

**Walking the tightrope – creating an ethical-legal framework for health research with children: Balancing child protection and participation with the facilitation of appropriate health research**

By

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This Research Project is submitted in fulfilment of the regulations for the PhD Degree, College of Law and Management, School of Law, at the University of KwaZulu-Natal, Pietermaritzburg.

**Declaration by supervisor**

As the candidate's supervisor I agree to the submission of this thesis.

Yousuf Abdoola Vawda

Signed:

Date: 17 July 2013

## Declaration of originality

I, Ann Elaine Strode, declare that:

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Ann Strode

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## Acronyms

AZT	Azidothymidine
CAB	Community Advisory Board
CAG	Community Advisory Group
CIOMS	Council for International Organisation of Medical Sciences
CRC	Convention on the Rights of the Child
DALY	Disability Adjusted Life Years
ENHRM	Essential National Health Research Model
EU	European Union
GCP	Good Clinical Practice Guidelines
HSCR	Human Sciences Research Council
ICCPRs	International Covenant on Civil and Political Rights
ICESCRs	International Convention on Economic, Social and Cultural Rights
ICH	International Conference on Harmonisation

MCC	Medicines Control Council
MRC	Medical Research Council
NHA	National Health Act
NHRC	National Health Research Committee
NHREC	National Health Research Ethics Council
PMTC	Prevention of Mother to Child Transmission
REC	Research Ethics Committee
SAHRC	South African Human Rights Commission
WHO	World Health Organisation
WHOs GCP	World Health Organisation's Guidelines on Good Clinical Practice
UDHGHR	Universal Declaration on the Human Genome and Human Rights
UNESCO	United Nations Educational, Scientific and Cultural Organisation
USA	United States of America

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## **Chapter One:**

### **Introduction: Health research with children – finding the balance between competing interests**

#### **1.1 Introduction**

This thesis is a critical evaluation of South Africa's ethical-legal framework for regulating health research with children.<sup>1</sup> It describes the evolution of the ethical-legal framework, sets out the current institutional and normative obligations for health research, and critiques the extent to which they protect child participants, facilitate child participation in research-related decisions and promote appropriate health research with children. It concludes with proposals for law and policy reform.

This thesis is premised on the notion that there are conflicting interests in research regulation, particularly research involving children, and that an ethical-legal framework is required to find a way of balancing these competing interests. It argues that this can be achieved by using the principles underlying children's rights and ethical guidelines to develop specific research-related legal norms which ensure child protection, child participation and research towards the improvement of health care products and services for children.

This particular chapter sets out the background to the thesis, it describes the importance of health research and of involving children in such research, discusses the competing interests that need to be balanced during the regulation of research, identifies key legal complexities regulating research with children, gives a brief overview of the evolution of the current ethical-legal framework and describes the specific objectives, research questions, premise and structure of this dissertation.

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<sup>1</sup> The scope of this thesis is limited to an investigation into the regulation of clinical trials and social science studies.

### 1.1.1 *The importance of health research in improving the quality of health care services*

Medicine and the provision of health care play a central role in ensuring that individuals have an adequate standard of living. The Preamble to the Constitution reflects the importance of socio-economic rights by stating that one of the purposes of the Constitution is to improve quality of life.<sup>2</sup> Section 27 reflects this principle as a right, stating that '(1) (e)everyone has the right to have access to . . . health care services, including reproductive health care; (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.'<sup>3</sup> Section 28(1)(c) provides further that children<sup>4</sup> are entitled to 'basic nutrition, shelter, basic health care services and social services'.<sup>5</sup>

Given the societal interest in high quality health care, great value has been attached to the development and improvement of health services through research. Accordingly, it has been argued that evidence-based medicine is a critical tool for physicians in clinical decision-making.<sup>6</sup> The mission statement of the national Health Research Policy in South Africa reflects this approach by stating that we must 'promote research that contributes towards the improvement of human health and welfare in South Africa.'<sup>7</sup> General Comment Number

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<sup>2</sup> Constitution of the Republic of South Africa, 1996.

<sup>3</sup> *Ibid.*

<sup>4</sup> Any person under the age of 18, s 28(3) *ibid.* The Children's Act also provides that children are persons under the age of 18, s 17 Children's Act 38 of 2005.

<sup>5</sup> There are also references to the right to health rights in a number of other places in the Constitution (note 2 above) including, s 12 the right to bodily integrity, s 24 the right to an environment that is not harmful to a person's health, s 27(3) the right not to be denied emergency care and s 35(2)(e) the rights of all arrested, detained and accused person's to adequate medical treatment.

<sup>6</sup> JP Burns 'Research in children' (2003) 31(3) *Crit Care Med* 127, 131.

<sup>7</sup> Department of Health, Health Research Policy in South Africa, (2001) available from <http://www.doh.gov.za/docs/index.html> [Accessed: 25 August 2008]. This policy is based on the principles established in the Department of Health's White Paper for the Transformation of the Health System in South Africa, available from <http://www.nhrc.org.za/> [Accessed: 8 February 2012]. The White Paper's stated aim was to address the transformation of South Africa's health services by reducing the high levels of social inequality in

Five of the Committee on the Convention on the Rights of the Child also requires that member states collect 'sufficient and reliable' data on children as part of national programmes.<sup>8</sup> Furthermore benefiting from health research can be regarded as a right in international law given that Article 15 of the International Convention on Economic, Social and Cultural Rights (ICESCRs) states that everyone has the right to 'enjoy the benefits of scientific progress and its applications'.<sup>9</sup>

### 1.1.2 *The importance of involving children in health research*

Traditionally in order to protect children from harm, they have been excluded from participating in health research. This exclusionary approach was largely in response to public concerns regarding research abuses including, amongst others, the inappropriate research on institutionalised children.<sup>10</sup> Given the absence of adequate controls establishing when and how children could participate in research, the exclusionary approach was seen as the only way in which children could be protected from research-related harm. The other argument for the exclusion of children from research was founded on a restrictive interpretation of the Nuremburg Code which requires a research participant to have legal capacity to consent to research. It was argued that in terms of this Code a person without the capacity to consent, such as a child or someone who was mentally disabled, was ineligible to volunteer as a research participant.<sup>11</sup>

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health. It recognised the importance of knowledge, information and evidence by stating that health research must be linked and integrated into planning, policies, programming and implementation.

<sup>8</sup> <http://www.unhcr.org/refworld/category/LEGAL/CRC,,4538834f11,0.html> [Accessed: 13 February 2009].

<sup>9</sup> [http://www.unhchr.ch/html/menu3/b/a\\_cescr.htm](http://www.unhchr.ch/html/menu3/b/a_cescr.htm) [Accessed: 29 August 2008]. However no similar right is included within our Bill of Rights (note 2 above).

<sup>10</sup> Burns (note 6 above). Also see R Gandhi 'Research involving children: Regulations, Review Boards and Reform' (2005) 8:2 *Journal of Health Law and Policy* 265; JA Singh 'Research and legal liability' (2009) 1125 *Acta Tropica* s 72, s 74 and Chapter Two for a more detailed discussion of these points.

<sup>11</sup> *Ibid* Gandhi 268. The first principle of the Nuremburg Code states 'The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an

This traditional exclusionary approach to protecting child research participants was never formally made part of our law in South Africa. In other words, laws did not expressly prohibit children from participating in health research. However elements of this protective approach were found within the Medical Research Council's (MRC's) Ethical Guidelines as they provided that parents could give proxy consent for non-therapeutic research with their children only if the study was observational in nature and did not pose more than a negligible risk of harm to the child.<sup>12</sup> A number of legal academics also argued that proxy consent for research which did not hold out the possibility of direct benefit to the participants was lawful only in very limited circumstances.<sup>13</sup> This approach excluded children from participating in virtually all clinical trials.<sup>14</sup>

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affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.' Nuremberg Code available from <http://ohsr.od.nih.gov/guidelines/nuremberg.html> [Accessed: 18 March 2011].

<sup>12</sup> Guidelines on Ethics for Medical Research: General Principles (Book One) Medical Research Council (1993) available from <http://www.mrc.ac.za/ethics/ethicsbook1.pdf> [Accessed: 3 February 2011].

<sup>13</sup> C Van Wyk 'HIV preventative vaccine research on children: Is this possible in terms of South African law and research guidelines?' (2005) Vol 68,35 *THRHR* 42, 46. Also see the earlier articles of RC Smit 'Clinical trials, children and the law' (1977) No. 2 *South African Medical Journal* 155 and J Burchell 'Non-Therapeutic Medical Research on Children' (1978) Vol 95 *South African Law Journal* 193. Non-therapeutic research has been defined as 'research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalisable knowledge', Regulation 1, Regulations relating to research on human subjects *Government Gazette* No. 29637 23 February 2007 available from <http://www.doh.gov.za/docs/regulations/2007/reg0135.pdf> [Accessed: 6 December 2012]. After the completion of this thesis on 1 May 2013 draft Regulations Relating to Research with Human Subjects were published for public comment in the *Government Gazette* No. R 378 *Gazette* No. 365083 dated 29 May 2013. These draft regulations are not dealt with in this thesis however a full explanation of their content and possible implications for future regulation of health research with children is set out in an addendum to this dissertation.

