities and rights. What is meant exactly by partial parental responsibilities and rights is not defined in the Children's Act. The nature of these responsibilities and rights would have to be determined by agreement between the parties or specified in a court order.[163] If a person has only partial (or specific) parental responsibilities and rights it means that he or she only has the responsibility and / or right to exercise one or more of the components of parental responsibilities and rights. Grandparents, for example, may be granted the responsibility and right to exercise contact with a child without them being awarded any other responsibilities and rights.

The concept of 'care' is defined very broadly in the section 1 of the Children's Act and includes what used to be referred to as custody. Custody referred to a person's capacity physically to have the child with him or her and to control and supervise the child's daily life. Thus it included caring for the child, supporting and guiding the child, and assuming responsibility for the child's upbringing, health, education, safety and welfare. The concept of care is broader, however.

---

161 S 1(2) of the Children's Act states that "[i]n addition to the meaning assigned to the terms 'custody' and 'access' in any law, and the common law, the terms 'custody' and 'access' in any law must be construed to also mean 'care' and 'contact' as defined in the Act."

162 S 18(2).

163 *Ibid*.

Generally speaking, a person acting as guardian of a minor child must administer and safeguard the child's estate, assist or represent the child in legal or administrative proceedings[164] or give or refuse consent as required by law, including consent to a child's application for a passport, departure or removal from the country, adoption, marriage and alienation or encumbrance of a child's immovable property.[165]

5.3 Identifying persons with parental responsibilities and rights

The Children's Act determines that one or more persons may have either full or partial (specific) parental responsibilities and rights in respect of a child.[166]

The biological mother of a minor child, irrespective of her marital status, has full parental responsibilities and rights in respect of her child[167] unless she is under 18 and unmarried at the time of the child's birth. Where she is younger than 18, is unmarried and the father of the child does not have guardianship in respect of the child, the guardian of the child's biological mother is also the guardian of the child.[168] Accordingly, the biological mother, as guardian of the child, has authority to consent to all forms of health research.[169]

Biological fathers do not automatically have full parental responsibilities and rights in respect of their children unless they are married to the biological mother or was married to her at the time of the child's conception, birth or any period in-between.[170] Unmarried fathers will only acquire full parental responsibilities and rights if, at the time of the child's birth, they were living with the biological mother in a permanent life partnership. If they were not living together, the unmarried father has to consent to being identified as the child's father and prove that he has, or has attempted to,

164 S 18(3).

165 Strode (et al) 2011 *SAJBL* 70.

166 S 18(1).

167 S 19(1).

168 S 19(2).

169 Strode (et al) 2011 *SAJBL* 70.

170 S 20(a) & (b).

contribute, in good faith, to the child's maintenance and upbringing for a reasonable period.[171]

Full or partial parental responsibilities may also be acquired by persons other than a child's biological parents in a number of ways. Firstly, the Children's Act allows for a competent court to award full or partial parental responsibilities and rights to any person having an interest in the care, wellbeing or development of a child.[172] These responsibilities and rights may, secondly, also be conferred upon another person by the bearer of parental responsibilities and rights by means of entering into an agreement.[173] So, for example, the biological mother of a child may enter into an agreement with the child's biological father, conferring on him contact rights even where the father does not comply with the requirements for unmarried fathers. In the third instance, a person with sole guardianship of a child may nominate another in his or her will to act as the child's guardian on his or her death[174] and, finally, parental responsibilities and rights may be conferred by an adoption order.[175]

Where more than one person has full parental responsibilities and rights, the Children's Act determines that they are all competent to exercise these obligations without the consent of the other. Consequently, only one guardian would, in principle, need to give consent for a minor child to participate in health research without consulting the other guardian or guardians. In major decisions involving the minor child's health, however, the Children's Act requires due consideration to be given to the views of children in light of their age, maturity and stage of development. The views of any co-holders of parental responsibilities and rights also have to be given due consideration.[176]