<sup>14</sup> However, it is not clear to what extent this approach was actually followed in practice by the MRC which conducted a number of non-therapeutic clinical trials with children during this period, for example, a microbicide study was completed which enrolled adolescents from 16, given that the study tested a vaginal microbicide it was clearly not observational or non-interventional, L van Damme, G Ramjee M Alary, B Vuysteke, V Chamndeying, H Rees, P Sirvongrangson, L Mukenge-Tshibakwa, V Ettiegne-Traore,

The extreme measure of protecting children through excluding them from health research has been increasingly criticised. It has been argued that, ironically, this approach undermines rather than protects children's health, as excluding any group from research impedes medical progress for that sector of the population.<sup>15</sup> Furthermore this blanket exclusion of children has the unintended consequence of ineffective and even harmful interventions being used on them as no evidence exists of, for example, drug efficacy or dosage with this age group.<sup>16</sup> The WHO has reported that as a result of children being excluded from drug trials limited information is available on the efficacy and safety of many medicines commonly used for children.<sup>17</sup> Given that children's bodies differ from adults and that they metabolise medicines differently, they may need different dosages.<sup>18</sup> There is also a wide range of weight and physical conditions that exists within children as a class, making these types of extrapolations difficult without child-specific information.<sup>19</sup> Without research data collected from children, physicians have had to use assumptions and extrapolate from adult data to develop paediatric dosages.<sup>20</sup> The lack of child-based evidence also means that interventions which have been found to be effective in adult populations only benefit children many years after they have been made available to adults, thus hindering access to care for this group.<sup>21</sup> Finally, an overly protective approach fails to recognise that children have evolving capacity

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C Uaheowitchai, S Abdool-Karim, B Masse, J Perriens & M Laga 'Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomized control study' (2002) Vol 360 *The Lancet* 971, 972.

<sup>15</sup> PH Caldwell 'Children in clinical trials' (2004) Vol 264 *The Lancet* 088, 803.

<sup>16</sup> *Ibid.*

<sup>17</sup> <http://www.who.int/childmedicines/questions/en/> [Accessed: 7 April 2009].

<sup>18</sup> HB Jaspen, CR Cunningham, TJP Tucker, PF Wright, SG Selt, RL Sheets, AS Rogers, LG Bekker, CM Wilson, A Duerr, JN Wasswerheit and the Vaccines Adolescent Trials Working Group 'Inclusion of adolescents in preventative HIV vaccine trials: Public policy and research design at a crossroads' (2004) Vol 47(1) *Acquired Immune Defic. Syndr.* 86, 87.

<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.* It has been argued by Jaspen et al that influential regulatory bodies such as the US Food and Drug Regulatory Authority now require all package inserts on drugs to be based on data obtained from clinical trials carried out on individuals similar to the proposed end users. Accordingly, they argue that child specific data is required to be obtained from clinical trials before drugs can be registered and prescribed for children.

<sup>21</sup> Burns (note 6 above) 131.

and that certain children have the capacity to participate in decision-making. Accordingly, in recent decades there has been a global shift back towards facilitating the inclusion of children in health research. This is based on the recognition of the importance of allowing children to participate and benefit from health research because:<sup>22</sup>

- (i) The number and severity of diseases that affect children is growing. Furthermore most of these diseases are either preventable or treatable.<sup>23</sup> According to the United Nations Children’s Fund (UNICEF) over nine million children under the age of five die each year from preventable diseases.<sup>24</sup> For example, over 1 700 children die every day of malaria<sup>25</sup> and 30 000 South African children (under the age of five) die every year of AIDS-related illnesses.<sup>26</sup>
- (ii) Some disorders occur only in children or are far more common in children, for example, cystic fibrosis and lymphoid interstitial pneumonitis;<sup>27</sup>
- (iii) Certain medication has a different impact on children as opposed to adults, for example, thalidomide causes phocomelia in unborn children;<sup>28</sup>

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<sup>22</sup> DG Hirtz & LG Fitzsimmons ‘Regulatory and ethical issues in the conduct of clinical research involving children’ (2002) 14 *Current opinion in Pediatrics* 600, 609.

<sup>23</sup> *South Africa’s Children: A Review of Equality and Child Rights* (2011) South African Human Rights Commission, UNICEF and the Department of Women, Children and People with Disabilities 32.

<sup>24</sup> See Chapter Four for further discussion on the leading diseases and causes of death amongst children in South Africa and how they should drive the research agenda.

<sup>25</sup> World Health Organisation (note 17 above).

<sup>26</sup> *South Africa’s Children* (note 23 above) 36. Furthermore, 60 per cent of all HIV positive adults in South Africa were infected before the age of 25. The Department of Health’s 2010 antenatal HIV prevalence survey showed that 14 per cent of pregnant girls between the ages of 15–19 were HIV positive, Q Abdool Karim, ABM Khamny, JA Frohlich, L Werner, M Mlotshwa, BT Madlala & SS Abdool Karim ‘HIV incidence in young girls in KwaZulu Natal South Africa – Public Health Imperative for the inclusion in HIV biomedical intervention trials’ (2012) published online 23 May 2012 *AIDS Behav.*

<sup>27</sup> *Ibid.* Likewise children may be a greater risk of certain disorders for example, Abdool Karim et al *ibid* argue that young women in South Africa are at high risk of HIV infection yet many are unable to abstain from sex, negotiate the use of safer sex practices or rely on consistent condom use. As a result they have very few options in reducing their risk to HIV infection. Accordingly, the authors argue that new female controlled HIV prevention technologies are urgently needed for this group. These can only be developed through research with the affected population – female adolescents.

<sup>28</sup> Caldwell (note 15 above) 803.

- (iv) Children have different biokinetics,<sup>29</sup> metabolism,<sup>30</sup> physiology,<sup>31</sup> and immunology<sup>32</sup> to adults;
- (v) There is a developing trend against allowing the licensing of drugs, vaccines and other interventions for children, before testing their safety and efficacy in this age group. There is also concern regarding the 'off label' use of medicines for children.<sup>33</sup> Arguments have been made regarding the inappropriateness of children being given drugs and treatments that have not been tested on them;<sup>34</sup> and
- (vi) Using the results from clinical trials on children has resulted in significant health benefits,<sup>35</sup> for example, the survival rate for children with lymphoblastic leukaemia increased from 25 per cent to more than 70 per cent following clinical trials into new forms of cancer treatment.<sup>36</sup>

Increasingly, arguments are put forward for the active inclusion of children in health research from social scientists using rights-based language:

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<sup>29</sup> Biokinetics is defined as 'the science of the movements within organisms', Free On-line Dictionary, available from <http://medical-dictionary.thefreedictionary.com/biokinetics> [Accessed: 14 February 2012].

<sup>30</sup> Metabolism is defined as the 'whole range of biochemical processes that occur within an organism. Metabolism consists both of anabolism and catabolism (the buildup and breakdown of substances, respectively). The term is commonly used to refer specifically to the breakdown of food and its transformation into energy' Medicine.Net.comm available from <http://www.medterms.com/script/main/art.asp?articlekey=4359> [Accessed: 14 February 2012].

<sup>31</sup> Physiology is defined as the 'biological study of the functions of living organisms and their parts' Free On-Line Dictionary, available from <http://www.thefreedictionary.com/physiology> [Accessed: 14 February 2012].

<sup>32</sup> Immunology is defined as the 'branch of biomedicine that is concerned with the structure and function of the immune system, innate and acquired immunity, and laboratory techniques involving the interaction of antigens with antibodies' Free On-Line Dictionary, available from <http://medical-dictionary.thefreedictionary.com/immunology> [Accessed: 14 February 2012].

<sup>33</sup> Jaspan et al (note 18 above).

<sup>34</sup> TF Smit 'Is it permitted by South African law to conduct HIV/AIDS preventative vaccine trials with adolescents?' (2005) Unpublished LLM thesis, University of Stellenbosch.

<sup>35</sup> Caldwell (note 15 above) 803.

<sup>36</sup> *Ibid.*

persons in their own right and as worthy of recognition, respect and voice. Their participation in research is akin to respecting and promoting their entitlement to have their opinions heard. It assumes that they are persons of value, their experiences are of interest to themselves, and to others, and that they have a valuable contribution to make to social and political life.<sup>37</sup>

This approach which is becoming increasingly common in social science research is based on 'an effort to move beyond constructing and reconstructing children's experiences based upon adult-centred ideals'.<sup>38</sup> It aims at obtaining the views of children directly on health interventions being designed for them:

We cannot hope to devise strategies or solutions that will address their concerns and will constantly be struggling to make sense of the world without some of the vital information that we need.<sup>39</sup>

## **1.2 The complexities of conducting health research with children**

There are pressing public health and human rights rationales for involving children in health research; however, there are three key complexities which impact on ethical-legal frameworks regulating health research with children. These are: the competing interests of the various stakeholders in the research relationship; the nature of health research itself; and various legal complexities relating to the children not having full legal capacity until adulthood.

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<sup>37</sup> A Graham & R Fitzgerald 'Children's participation in research: some possibilities and constraints in the current Australian research environment' (2012) Vol 46(2) *Journal of Sociology* 133, 135. Also see the similar views expressed in G Clacherty & D Donald 'Child participation in research: reflections on ethical challenges in the Southern African context' (2007) 6(2) *African Journal of AIDS Research* 145, 147 and J Cashmore 'Ethical issues concerning obtaining children's consent to reports on their experience of violence' (2006) Vol 30 *Child Abuse & Neglect* 969, 969.

<sup>38</sup> R Balen, E Blyth, H Calabretto, C Fraser, C Horricocks & M Manby 'Involving children in health and social research: "human becomings" or "active beings"'? (2006) 13(1) *Childhood* 29, 31.

<sup>39</sup> E Ivan-Smith & V Johnson 'The way forward' in E Ivan-Smith & V Johnson (eds) *Stepping Forward: Children and Young people's participation in the Development Process* (1998) 290, 299.

### 1.2.1 Complexities flowing from the competing interests in health research with children

There are competing interests in research. Health research frequently requires the use of human volunteers who may bear some risk in order to generate new knowledge. Their interests are pitted against the interests of science which renders balancing the protection of human subjects with the facilitation of research, a complex issue.<sup>40</sup>

A central concern in the regulation of health research is ensuring that the interests of society and of science do not override the individual interests of research participants.<sup>41</sup> The individual interests of research participants include protecting their autonomy, the freedom to enter into contracts, ensuring respect for amongst others their rights to dignity, privacy and equality.<sup>42</sup> The interests of science, on the other hand, include the freedom to research and develop knowledge to improve efficiency in medical care and public administration.<sup>43</sup>

There are also numerous other competing interests such as:

- (a) Many researchers are health professionals and may face conflicts between their duty of care, and their sense of responsibility to public health concerns that could be addressed through research;

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<sup>40</sup> F Fisher *Medical Ethics Today its Practice and Philosophy* (1993) 195.

<sup>41</sup> *Ibid.* The World Medical Association in the Helsinki Declaration states that 'medical progress is based on research which ultimately must rest in part on experimentation involving human subjects . . . in medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society': Declaration of Helsinki, <http://www.wma.net/e/policy/b3.htm> [Accessed: 19 August 2008]. See Chapter Two for a more detailed discussion on this point.

<sup>42</sup> L Nielsen 'From bioethics to biolaw' in CM Mazzoni (ed) *A legal framework for bioethics* (1998) 39, 40.

<sup>43</sup> Fisher (note 40 above) 196 refers to a number of authors who discuss the moral imperative on scientists to peruse the goals of science.

- (b) Researchers may face conflicts between their personal interests, such as obtaining postgraduate degrees, enhancing their publication records and securing opportunities for promotion at work versus the interests of research participants;<sup>44</sup>
- (c) Different interest groups may have specific research interests which are linked to political or other objectives, for example, under apartheid considerable government funding was invested in genomic research which was aimed at establishing a scientific rationale for the state's racial segregation policy;<sup>45</sup>
- (d) The community at large has an interest in maintaining the public's confidence in research to ensure continuing medical advances;<sup>46</sup> and
- (e) The profit motives of powerful corporate institutions, such as the pharmaceutical industry and health insurance companies.<sup>47</sup>

These tensions between the interests of individuals and the interests of science are heightened when children are to be enrolled as research participants. Children's rights ideology posits that decision-makers act in the best interests of the child.<sup>48</sup> This requires society to protect children from their youth and inexperience whilst promoting participation by respecting their emerging autonomy and views.<sup>49</sup> It also requires that children benefit

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<sup>44</sup> M Heywood 'Health research and ethical principles' in A Hassim, M Heywood, J Berger (eds) *Health and democracy* (2007) 393, 394.

<sup>45</sup> JA Singh & AE Strode 'An analysis of South Africa's health systems and research regulation schemes' (2004) unpublished (on file with author). Singh & Strode illustrate this point with a quote from the political leader Hofmeyr who stated that research ought to aim at establishing 'the lines along which white and coloured races can best live together in harmony and to their common advantage.' JH Hofmeyr 'Africa and Science'. In: *British Medical Association for the Advancement of Science*. Report of the 97<sup>th</sup> Meeting, South Africa, 1929 (1930) 7.

<sup>46</sup> Fisher (note 40 above) 202.

<sup>47</sup> HDC Roscam Abbing 'Medical research involving incapacitated persons: What are the standards?' (1994) Vol 1 *European Journal of Health Law* 140, 147. These interests may impact directly on the research relationship if the researcher receives a grant or other forms of funding from industry.

<sup>48</sup> Article 3, Convention on the Rights of the Child (, available from <http://www.unhcr.ch/html/menu3/b/k2crc.htm> [Accessed: 13 April 2009] and Section 28 Constitution of the Republic of South Africa (note 2 above).

<sup>49</sup> RA Jordaan & CJ Davel *Law of Persons* 4 ed (2005) 52–53 and C Slack, A Strode & M Mamashela 'Ethical-legal challenges in adolescent HIV vaccine trials' 2007) Vol (2) *Southern African Journal of HIV Medicine* 12, 12.

from scientific progress. These competing rights and duties (of parents, children, researchers and the state) can create disharmony within the context of health research. Table 1 below contrasts the interests that must be balanced in health research with children.

**Table 1: Competing interests in health research with children**

	<b>Individual interests</b>	<b>Scientific interests</b>	<b>Other interests</b>
<b>General interests</b>	Benefit from scientific progress; Ability to exercise individual autonomy; Freedom to enter into contracts; Protection of the rights to dignity, privacy and equality.	Freedom to research and develop knowledge; Improve efficiency in medical care.	Doctor's duty of care to an individual patient vs responsibility to address public health concerns; Personal interests of researchers; Social policy objectives of interest groups; Maintaining public confidence in research; Economic interests of the pharmaceutical industry and health insurance companies.
<b>Child specific interests</b>	Protection from harm; Best interests of the child.	Develop child specific health interventions.	Manage the different interests of parents/guardians and children.

Roscam Abbing argues that individually, each of these interests may be legitimate but taken collectively they can easily conflict with one another. It is this conflict and the need to protect the dignity and integrity of research participants that has led to the introduction of

legislation in this field.<sup>50</sup> Resultantly, this thesis argues that establishing when concerns relating to the well-being of individuals ought to take priority over the interests of science is an issue that must be managed by an ethical-legal framework.<sup>51</sup> Furthermore, based on the precedence principle which is a well-established ethical concept requiring a consideration of context when resolving ethical dilemmas,<sup>52</sup> this thesis argues that an ethical-legal framework regulating research with children should be cognisant of balancing the following contextual principles, namely the:

- Protection of children;
- Participation of children by recognising their evolving capacity; and
- Facilitation of appropriate health research.

### 1.2.2 Complexities posed by the nature of health research involving children

A wide range of health research occurs with children. This dissertation has confined itself to clinical and social science research, since these two major categories cover most forms of health research. Some authors divide health research into therapeutic and non-therapeutic research and this language is also used in some ethical guidelines and the NHA. Therapeutic research is defined as research on sick persons which aims to develop generalisable information by providing medically beneficial therapy to individuals.<sup>53</sup> Non-therapeutic research is undertaken with healthy volunteers and has been defined as seeking generalisable knowledge, but not by providing therapy to benefit the individuals directly.<sup>54</sup> However in recent years, this approach of classifying studies into either therapeutic or non-

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<sup>50</sup> Roscam Abbing HDC 'Medical research involving incapacitated persons: What are the standards?' (1994) Vol 1 *European Journal of Health Law* 140, 148.

<sup>51</sup> I Kennedy & A Grubb *Medical Law* 3 ed (2000) 1667–1668.

<sup>52</sup> See <http://www.answers.com/topic/ethics-of-public-health> [Accessed: 16 August 2012] for a detailed explanation of this concept. The authors suggest that in using this principle ethical tensions are 'resolved by taking the overall context of the issue of concern into consideration. Above all, an ethical analysis is not conducted against a checklist. Rather, it is a thoughtful appraisal of all related concerns, paying due cognizance to the broader social context that gave rise to the tension in the first place' *ibid*.

<sup>53</sup> *Ibid*. For example, a study into whether a new cancer drug can assist persons with lung cancer.