171 S 21(1).

172 S 23 & 24.

173 S 22(1).

174 S 27(1) & (2).

175 S 242(2)(a).

176 Strode (et al) 2011 *SAJBL* 70.

5.4 Caregivers

'Caregiver' is defined by the Children's Act as "any person other than a parent or guardian who factually cares for a child."[177] This includes foster parents, persons caring for children with the implied or express consent of a parent or guardian, persons caring for children who have been placed in temporary safe care, heads of shelters and care centres, children and youth care workers caring for children who are without appropriate family care in a community and children at the head of child-headed households.[178] These persons provide day-to-day care for children without having parental responsibilities and rights such as parents or legal guardians have.

The Children's Act refers to 'caregivers' frequently without explaining the interface between their rights and those of persons with parental responsibilities and rights. Some 'caregivers' such as foster parents and a child who heads a child-headed household enjoy specific statutory authority, whereas others appear to have no form of parental responsibilities and rights.[179]

There exists a clear dividing line between those persons acting as caregivers and those having parental responsibilities and rights. The dividing line is so strong that it is considered a criminal offence for a caregiver to represent that, or lead the child or any other person to believe that he or she is the child's natural or adoptive parent.[180]

Although caregivers are not the bearers of parental responsibilities and rights, they are the bearers of a number of duties (which includes decision-making powers). Section 32 of the Children's Act determines that a caregiver must "safeguard the child [in his or her care's] health, well-being and development and protect the child from maltreatment, abuse, neglect, degradation, discrimination, exploitation, and any other physical, emotional or mental harm or hazards."[181] These responsibilities are also mentioned in the broad definition of care which is an element of parental

177 S1.

178 S1.

179 Schafer *Child Law in South Africa: Domestic and International Perspectives* (2011) 259.

180 *Ibid*.

181 S 31(1).

responsibilities and rights. In order to fulfil these requirements, the Children's Act mandates that caregivers may exercise any parental responsibilities and rights reasonably necessary to comply with their obligations. This would include the right to consent to any medical examination or treatment of a child if consent by a parent or guardian cannot be reasonably obtained.[182] Section 129(4) of the Children's Act specifically provides for a caregiver to give consent to medical treatment and section 130(2)(b) allows a caregiver to give consent to HIV testing. To consent to treatment and HIV testing, in turn, promotes a child's health and well-being.

5.5 Consent to medical research by caregivers

Strode and Slack[183] argue that, where consent is necessary for medical research, such consent from caregivers with no parental responsibilities and rights but who provide day-to-day care of children, ought to be permissible where the medical research approximates only a minimal risk or a minor increment over minimal risk (and other requirements are met such as that the adolescent cannot consent independently, no person with parental responsibilities in respect of the child should be available or not reasonably available).[184] The reason is that, in many instances, decisions regarding children's participation in minimal risk research approximate decisions regarding children's day-to-day care as these risks are those encountered in daily life or during routine medical or psychological examinations. Minor increases over minimal risks are linked to risks commensurate with those in a child's medical, dental, psychological, social or educational setting.[185] This would not only facilitate research with children but it would act as an important protection for them.

Caregiver consent should, however, not be extended to clinical trials as decisions about participation in clinical trials cannot as easily be equated with decisions about day-to-day care. This is because of the potentially higher risks involved in, and the exceptional nature of, clinical trials.[186]

---

182 S 32(2).

183 Strode (et al) 2011 *SAJBL* 69.

184 Strode (et al) 2011 *SAJBL* 71.

185 *Ibid*.