<sup>54</sup> *Ibid*. For example, a study into whether a candidate HIV vaccine can prevent new HIV infections amongst persons at risk but not infected with HIV.

therapeutic has been criticised as many forms of research do not fall neatly into either category.<sup>55</sup> This thesis uses the terms ‘therapeutic’ and ‘non-therapeutic’ when they are the terms used in legislation or ethical guidelines. In all other instances it refers to either research which holds out the prospect of direct benefit or research which does not hold out the prospect of direct benefit as these are the terms used in the national ethical guidelines issued by the National Health Research Ethics Council (NHREC).<sup>56</sup>

The National Health Act (the NHA) defines a clinical trial as ‘a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment’.<sup>57</sup> The Good Clinical Practice Guidelines define a clinical trial as a pre-planned, usually controlled clinical study to determine the safety, efficacy or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans selected according to predetermined criteria of eligibility.<sup>58</sup> Clinical trials can take various forms and occur in a number of different phases. They are generally interventionist in nature, for example, testing a new drug which volunteers must use as prescribed. The stages within clinical trials ensure that the research progresses along a continuum from safety to efficacy studies. Stobie, Strode and Slack describe how such phases would work in relation to adolescent HIV vaccine trials. It is submitted that the phases that would be followed in moving an HIV vaccine from concept to a product ready for registration, are similar to those that would be followed in any other clinical trial involving an investigational drug or new therapy:

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<sup>55</sup> C Slack & M Kruger ‘The South African Medical Research Council’s Guidelines on Ethics for Medical Research – implications for HIV preventative vaccine trials with children’ (2005) Vol 95(4) *South African Medical Journal* 269, 269. Many authors now refer to research holding out the possibility of direct benefit (therapeutic research) or research not holding out the possibility of direct benefit (non-therapeutic research). See Chapter Six for further discussion on these criticisms.

<sup>56</sup> Ethics in Health Research: Principles, Structures and Processes, Department of Health (2004) <http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/editors.pdf> [Accessed: 8 March 2012].

<sup>57</sup> S 72(7) National Health Act 61 of 2003.

<sup>58</sup> Guidelines for Good Clinical Practice in the Conduct of Clinical, Department of Health (2006) 56 available from [www.doh.gov.za](http://www.doh.gov.za) [Accessed: 1 February 2011].

Phase I clinical trials include a small group of humans, to determine toxicity, safety and immunogenicity. Phase I trial participants do not have to be at high risk of HIV infection, as efficacy is not being tested. Phase II and III trials are conducted on larger scales, including trial participants who are at somewhat higher risk of HIV infection, to determine efficacy and ongoing safety. Phase II and III trial participants should be at somewhat higher risk of HIV infection, in order for efficacy to be tested. Results of the third phase are hoped to show that the vaccine has succeeded in stimulating an immune response to the HI virus that can prevent HIV infection or disease progression. In addition to these three phases, bridging trials can take place, to answer specific questions not asked in the previous three phases, building on from the knowledge gained in the previous trial. Children may well be involved in such bridging trials. Phase IV entails post-licensing monitoring of the efficacy and side-effects of the drug.<sup>59</sup>

Within each phase of the trial the research may be made up of a range of different health interventions, not all of which are research related. For example, within HIV prevention research it is likely that at least some of the following interventions would form part of the protocol and be provided to participants:

- General physical examinations and medical history-taking;
- Assessment of HIV risk factors including personal questions about sex and substance use;
- Personalised risk reduction counselling;
- Administration of the experimental HIV vaccine or placebo via injection;
- Blood draws for safety testing; and
- Regular testing for HIV infection.<sup>60</sup>

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<sup>59</sup> M Stobie, A Strode & C Slack 'The dilemma of enrolling children in HIV vaccine research in South Africa: what is in "the child's best interests"?' in A van Niekerk and L Kopelman (eds) *Ethics and AIDS in Africa* (2005) 190, 190–191.

<sup>60</sup> A Strode & C Slack 'Legal opinion for the University of Cape Town's Research Ethics Committee' September 2005 (unpublished).

In other words, the research may be made up of numerous types of health interventions, some of which may benefit the research participants directly, for example, treatment of sexually transmitted infections. Other interventions, such as the administration of an experimental vaccine, may be of no direct benefit to the child.<sup>61</sup>

Social science research, which spans a wide range of disciplines including sociology, psychology, anthropology, economics, political science, and history, is defined in the Human Sciences Research Council Act as ‘the generation, preservation, augmentation and improvement of knowledge by means of scientific investigation and methods in the field of the human sciences’.<sup>62</sup>

Like clinical trials, social science research can also take many forms and use different methodologies, including questionnaires, key informant interviews and focus group discussions. For example, the Birth to Twenty Project is an on-going longitudinal study of the health and well-being of urban South African children.<sup>63</sup> It aims at understanding the holistic determination of child and adolescent health and development in Johannesburg and Soweto.<sup>64</sup> In other words, it uses certain key health outcomes to measure whether children are getting healthier as we move further into our democracy. Child participants in this study are offered a range of health care and counselling services.<sup>65</sup>

Social science research can also include observation studies, for example, the care of sick children in South Africa in the context of the AIDS pandemic, was an observational study

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<sup>61</sup> The different interventions within a study have consent implications. In Chapter Five it is argued that some children have the capacity to consent to certain health interventions independently, such as HIV testing, even though their parents or legal guardian may be providing over-arching consent for them to participate in the research.

<sup>62</sup> Act 17 of 2008.

<sup>63</sup> <http://web.wits.ac.za/Academic/Health/Research/BirthTo20/AboutUs/WhoWe+Are.htm> [Accessed: 26 March 2011].

<sup>64</sup> *Ibid.*

<sup>65</sup> *Ibid.*

undertaken by the Human Sciences Research Council (HSRC). It 'examined psychosocial care approaches to improve the care of children in over-burdened hospital conditions. A situational analysis using observational methodology involved nurses, children and care-givers in identifying challenges and priorities for interventions. Naturalistic observations captured spontaneous care strategies indicating opportunities for feasible low cost interventions'.<sup>66</sup>

The complexities posed by the nature of health research with children are: firstly, the research can take many forms with differing risks from non-invasive, observational studies to highly invasive clinical trials. Secondly, some health research includes a number of interventions some of which may provide direct therapeutic benefits to child participants. Thirdly, some studies offer no direct therapeutic benefit and require healthy children to act altruistically for the benefit of others.

### 1.2.3 *Legal complexities of research involving children*

Although compelling scientific arguments can be made for including children in health research, regulating such research is legally complex for a number of reasons.

Firstly, there is an over-arching constitutional obligation to act in the best interests of children.<sup>67</sup> This requires a wide range of factors to be considered to promote a child's physical, moral, emotional and spiritual welfare during decision-making affecting the child.<sup>68</sup> This principle limits the autonomy of parents and other decision-makers as the 'best interests' approach has both subjective and objective elements.<sup>69</sup> Accordingly, decisions on, for example, how schools should discipline children must be guided by standards established

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<sup>66</sup> [http://www.hsrc.ac.za/Research\\_Project-752.phtml](http://www.hsrc.ac.za/Research_Project-752.phtml) [Accessed: 25 March 2011].

<sup>67</sup> S 28(2) Constitution of the Republic of South Africa (note 2 above).

<sup>68</sup> *McCall v McCall* 1994 (3) SA 201 (C) 204, s 28(2).

<sup>69</sup> *In the Marriage of Homan* (1976) FLC 90-024 .

by the Constitution rather than solely on a parent's religious beliefs.<sup>70</sup> The implications of this for research are that public policy considerations may limit the autonomy of parents or guardians to enrol their children in certain forms of research.<sup>71</sup> It can also mean that the person giving proxy consent, ie the parent, is under an obligation to protect the interests of children and does not therefore have the capacity to consent to enrol them in certain forms of research, such as research with unacceptable risk levels.<sup>72</sup>

Secondly, there is a constitutional obligation on parents and the state to protect children from harm because of their vulnerability resulting from their lack of knowledge and experience.<sup>73</sup> Protection is achieved through numerous legal mechanisms including limiting their legal capacity and ensuring children have legal guardians able to act on their behalf.<sup>74</sup> This results in several implications for the regulation of research. It introduces additional parties into the research relationship making it an alliance between the state (as the overall regulator), researchers, parents or proxy consenters and the child, all of whom could have potentially different interests. Ethical principles require that even if adults give consent, children should assent to participation and must be able to withdraw from the research with or without parental approval.<sup>75</sup> In practice however, the power disparities between children and adults make managing this process difficult, especially in societies which place a high

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<sup>70</sup> *Christian Education of South Africa v Minister of Education* 2000 (4) SA 757 (CC) para 41.

<sup>71</sup> For example, the National Health Act (note 57 above) provides in s 71 that therapeutic research is only permissible if it is in the best interests of the child, see Chapters Five and Six for more discussion on this point.