186 Strode (et al) 2011 *SAJBL* 72.

Several complexities associated with the giving of consent by a caregiver for minimal risk research may exist. These include conflicts between caregivers and parents or guardians who may wish to be involved in decision-making related to their children. Other issues may include a parent or guardian not being reasonably available or certain caregivers themselves being especially vulnerable such as the heads of child-headed households. In the long run, however, the advantages of adopting an approach allowing for consent by caregivers outweigh these complexities.[187]

Strode and Slack suggest that, for a caregiver to consent to research, the following conditions ought to be complied with: (i) the risk should be minimal or a minor increase over minimal risk; (ii) the child or children themselves should not be able to consent independently, for example, in the case of older adolescents; (iii) a person with full parental responsibilities and rights should not be available, or reasonably available, to provide consent; (iv) the adult from whom consent is sought should be a caregiver as defined in the Children's Act; and (v) where possible, written notice should be sent to the bearer of full parental responsibilities and rights informing them of the child's involvement in research and the proxy consent that was given by the child's caregiver.[188]

Although clinical trial guidelines used to allow for caregivers to consent to participation in medical research involving increased risk, such as clinical trials, it is suggested that this approach is less logical and cannot be equated with decisions about a child's day-to-day care. The Children's Act has excluded caregivers from making some highly exceptional decisions[189] and participation in clinical trials might also be argued to be highly exceptional.[190]

---

187 Strode (et al) 2011 *SAJBL* 71.

188 Strode (et al) 2011 *SAJBL* 72.

189 For example, they cannot consent to a child's marriage. In terms of section 18(3)(c) only the guardians of a child may consent.

190 Strode (et al) 2011 *SAJBL* 72.

5.6 Summary

The National Health Act's requirement that parental consent is always necessary for a child to participate in medical research contradicts the approach in the Children's Act where caregivers are allowed to consent to the medical treatment of children in their care.

The bearers of full parental responsibilities and rights automatically have the responsibility and right to consent for the child, in respect of whom they have these responsibilities and rights, to participate in medical research.

Caregivers who have no parental responsibilities and rights are, nonetheless, expected to comply with several duties in respect of a child in their care. In order to fulfil these requirements, the Children's Act mandates that caregivers may exercise any parental responsibilities and rights reasonably necessary to comply with their obligations. This would include the right to consent to any medical examination or treatment.

It has been suggested that, where proxy consent is necessary for medical research, such consent from caregivers with no parental responsibilities and rights but who provide day-to-day care of children, ought to be permissible where the medical research approximates only a minimal risk or a minor increment over minimal risk. With regards to medical research involving an increased risk such an approach is less logical and cannot be equated with decisions about a child's day-to-day care.

It is my submission that the principles of the Children's Act can be used to address the problem and allow caregivers to consent to research which involves minimal risk.

CHAPTER 6: COMPARATIVE STUDY

6.1 Introduction

Most individual countries have their own codes and guidelines related to medical research in general and the participation of children specifically. Although these guidelines vary from country to country and from state to state, their underlying principles remain the same.

The matter of *Gillick v West Norfolk and Wisbech Area Health Authority and the DHSS* has had a profound effect on the participation of children in all kinds of medical interventions not only in the United Kingdom but in most legal systems based on the English common law.

What follows is a brief discussion of how medical research is conducted in the United Kingdom and Australia specifically where children are involved.

6.2 Position in Australia

Research in Australia is primarily governed by ethical guidelines issued in accordance with the National Health and Medical Research Council Act of 1992. To that effect, the Australian National Statement of 2007 sets out a series of guidelines intended for use by medical researchers, members of ethical review bodies, persons involved in research governance and potential research participants.[191]

The Statement understands human research to include, *inter alia*, participation in surveys and interviews, undergoing psychological or medical testing or treatment, and the collection and use of body organs, tissues or fluids.[192]

---

191 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) Summary information.

192 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 8.

Different levels of maturity in children are identified ranging from infants, who are unable to partake in discussions about specific research and its effects, to "young people who are mature enough to understand and consent and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian." It also recognises that fixed ages should not be set as a child or young person might be sufficiently mature to participate in one kind of research but not in another. Researchers are, nonetheless, encouraged to engage even young children with very limited cognitive abilities.[193]

A 'child' is defined in the Statement as "a minor who lacks the maturity to make a decision whether or not to participate in research" whereas a 'young person' is defined as "a minor ... who may have the maturity to make a decision whether or not to participate in research."[194]

The Statement requires consent to research to be obtained from the child or young person whenever he or she has the capacity to make the relevant decision.[195] In addition to the child or young person's consent, the consent of the parent or parents is generally also required or, where applicable, that of the child or young person's legal guardian or primary caregiver or any person[196] or organisation required by law.[197] The Statement, however, allows ethical review bodies to approve research to which only a young person consents if it believes the young person is mature

193 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 55.

194 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 99 & 102.

195 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 56.

196 Who this primary caregiver or other person is differs from state to state and territory to territory within the Commonwealth of Australia. According to s 61C of the Family Law Act 1975, both parents of a child (person aged 18 or less), have parental responsibility for their child. This responsibility continues, despite any changes in the nature of the parental relationship of a child such as due to divorce or remarriage.

197 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 56.

enough to understand and consent and not vulnerable enough through immaturity to require consent from a parent or guardian.[198]

A review body may also approve research to which only a young person consents even if that young person is relatively immature in certain respects. In such instances the research should involve only low risk and the young person should either be estranged or separated from his or her parents, or seeking their consent would be against the child's best interests.[199]

Provision is made also for 'standing parental consent' which a parent would give at the commencement of each school year for the child to be involved in certain types of research in the school setting during the year. Parents are notified of each project but further consent is not required although they are able to withdraw their consent. Such consent only relates to overt observations in school or anonymous questionnaires or surveys, the completion of which would be for the benefit of children in general.[200]

6.3 Position in the United Kingdom

The United Kingdom's General Medical Council regards the seeking of consent to be of fundamental importance when it comes to research on human subjects. Participants' consent is, however, only legally valid and professionally acceptable if they have the capacity to give the requisite consent, have been properly informed and have agreed to participate without pressure or coercion.[201]

198 *Ibid*.

199 *Ibid*.

200 National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007) 57.

201 General Medical Council *Consent to Research* (2010) 8.

Children or young people[202] should only be involved in research when research on adults cannot provide the same benefits. The research has to have potential benefits for children or young people in general and only amount to minimal or low risk of harm or potential therapeutic benefits that outweigh any foreseeable risks.[203]

Before involving children or young persons in research, consent must be obtained from a parent, preferably both if possible, especially if the research involves more than low or minimal risk of harm. Even if a child or young person is able to give independent consent, a researcher still has to consider involving the child or young person's parents.[204] In general, it is recommended that a child should not be involved in research if consensus cannot be reached with the parents, unless treatment can only be accessed as part of a research project and participation is judged to be in the child or young person's best interests.[205]

The evolving capabilities and increased participation of children in decisions affecting their lives was noted in *R (Axon) v Secretary of State for Health*[206] in which the court noted that "the right of young people to make decisions about their own lives by themselves at the expense of the views of their parents has now become an increasingly important and accepted feature of family life."[207]

---

202 The difference between 'children' and 'young people' are similar to the Australian understanding. In the United Kingdom it is generally accepted that a child can make independent decisions about his or her own care from the age of 16. For those children under sixteen, the decision in *Gillick* in relation to treatment suggests that those who are deemed to be of sufficient maturity and understanding, i.e. fully understand all the implications of what is proposed would be able to consent to participation in therapeutic research where they stand to benefit directly from it. See Hagger (et al) "Children and Research: A Risk of Double Jeopardy?" 2005 *IJCR* 55.

203 General Medical Council *0-18 years: guidance for all doctors* par 37.

204 General Medical Council *Consent to Research* (2010) 10.

205 *Ibid*.

206 [2006] EWHC 37 (Admin).

207 [79].