<sup>72</sup> Kennedy & Grubb (note 51 above) 1727.

<sup>73</sup> S 28(1)(d) Constitution of the Republic of South Africa (note 2 above) where it states that children have the right to 'be protected from maltreatment, neglect, abuse or degradation'. The CRC also provides in Article 3(2) (note 48 above) that states are to 'undertake to ensure the child such protection and care as is necessary for his or her well-being, taking into account the rights and duties of his or her parents, legal guardians, or other individuals legally responsible for him or her, and, to this end, shall take all appropriate legislative and administrative measures'.

<sup>74</sup> Jordaan & Davel (note 49 above) 52–53.

<sup>75</sup> Clacherty & Donald (note 37 above) 152. For a more general discussion of the ethical complexities of involving children in health research see L Kopelman 'Children as Research Subjects: A Dilemma' (2000) Vol 25 *Journal of Medicine and Philosophy* 745-764.

social value on obedience.<sup>76</sup> In addition, obtaining proxy consent from parents may be complex as oftentimes children are not living with their biological parents and there is a high proportion of illiterate care-givers, especially in rural areas.<sup>77</sup> In some instances parental consent is not attainable as the parents are deceased.<sup>78</sup> Furthermore, given the involvement of parents or guardians in the research relationship, maintaining a child's right to privacy may prove difficult. Even where parents have no right to the research information provided by their children, they may expect access. For example, adolescents in HIV prevention trials may disclose information about high risk behaviours such as underage sex or drug-taking to researchers, and parents who have provided consent for enrolment into the trial may have an expectation that they will be provided with this information.<sup>79</sup> The potential disclosure of private information to parents may also act as a deterrent to the enrolment of adolescents in research.<sup>80</sup>

Thirdly, whilst there is an obligation on the parents and the state to protect children the law also recognises their evolving autonomy. The obligation to protect children means that steps must be taken to ensure that children do not face physical or psychological harm during research.<sup>81</sup> Children evolve through distinct developmental stages, including infancy (0–6 years), middle childhood (6–10 years), early adolescence (10–14 years) and late adolescence

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<sup>76</sup> Clacherty & Donald (note 37 above) 152.

<sup>77</sup> *Ibid.* For example, data in *South Africa's Children* shows that 500 000 children live with foster parents and 80 per cent of children who are not living with their parents live with their grandparents or relatives (note 23 above) 52.

<sup>78</sup> Abdool Karim et al (note 26 above). It has also been argued that this may mean that such children are disadvantaged as they will be ineligible to enrol in such studies, CA McClure, G Gray, K Rybezyk a HIV and PF Wright 'Challenges to conducting HIV preventative vaccine trials with adolescents' (2004) 36(2) *Acquired Immune Defic. Syndr* 726, 728. Also see JA Singh, SS Abdool Karim, Q Abdool Karim, K Mlisana, C Gray, M Govender & A Gray 'Enrolling adolescents in research on HIV and other sensitive issues: Lessons from South Africa' (2006) Vol 2(7) *PLoS* 0001 where it is argued that there are increasing numbers of child-headed households.

<sup>79</sup> A Strode & C Slack 'The privacy rights of adolescent research participants in HIV prevention research: a Cinderella issue?' a poster presentation at the 4<sup>th</sup> Southern African HIV/AIDS Conference Durban South Africa, 31 March – 3 April 2009. See Chapters Five and Six for more detailed discussion on this point.

<sup>80</sup> Singh et al (note 78 above) 0002.

<sup>81</sup> Abdool Karim et al (note 26 above).

(14–18 years).<sup>82</sup> A child’s evolving capacity is linked to these developmental stages as their cognitive and physical abilities evolve. This has implications for, amongst others, the point at which children have the capacity to consent independently to research. Table 2 below shows the ages at which children can consent independently to various health interventions. Debates abound regarding when children possess sufficient cognitive capacity to consent independently to health research.<sup>83</sup>

**Table 2: Age at which children can consent independently to health interventions**

Intervention	Age of consent	Source
Medical treatment	12, if the child has ‘sufficient maturity’ and the mental capacity to make the decision	S 129, Children’s Act, No. 38 of 2005
HIV testing	12	S 130, Children’s Act
Contraceptives and contraceptive advice	12	S 134, Children’s Act
Male circumcision	16	S 12(9), Children’s Act
Operations	12, if the child has ‘sufficient maturity’ and the mental capacity to make the decision and is ‘assisted’ by his/her parents	S 129 Children’s Act
Research	18	S 71, National Health Act, No. 61 of 2003
Terminations of pregnancy	Any age	S 1 and 5, Choice of Termination of Pregnancy Act, No. 92 of 1996

The implications are that whilst parents or legal guardians may provide consent for their children to participate in health research, older adolescents may have the capacity to

<sup>82</sup> S Zinner ‘The role of cognitive development in paediatric medical decision-making’ (2004) Vol 5(1) *Global Virtue Ethics Review* 22, 23.

<sup>83</sup> Abdool Karim et al (note 26 above).

consent independently to various health procedures and interventions offered within a study.<sup>84</sup> This is particularly relevant within clinical trials where a range of health services may be provided alongside the research intervention. The complexity of having various ages of consent is that researchers must be cognisant of the age of consent of each of these individual health interventions and of any corresponding privacy obligation. For example, children can independently obtain contraceptives from the age of 12 and they have the right to privacy regarding their use of such services.<sup>85</sup>

Fourthly, these legal complexities are heightened by structural problems within ethical-legal frameworks which have failed to deal adequately with the participation of children within health research. In many instances, legal frameworks are inappropriate or inconsistent. For example, many African countries do not have dedicated research laws which set the norms for research participation and this means that general principles of the law, particularly those relating to medical treatment, have to be applied to a research context.<sup>86</sup> Resultantly, in many instances, the legal position is unclear. For example, recent research undertaken by the African AIDS Vaccine Initiative in Botswana, Ethiopia, Kenya, Tanzania and Uganda concluded that it could not be established definitively when and how children could participate in HIV vaccine trials.<sup>87</sup>

Fifthly, there are a range of non-research specific laws that may impact on the way in which research with children is conducted, for example, the age of consent to sex or the obligations

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<sup>84</sup> Strode, Slack & Mamashela (note 49 above) 13.

<sup>85</sup> S 134, Children's Act (note 4 above).

<sup>86</sup> C Slack, A Strode, T Fleischer, G Gray & C Ranchod 'Enrolling adolescents in HIV vaccine trials: reflections on legal complexities from South Africa' (2007) *BMC Medical Ethics* Vol 8(5) 1, 1.

<sup>87</sup> CJ Grant 'The ethical-legal regulation of HIV vaccine research in Africa: A study of the regulation of health research in Botswana, Ethiopia, Kenya, Tanzania and Uganda to determine their capacity to regulate HIV vaccine research' (2009) African AIDS Vaccine Programme. Similar comments are made in A Nienaber 'The protection of participants in clinical research in Africa: Does domestic human rights law have a role to play?' (2008) Vol 8 *African Journal of Human Rights Law* 138, 145.

on certain adults (such as medical practitioners) to report abuse.<sup>88</sup> Applying these laws to health research adds a further layer of legal complexities.

### **1.3 The regulation of health research with children in South Africa**

The need for an ethical-legal framework to regulate health research and to ensure that competing interests are managed is internationally recognised.<sup>89</sup> It is argued that research regulation ought to balance the competing interests described above. However, few frameworks have been able to achieve this with any real success. Glantz argues that the balance ought to be created by procedural protections by the very adults who control research and ensure that children are not exploited.<sup>90</sup> Friedman Ross refers to this issue as the access versus protection dilemma, in which legal and policy frameworks have acted as a pendulum swinging between over-protection resulting in the exclusion of children from research, and access resulting in the inappropriate use of children in research.<sup>91</sup>

#### *1.3.1 The development of the ethical-legal framework for regulating health research with children in South Africa*

South Africa's ethical-legal framework has evolved through three distinct phases.<sup>92</sup> In the first phase there was no formal, legally established ethical-legal framework. There were however a limited number of institutions to regulate research, and some legally binding

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<sup>88</sup> These obligations are dealt with in detail in Chapter Five.

<sup>89</sup> TL Hervey & JV McHale *Health law and the European Union* (2004) 237.

<sup>90</sup> LH Glantz 'The law of human experimentation with children' in MA Grodin & LH Glantz (ed) *Children as research subjects, Science, Ethics and Law* (1994) 120, 128.

<sup>91</sup> L Friedman Ross *Children in Research: Access versus Prevention* (2006) 2–3.

<sup>92</sup> See Chapter Three for a detailed description of these three phases.

norms and standards.<sup>93</sup> In this phase the focus was on self-regulation with many forms of research not being required by statute to, for example, obtain ethical approval.<sup>94</sup>

The second stage of the ethical-legal framework came into being with the partial implementation of the NHA in 2005.<sup>95</sup> This created a formal ethical-legal system consisting of a number of key institutions able to set the policy agenda, establish norms and standards, and review and/or regulate individual studies. Legally enforceable norms in ethical guidelines could be established to set substantive and procedural ethical guidelines for health research, including research with children.<sup>96</sup> Monitoring and enforcement through, amongst others, Research Ethics Committees (RECs) and the National Health Research Ethics Council (NHREC) were also introduced. However the framework did not include comprehensive legal norms regulating research with children.

The third or current stage of the ethical-legal framework came into being on 1 March 2012 with the implementation of sections 11 and 71 of the NHA.<sup>97</sup> This completed the introduction of a comprehensive ethical-legal framework by operationalising the legal norms in the NHA on how and when research with human subjects may be conducted, and included specific provisions on research with minors.<sup>98</sup>

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<sup>93</sup> A Pope 'HIV preventative research with minors' (2007) Vol 124(1) *SALJ* 167, 170. There were however some ethical-legal obligations on clinical trials and research conducted by the MRC. This included ethical guidelines which were issued by the MRC, Guidelines on ethics for medical research: General Principles (note 13 above). See Chapter Three for more detail on this point.

<sup>94</sup> A Strode, C Slack & M Mushariwa 'HIV vaccine research: South Africa's ethical-legal framework and its ability to promote the welfare of trial participants' (2005) Vol 95(8) *South African Medical Journal* 598, 599.

<sup>95</sup> National Health Act (note 57 above) parts of the Act were brought into operation by a notice in the *Government Gazette* No. 27503, 18 April 2005.

<sup>96</sup> See Chapters Three and Four for a detailed description of these norms.

<sup>97</sup> *Government Gazette* No. 35081, 27 February 2012.

<sup>98</sup> See Chapter Five for a more detailed discussion of these legal norms.

### 1.3.2 *Problems with the way in which health research with children was regulated in the past*

Previously the legal provisions regulating health research, where they existed, were contained in different pieces of legislation.<sup>99</sup> For example, the Constitution provides in s 12(2)(c), in respect of the right to freedom and security of the person that '(E)veryone has the right to bodily and psychological integrity, which includes the right . . . not to be subjected to medical or scientific experiments without their informed consent.'<sup>100</sup> On the other hand, the nature of ethical review was set out in the NHA which provided that institutions undertaking health research must have access to an REC.<sup>101</sup> There was no child-specific research legislation.<sup>102</sup>

Given this vacuum, researchers and RECs had to be guided by the general legal principles particularly those relating to medical treatment, and the provisions in ethical guidelines.<sup>103</sup> For example, in using the principles relating to consent to medical treatment, certain RECs allowed children to consent to so-called therapeutic research at 12 years of age as they have the capacity to consent to medical treatment at this age in terms of section 129 of the Children's Act.<sup>104</sup> In a similar vein, some RECs used the principles in ethical guidelines to establish norms for, amongst others, appropriate risk standards.<sup>105</sup> For example, the national ethical guidelines, *Ethics in Health Research: Principles, Structures and Processes*, provide that research with children which poses greater than minimal risk, and does not hold out the

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<sup>99</sup> Strode, Slack & Mushariwa (note 94 above) 601.

<sup>100</sup> Constitution of the Republic of South Africa (note 2 above).

<sup>101</sup> S 73 National Health Act (note 57 above). See Chapter Four for more detailed discussions of these provisions.

<sup>102</sup> Pope (note 93 above) 168. Section s 71 of the National Health Act *ibid* deals directly with the participation of minors in research.

<sup>103</sup> Stobie, Strode & Slack (note 59 above) 194. The two most significant ethical guidelines were, *Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa* (note 58 above) and *NHREC Guidelines* (note 56 above). See Chapters Three, Four, Five and Six for a more detailed discussion on the current ethical-legal framework.

<sup>104</sup> F van Oosten 'The law and ethics of information and consent in medical research' (2000) Vol 63 *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 18.

<sup>105</sup> Stobie, Strode & Slack (note 59 above)

prospect of direct benefit to child participants, should only be approved by an REC if there is a high probability of generating significantly generalisable knowledge. Furthermore, the risks of the study should not exceed a minor increase over minimal risk. The term 'minimal risk' is defined as being the risks of daily life or of routine medical or psychological examinations.<sup>106</sup>

The previous framework with its lack of clear legal guidance was fraught with implementation problems.<sup>107</sup> Firstly, in many instances given that it was left to either RECs or the Medicines Control Council (MCC) to interpret general legal principles or apply ethical guidelines, inconsistencies occurred between committees and institutions. Often inconsistencies arose in relation to, for example, the age at which children could consent independently to research. Using the different guidelines, RECs adopted divergent approaches, for example, one REC allowed adolescents of 16 years and older to participate independently in clinical trials testing a microbicide,<sup>108</sup> whilst another required a socio-behavioural study as part of the South African Studies on HIV in Adolescents Project to obtain consent from parents or guardians.<sup>109</sup> Secondly, as the research relationship is different in its nature and objective to a therapeutic one, applying the principles relating to medical treatment has in some instances resulted in anomalies; for example, it is difficult to equate so-called non-therapeutic research to any form of medical treatment and thus there was little guidance on when children could consent independently to this form of health research. Thirdly, there was a lack of harmonisation amongst the three key sets of ethical guidelines, particularly with regard to the permissible risk level for research which does not

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<sup>106</sup> MRC Book One (note 12 above).

<sup>107</sup> See Chapter Three for a more detailed critique of the previous ethical-legal frameworks.

<sup>108</sup> Van Damme et al (note 14 above) 972.

<sup>109</sup> Personal communication, Dr Melissa Wallace, SASHA study, 4 February 2009. This study used the licensed HPV vaccine as a proxy for an HIV vaccine and thereby identified potential challenges to the inclusion of adolescents in HIV prevention trials <http://www.desmondtutuhivcentre.org.za/en/article/research/adolescent-prevention/sasha.html> [Accessed: 24 May 2009].

hold out the prospect of direct benefit to the participants.<sup>110</sup> Thus RECs, depending on the ethical guidelines they were consulting, applied different risk standards. For example, Van Wyk argued that adolescents would not be able to participate in HIV vaccine trials as the MRC's Ethical Guidelines allowed non-therapeutic research with minors only if the research was classified as being observational in nature, and not posing more than a minor increase over minimal risk.<sup>111</sup> Given that HIV vaccine trials will in all likelihood involve the injection of a vaccine they clearly cannot be considered observational research.<sup>112</sup> On the other hand Smit submitted that minors could participate in such studies provided the risks of participation did not exceed a minor increase over minimal risk, which is allowed by the national ethical guidelines issued by the NHREC and the Good Clinical Practice Guidelines.<sup>113</sup> In other words, this lack of harmonisation meant that these two discrete positions adopted by RECs were both justifiable depending on which ethical guidelines were being applied.

Overall, the previous ethical-legal frameworks failed as they did not adequately protect child research participants or sufficiently promote child participation. They were however facilitative of health research.

### 1.3.3 *Overview of the current ethical-legal framework for regulating research with children*

The legislature has attempted to resolve this lack of normative guidance within the ethical-legal framework by inserting child specific provisions into the research chapter of the NHA.<sup>114</sup> Sections 11 and 71 of the NHA were operationalised on 1 March 2012 by a notice in the

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<sup>110</sup> Stobie, Strode & Slack (note 59 above) 194, MRC Book One (note 12 above), GCP (note 57 above) and NHREC Guidelines (note 56 above)

<sup>111</sup> Van Wyk (note 13 above) 50.

<sup>112</sup> The MRC Guidelines classify observational research as non-invasive research involving no interface with mental or physical integrity and poses no risk to the participants (note 12 above).

<sup>113</sup> Smit (note 34 above). Similar arguments are made by Stobie, Strode & Slack (note 59 above).

<sup>114</sup> See Chapter Nine, National Health Act (note 57 above). A Strode, C Grant, C Slack & M Mushariwa 'How well does South Africa's National Health Act regulate research involving children?' (2005) Vol 95(4) *South African Medical Journal* 264, 265. See Chapters Four and Five for a more detailed discussion of the current ethical-legal framework.

*Government Gazette*.<sup>115</sup> This has completed the inauguration of a comprehensive ethical-legal framework by establishing norms for the manner in which health research ought to be conducted, including research involving children. These provisions are important as they deal with the lacuna in our law vis-à-vis the participation of children in health research.