'Parents' in the context of medical research usually refers to those people that have parental responsibility[208] in respect of the child. Mothers and married fathers have parental responsibility as well as unmarried fathers as long as their names appear on the child or young person's birth certificate. If they are not named on the child's birth certificate they acquire parental authority by way of a Parental Responsibility Agreement with the mother or Parental Responsibility Order from a competent court.[209]

If a child is taken into local authority care in terms of a care order (akin to a South African alternative care placement) the local authority shares parental authority with the child's parents. Local authorities therefore have parental authority while a child is subject to a care order. If the child is in voluntary care, the local authority has no parental responsibility.[210]

People who exercise *de facto* care of children, even without parental authority, may do what is reasonably necessary to safeguard or promote a child's welfare. Researchers can, in general, rely on their consent if they are authorised by the parents to care for the child.[211]

6.4 Summary

Most countries have their own codes and guidelines related to medical research and the participation of children therein. All these guidelines' underlying principles remain the same and a great measure of similarity in the guidelines can be detected.

---

208 "A person with parental responsibility means someone with the rights and responsibilities that parents have in law for their child, including the right to consent to medical treatment for them, up to the age of 18 in England, Wales and Northern Ireland and 16 in Scotland. See General Medical Council *Protecting children and young people: the responsibilities of all doctors* (2012) 51"

209 General Medical Council *0-18 years: guidance for all doctors* 35.

210 General Medical Council *0-18 years: guidance for all doctors* 35.

211 General Medical Council *0-18 years: guidance for all doctors* 36.

In Australia and the United Kingdom a differentiation is made between children, who are minors that lack the capacity to agree independently to participate in medical research, and young persons who are minors that may have the maturity to make a decision whether or not to participate.

In Australia the consent of a child or young person is necessary for him or her to participate in medical health research. In addition to the minor's consent, the consent of a parent, guardian or primary caregiver also has to be obtained. Allowance is, however, made for only a young person to consent if it is believed that the young person is mature enough to understand and consent and not vulnerable enough through immaturity to require consent from a parent or guardian.

CHAPTER 7: CONCLUSION AND RECOMMENDATIONS

Adolescent research in South Africa is of great importance. On the one hand it is important to maintain high standards in medical research and treatment of children, but on the other hand, it is also of similar importance to ensure that children, as a vulnerable group in society, are not exploited.

The National Health Act has the noble aim of protecting participants in medical research. The Act, however, does so at the expense of children's evolving capabilities. Instead of protecting and promoting children's autonomy, section 71 excessively regulates consent and makes independent consent by adolescents to participate in medical research impossible. This excessive regulation might be infringing children's, specifically adolescents', rights to human dignity and bodily and psychological integrity as enshrined in the Constitution and does not harmonise with other pieces of legislation in which adolescents may consent independently to various medical interventions.[212]

The Act also seems disconnected from the reality that many children reside with caregivers other than parents or guardians. The approach of the Children's Act, by which caregivers may exercise any parental responsibilities and rights reasonably necessary to comply with their obligations, is preferable over the approach employed by the National Health Act.[213]

To preserve children their right to self-determination and to recognise their real social circumstances, I call for a re-evaluation of the provisions of section 71 of the National Health Act.

[212] See discussion in ch 3.

[213] See discussion in ch 4.

Where adolescents are capable of consenting to participation in medical research entailing minimal risk or a minor increment over minimal risk, they should be allowed to do so independently. In order to achieve this, the provisions of the National Health Act should be harmonised with the Children's Act, specifically as they relate to ages of consent and the determination of whether children have sufficient maturity and understanding to give independent consent. It would be prudent, as in Australia, not to get fixated on specific ages though, and to ensure that even young children with very limited cognitive abilities are engaged.

In addition to the above, consent from caregivers ought to be permissible where the medical research approximates only a minimal risk or a minor increment over minimal risk. Caregiver consent should, however, not be extended to clinical trials as decisions about participation in clinical trials cannot as easily be equated with decisions about day-to-day care and usually entails higher risks.