#### 1.3.4 *Problems with the current approach to regulating research with children*

Many shortcomings have been identified with regulation of health research by the NHA. For example, the protections are based on the controversial notion of classifying research into therapeutic and non-therapeutic research,<sup>116</sup> it focuses on consent as the primary protection for participants<sup>117</sup> and it is inconsistent with many of the principles in the Children's Act and national ethical guidelines.<sup>118</sup> Furthermore, the NHA raises a range of new issues, such as adding an additional administrative burden on researchers by requiring ministerial consent for all non-therapeutic research involving minors.<sup>119</sup> Finally, given that it was brought into operation without the proclamation of accompanying regulations, it is argued that some of its provisions, such as the obligation to obtain ministerial consent for non-therapeutic research with minors, are not implementable.<sup>120</sup>

At a macro level it has been argued that the current system is overly protectionist through its very restrictive consent norms. For example, requiring consent from parents or legal guardians and not care-givers for all forms of health research with minors will halt some forms of low risk, school-based research as many children are sent away from home to

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<sup>115</sup> *Government Gazette* No. 35081 (note 96 above).

<sup>116</sup> See a critique of this approach in C Slack & M Kruger (note 55 above) and Stobie, Strode & Slack (note 59 above) 197.

<sup>117</sup> See Chapter Six for a more detailed critique on this point.

<sup>118</sup> Strode, Slack, Grant & Mushariwa (note 114 above) 266.

<sup>119</sup> AE Strode, CM Slack, DR Wassenaar & JA Singh 'One step forward, two steps back – requiring ministerial approval for all forms of non-therapeutic health research with minors' (2007) Vol 97(3) *South African Medical Journal* 200. The authors argue that requiring ministerial consent for all forms of non-therapeutic research with minors including low risk studies is an unnecessary administrative burden which offers very little, if any, protection to child research participants. For further discussion on this issue see Chapters Five and Six.

<sup>120</sup> See Chapter Six for a detailed critique of the ministerial consent requirement.

relatives or others in order to be educated.<sup>121</sup> The system also fails to adequately recognise the importance of child participation in decisions which they have the capacity to undertake. Whilst the Children's Act clearly describes the ages at which children may consent to various health interventions, such as HIV testing and medical treatment, the NHA only allows independent consent to health research at 18.<sup>122</sup> In other words the NHA fails to recognise that children may have the capacity to consent to some forms of health research below the age of 18.<sup>123</sup> Finally, the overly protective approach hinders health research with children and, as a result, a number of universities and research institutions have notices on their websites indicating that they will not be implementing these sections until further clarity is obtained.<sup>124</sup>

## **1.4 Objectives, research question, premise and structure of this thesis**

### *1.4.1 Objectives of this thesis*

This thesis aims to contribute to the current discourse on the development of an ethical-legal framework that protects child research participants, recognises and enables children's participation in studies, and facilitates appropriate health research.<sup>125</sup> It attempts to do so by describing the institutional and normative foundations of an ideal ethical-legal framework,<sup>126</sup> setting out the current ethical-legal framework and how it has evolved over the last 50 years, identifying key problems with the current framework, and making proposals for law and policy reform based on a conceptual model of protection, participation and research promotion. Accordingly, the primary aims of this thesis are to:

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<sup>121</sup> M Zuch, AJ Mason-Jones, C Mathews & L Henley 'Changes to the law on consent in South Africa: Implications for school-based adolescent sexual health research' (2012) Vol 12(3) *BMC* 1, 3.

<sup>122</sup> Ss 129–130 Children's Act (note 4 above) and s 71 National Health Act (note 57 above).

<sup>123</sup> Zuch et al (note 121 above) 3.

<sup>124</sup> See for example, the statement by the Bio-medical Research Ethics Committee, University of KwaZulu-Natal <http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx> and a similar one by the Human Sciences Research Council [www.hsrc.ac.za](http://www.hsrc.ac.za) [Accessed: 2 January 2013].

<sup>125</sup> This thesis defines a child as a person under the age of 18 in accordance with s 17 Children's Act (note 4 above).

<sup>126</sup> Chapter Two identifies the key institutional and normative principles that ought to underpin an ethical-legal framework from international law and recognised international ethical codes.

- (i) Describe and critique the current ethical-legal framework for health research with children in order to inform law and policy reform proposals;
- (ii) Develop a theoretical model which can be used to develop norms which balance the need to protect children, facilitate their involvement in research-related decisions and promote health research which benefits them; and
- (iii) Contribute towards the development of a more effective ethical-legal framework for health research with children in South Africa through the development of law and policy reform proposals based on both ethical principles and children's rights as articulated in the CRC, the Constitution and the Children's Act.

It should be noted that, as stated above, this thesis has limited its focus to health research which can be classified as either a clinical trial or a social science study.

#### 1.4.2 *The research questions*

This thesis investigates two key research questions. The first is: to what extent does the current ethical-legal framework meet the needs of protecting research participants, enabling child participation in accordance with the child's evolving capacity and the facilitating of appropriate health research? This question is answered through a critique of the current ethical-legal framework. The critique is grounded in (a) an examination of the extent to which the ethical-legal framework meets the international standards, and (b) an evaluation of the extent to which it is able to balance the three principles which underpin this thesis.

The second research question: is how can the three principles of protection, participation and promotion be used to establish the key legal norms that ought to inform the development of laws regulating health research with children? Accordingly, this thesis attempts to investigate whether the principles underlying children's rights can be used to develop a framework for legislation regulating health research when linked to well-established ethical norms. This thesis attempts to answer this second research question by

describing these principles and demonstrating how balancing them can result in the development of a framework which is protective, participatory and facilitative. It makes specific recommendations to show how these principles could be operationalised in South Africa through the introduction of law and policy reform.

#### 1.4.3 *Central premise of this thesis*

Walking the tightrope between protecting child research participants, empowering them through child participation according to their evolving capacity, and facilitating appropriate research with them, is the central theme of this thesis. It concerns not only when but also under what circumstances children ought to participate in health research in South Africa.

The term ‘child protection’ is a broad one referring to the obligation to protect children from harm in various ways. Section 28 of the Constitution<sup>127</sup> places obligations on parents and the state to protect children by providing them with, amongst others, a right to family or alternative care, requiring them to be protected from ‘maltreatment, neglect, abuse, or degradation’, and prohibiting child labour.<sup>128</sup>

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<sup>127</sup> S 28(1) ‘Every child has the right –

(a) to a name and a nationality from birth; (b) to family care or parental care, or to appropriate alternative care when removed from the family environment; (c) to basic nutrition, shelter, basic health care services, and social services; (d) to be protected from maltreatment, neglect, abuse, or degradation; (e) to be protected from exploitative labour practices; (f) not to be required or permitted to perform work or provide services that –

(i) are inappropriate for a person of that child’s age; or (ii) place at risk the child’s well-being, education, physical or mental health, or spiritual, moral, or social development; (g) not to be detained except as a measure of last resort, in which case, in addition to the rights a child enjoys under sections 12 and 35, the child may be detained only for the shortest appropriate period of time, and has the right to be – (i) kept separately from detained persons over the age of 18 years, and (ii) treated in a manner, and kept in conditions, that take account of the child’s age; (h) to have a legal practitioner assigned to the child by the state, and at state expense, in civil proceedings affecting the child, if substantial injustice would otherwise result; and (i) not to be used directly in armed conflict, and to be protected in times of armed conflict.

(2) A child’s best interests are of paramount importance in every matter concerning the child.

(3) In this section, “child” means a person under the age of 18 years’, Constitution of the Republic of South Africa (note 2 above).

<sup>128</sup> *Ibid.*

The Children's Act has also been drafted with due consideration to the principles contained in both the CRC and section 28 of the Constitution. Section 6 sets out some general principles to guide the interpretation and implementation of the Children's Act. These principles include a strong focus on protection by providing for the importance of respect for children's rights, respect for a child's dignity, treating children fairly and equitably, and protection from unfair discrimination.<sup>129</sup> The obligation to protect children also flows from the concept of parental responsibilities and rights. These are duties owed by certain persons, such as parents to children, and include an obligation to care for the child and to act as guardian of the child.<sup>130</sup> The Children's Act also contains special obligations for interventions where there is a possibility that a child is in need of care or protection. This includes mandatory reporting obligations if children are being abused, neglected or are in need of care and protection.<sup>131</sup> These principles recognise the vulnerability of children and the need for special measures to ensure that their best interests are promoted.

It is submitted that in the context of research, the term child protection means there are special obligations on researchers and regulators to ensure that children are not harmed physically or psychologically by participating in the study.<sup>132</sup> This can be achieved for example, through measures such as requiring parental, guardian or care-giver consent for research participation involving children under the age of 12, or by setting upper limits on the risks that children may be subjected to during health research.<sup>133</sup>

The term 'child participation' refers to the involvement of children in decision-making according to their evolving capacity. The principle is one of the four fundamental pillars

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<sup>129</sup> S 6 Children's Act (note 4 above).

<sup>130</sup> S 18(2) *ibid.*

<sup>131</sup> S 110 Children's Act *ibid.* See Chapter Five for the definitions of these terms.