I recommend that the following conditions be attached to medical research on children –

(i) The risk should only be minimal or a minor increase over minimal risk;
(ii) A child should be able to consent independently if sufficiently mature to understand the benefits, risks, social and other implications of the research, for example, in the case of older adolescents;
(iii) If a child does not understand the aforesaid, a parent or legal guardian (i.e. a person with parental responsibilities and rights) will have to give the requisite consent;
(iv) If there is no person with parental responsibilities and rights available or reasonably available, a caregiver (as defined in the Children's Act) should be allowed to give the requisite consent; and
(v) Where possible, written notice should be sent to the bearer or bearers of full parental responsibilities and rights informing them of the child's involvement in research and the proxy consent that was given by the child's caregiver.
(vi) Whether the heads of child headed households should be able to consent, has to be investigated further.

It is important to note that committees must, in any event, approve research to ensure an adequate balance of risks and benefits regardless of whether parental consent has been given or not.

We can no longer deny the fact that the right of young people to make decisions about their own lives by themselves and at the expense of their parents' views will become, as in the United Kingdom, an increasingly important and accepted feature of family life.

BIBLIOGRAPHY

BOOKS

Beauchamp TL & Childress JF *Principles of Biomedical Ethics* 6th ed (2009) Oxford University Press.

Carstens P & Pearmain D *Foundational principles of South African medical law* (2007) Lexis Nexis 879-883.

Matthias C & Zaal N "Alternative care" in Davel CJ & Skelton AM (eds) *Commentary on the Children's Act* (2007) Juta (Cape Town).

Schafer L *Child Law in South Africa: Domestic and International Perspectives* (2011) Lexis Nexis (Durban).

Sloth-Nielsen J "Protection of Children" in Davel CJ & Skelton AM (eds) *Commentary on the Children's Act* (2007) Juta (Cape Town).

JOURNALS

Britz R & Le Roux-Kemp A "Voluntary Informed Consent and Good Clinical Practice for Clinical Research in South Africa: Ethical and Legal Perspectives" 2012 *SAMJ* 746.

Davidson AJ & O'Brien M "Ethics and Medical Research in Children" 2009 *Pediatric Anesthesia* 994.

Donnelly M & Kilkelly U "Child-Friendly Healthcare: Delivering on the Right to be Heard" 2011 *Med Law Rev* 27.

Hagger L & Woods S "Children and Research: A Risk of Double Jeopardy?" 2005 *Int'l J. Child. Rts.* 51

Himonga C & Cooke A "A Child's Autonomy with Special Reference to Reproductive Medical Decision-Making in South African law: Mere Illusion or Real Autonomy?" 2007 *Int'l J. Child. Rts*. 323.

Jordaan DW "Autonomy as an Element of Human Dignity in South African Case Law" 2009 *The Journal of Philosophy, Science and Law* 1.

Kruger H "Traces of Gillick in South African jurisprudence: Two variations on a theme" 2005 *Codicillus* 1.

Nienaber A "Consent to research by mentally ill children and adolescents: the implications of Chapter 9 of the National Health Act" 2013 *S Afr J Psych* 19.

Pieterse M "Children's Access to Health Care Services Within and Outside of the Parent-Child Relationship" 2010 *THRHR* 230.

Pieterse M "The Interdependence of Rights to Health and Autonomy in South Africa" 2008 *SALJ* 553.

Shuster E "Fifty Years Later: The Significance of the Nuremberg Code" 1997 *N Engl J Med* 1436.

Strode A, Slack C & Essack Z "Child consent in South African law: Implications for researchers, service providers and policy-makers" 2010 *SAMJ* 247.

Strode A, Grant C, Slack C & Mushariwa M "How well does South Africa's National Health Act regulate research involving children?" 2005 *SAMJ* 265.

Strode AE & Slack CM "Using the concept of parental responsibilities and rights to identify adults able to provide proxy consent to child research in South Africa" 2011 *SAJBL* 69.

Thomas SB & Crouse-Quinn S "The Tuskegee Syphilis Study, 1932 to 1972: Implications for HIV Education and AIDS Risk Education Programs in the Black Community" 1991 *American Journal of Public Health* 1498.

LEGISLATION

Child Care Act 74 of 1983

Children's Act 38 of 2005

Choice on Termination of Pregnancy Act 92 of 1996

Constitution of the Republic of South Africa, 1996.

National Health Act 61 of 2003.

National Health Act *Regulations Relating to Research on Human Subjects* (29 May 2013).

CASE LAW

Barkhuizen v Napier (CCT72/05) [2007] ZACC 5.

Castell v De Greef 1994 (4) SA 408.

Centre for Child Law and Another v Minister of Home Affairs and Others 2005 (6) SA 50 (T).

Centre for Child Law v MEC for Education and Others 2008 (1) SA 223 (T).

Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as amicus curiae) 2005 (1) SA 509 (T).

Gillick v West Norfolk and Wisbech Area Health Authority and the Department of Health and Social Security [1985] 3 ALL ER 402. This case is available at www.bailii.org/uk/cases/UKHL/1985/7.html

Government of the Republic of South Africa and Others v Grootboom and Others 2001 (1) SA 46 (CC).

Minister of Health v Treatment Action Campaign (no.2) 2002 (5) SA 721 (CC).

Minister of Welfare and Population Development v Fitzpatrick and Others 2000 (3) SA 422 (CC).

National Coalition for Gay and Lesbian Equality and Another v Minister of Justice and Others (CCT11/98) [1998] ZACC.

R (Axon) v Secretary of State for Health [2006] EWHC 37 (Admin).

Richter and another v Estate Hammann 1967 3 SA 226 (C).

S v M 2008 (3) SA 232 (CC).

Stoffberg v Elliott 1923 CPD 148.

GUIDELINES, POLICIES ETC.

Department of Health *Ethics in Health Research: Principles, Structures and Processes* (2004). This document is available at http://www.hsrc.ac.za/uploads/pageContent/181/HEALTHETHICS,NATIONALDEPTOFHEALTH.pdf

Department of Health *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (2006). This document is available at http://www.doh.gov.za/docs/policy/trials/trials_09.html

General Medical Council *0-18 years: guidance for all doctors*. This document is available at http://www.gmc-uk.org/guidance/ethical_guidance/children_guidance_index.asp>

General Medical Council *Consent to Research* (2010). This document is available at http://www.gmc-uk.org/static/documents/content/Research_guidance_FINAL.pdf>

General Medical Council *Protecting children and young people: the responsibilities of all doctors* (2012). This document is available at http://www.gmc-uk.org/static/documents/content/Child_protection_-_English_0712.pdf.

National Health and Medical Research Council *National Statement on Ethical Conduct in Human Research* (2007). This document is available at http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72_national_statement_130813.pdf.

South African Medical Research Council *Guidelines on Ethics for Medical Research: General Principles* (2002).

REPORTS

Lansdown G “The Evolving Capabilities of the Child” 2005 UNICEF. This document is available at http:// www.unicef.org/india/Evolving_capacities_of_the_child.pdf.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979). This document is available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

ELECTRONIC MEDIA

Mahery P “Consent Laws Influencing Children’s Access to Health Care Services” in Ijumba & Padarath (eds) *South African Health Review 2006* 167. This document is available at http://www.hst.za/uploads/files/chap10_06.pdf.

Spriggs M “Understanding consent in research involving children: the ethical issues: a handbook for human research ethics committees and researchers”. This document is available at http://www.mcri.edu.au/media/62539/handbook.pdf.

Zuch M, Mason-Jones AJ, Mathews C & Henley L “Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research” 2012 *BMC International Health and Human Rights* 1. This document is available at http://www.biomedcentral.com/1472-698X/12/3.

INTERNATIONAL DECLARATIONS, CONVENTIONS, CHARTERS AND STANDARD RULES

United Nations Convention on the Rights of the Child, 1989.

World Medical Association *Declaration of Helsinki* (1964).