<sup>132</sup> Abdool Karim et al (note 26 above)

<sup>133</sup> See Chapter Two point 2.4.3 for a more detailed discussion on the limitations of consent as a protective measure if it is not coupled with ethical review.

underlying the CRC<sup>134</sup> which recognises that children are the bearers of rights and, as such, ought to participate in decisions that affect them in accordance with their evolving capacity.<sup>135</sup> This requires a consideration of how children can be involved in decision-making, both when they have capacity and in circumstances where they require assistance.<sup>136</sup> The principle has been formally recognised in section 10 of the Children's Act which provides that every 'child that is of such an age, maturity and stage of development as to be able to participate in any matter concerning that child has the right to participate in an appropriate way and views expressed by the child must be given due consideration'.<sup>137</sup>

This thesis argues that child participation in research decision-making is particularly important given the shift within the context of medical relationships away from paternalism to patient autonomy.<sup>138</sup> In the context of research it is submitted that this means involving children in deciding whether to participate in the study, obtaining their consent or assent, and ensuring respect for their wishes should they wish to withdraw at any point.

The third and final principle underpinning this thesis is research facilitation. It is based on an acceptance that children have a right to benefit from scientific progress. However, they can only do so if appropriate child research takes place. The thesis argues that this principle requires an ethical-legal framework which provides that children have a right to participate in research and to benefit from its outcomes. In other words, structures and norms are needed which do not exclude children from research participation, but rather facilitate their

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<sup>134</sup> S Human 'The theory of children's rights' in CJ Davel (ed) *Introduction to child law* (2000) 165.

<sup>135</sup> Article 12 Convention on the Rights of the Child (note 48 above).

<sup>136</sup> McClure et al (note 78 above) 728 where the authors argue that in a research context children who have capacity should participate through the consent process whilst those who do not should still be engaged through giving their assent provided that they are over the age of seven.

<sup>137</sup> Children's Act (note 4 above).

<sup>138</sup> *Castel v de Greef* 1994 (4) SA 408 (C) 421, 426B.

involvement in a protective manner.<sup>139</sup> Nevertheless, this must be research which can be justified on objective, scientific grounds.

It is argued that balancing competing interests when regulating research with children is complex, as greater emphasis must be placed on protecting children, particularly those who are required to act altruistically, whilst nevertheless facilitating health research.

Furthermore, protections must be balanced with the recognition of a child's evolving capacity and the need to involve and empower older or more mature children to act independently. In this tightrope walk, protectionist and empowering measures need to be found which do not exclude children but rather protect and promote their rights and welfare during research. This approach is aptly described by the WHO/UNAIDS/AAVP Expert Group:

Children and adolescents represent vulnerable individuals who must be afforded special protections. At the same time, epidemiological data show that sexually active adolescents are especially affected by the HIV epidemic, both biologically and behaviourally. As with all medical regulatory decision making, risks should be weighed against potential benefits for specific target populations. Clinical research involving healthy minors should thus be considered and balanced against the moral obligation to protect adolescents from disease, if possible through vaccination. Therefore, consideration should be given to the consequences of overly protective laws and regulations that limit the participation in HIV vaccine-related research and clinical trials of those groups who are precisely more likely to benefit from a successful HIV vaccine.<sup>140</sup>

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<sup>139</sup> For example, Strode and Slack argue that ethical guidelines should be revised so as to recognise that in certain circumstances in the absence of parents or guardians proxy consent could be provided by a care-giver as defined in the Children's Act, A Strode & C Slack 'Using the concept of parental responsibilities and rights to identify adults able to provide proxy consent to child research in South Africa' (2010) Vol 3(2) *South African Journal of Bioethics and Law* 55, 56–57.

<sup>140</sup> WHO/UNAIDS/AAVP Expert Group 'Executive summary and recommendations from WHO.UNAIDS/AAVP consultation on: 'The inclusion of adolescents in HIV vaccine trials' 15–18 March 2005, Gaborone, Botswana' (2007) Vol 21(1) *AIDS* 1, 5.

This is not an approach unique to research regulation. In recent years there has been a shift within the children's rights' discourse from protection to autonomy, from nurturing to self-determination, and from welfare to justice.<sup>141</sup> This thesis argues that such a shift ought to be reflected in legislation regulating the participation of children in research. The three principles of autonomy, self-determination and justice, when combined with the others underlying the CRC, the constitutional provisions on children, and those articulated in the Children's Act, can help create a framework for the development of a set of norms which inform legislation regulating health research with children.<sup>142</sup>

#### 1.4.4 Overview of the structure of this thesis

This thesis draws on work done by the author in a series of articles written over the last 12 years on a range of issues relating to the participation of children in health research, with a special focus on the participation of adolescents in HIV prevention research.<sup>143</sup> It develops this work into a more cohesive and comprehensive discussion on how an ethical-legal

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<sup>141</sup> MDA Freeman 'Introduction: rights, ideology and children' in M Freeman & P Veerman (eds) *The ideologies of children's rights* (1992) 3.

<sup>142</sup> These issues are discussed further in Chapters Seven and Eight.

<sup>143</sup> Including, Stobie, Strode & Slack (note 50 above); Strode, Slack, Wassenaar & Singh (note 118 above); Slack, Strode & Mamashela (note 49 above); Slack, Strode, Fleicher, Gray & Ranchod (note 85 above); Strode, Slack, Grant & Mushariwa (note 113 above); Strode & Slack (note 137 above); A Strode, C Slack & Z Essack 'Child consent in South African law: Implications for researchers, service providers and policy makers' (2010) Vol 100 No. 4 *South Africa Medical Journal* 247; A Strode & C Slack 'Sex, Lies And Disclosures: Researchers And The Reporting Of Under-Age Sex' (2009) No. 2 *Southern African Journal Of HIV Medicine* 8; HB Jaspan, NG Soka, AE Strode, C Mathews, D Mark, AJ Fisher, R Wood & LG Bekker 'Community perspectives on the ethical issues surrounding adolescent HIV vaccine trials in South Africa' (2008) Vol 26 *Vaccine* 5679; Strode, Slack & Mushariwa (note 93 above); H Jaspan, LG Bekker, C Grant, C Slack, A Strode & J Berwick 'Protecting South Africa's children from HIV: Giving them our best shot' (2005) Vol 101 *South African Journal of Science* 216; A Strode, C Slack, K Grant & M Mushariwa 'Ethical And Legal Challenges In Enrolling Adolescents In Medical Research In South Africa: Implications For HIV Vaccine Trials' (2005) Vol 101 *South African Journal of Science* 224; C Slack, A Strode, K Grant & C Milford 'Implications of the Ethical-Legal Framework for Adolescent HIV Vaccine Trials: Report of a Consultative Forum' (2005) Vol 95(9) *South African Medical Journal* 682; C Slack, G Lindegger, E Vardas, L Richter, A Strode & D Wassenaar 'Ethical issues in HIV vaccine trials in South Africa' (2000) Vol 96 *South African Journal of Science* 291A; and C Slack, P Singh, A Strode & Z Essack 'Compensation for research-related injury in South Africa: A critique of the Good Clinical Practice Guidelines (GCP)' (2012) Vol 5(2) *South African Journal of Law and Bioethics* 91–94.

framework can protect children, promote their participation in research-related decisions and facilitate appropriate health research.

In this thesis, Chapter One deals with the background to this thesis, includes a discussion of the three strands that ought to underpin research regulation with children and describes a children's rights framework. Chapter Two sets out the ethical-legal norms for regulating health research as established in international law and ethical codes. Chapter Three describes the evolution of the ethical-legal framework from an informal and largely voluntary system to a highly regulated framework created by law. Chapter Four sets out the current institutional framework regulating research in South Africa. Chapter Five describes the current normative framework regulating research with children. Chapter Six is a critique of the extent to which the current ethical-legal framework protects children, promotes child participation and facilitates research with children. Chapter Seven describes the principles that ought to inform law reform and how they can be used to create a legislative framework which protects children, enables them to participate in research-related decisions and enables appropriate research to take place with this population. It provides details of the proposed law and policy reform proposals. Chapter Eight concludes this dissertation by setting out the broad conclusions of this study.

## **1.5 Conclusion**

It is clear that children need to participate in health research in order to develop and enhance provision of health care services designed for them. However, involving children in research is legally complex and many competing interests need to be balanced. The limitation of an exclusionary approach is that it undermines the future development of child health, while an overly inclusionary approach may compromise children's rights.

In this context, this study argues that it is an oversimplification to view this as an 'access versus protection' dilemma. Rather, it is important to develop a standard which accommodates the three competing interests of protection, child participation and research facilitation. An ethical-legal framework is required to achieve the balance described above if it is to be in the best interests of children. It does not argue that a perfect equilibrium must be found, but rather a system which strives as far as possible to balance these interests, under the over-arching principle of the best interests of the child.

In South Africa, neither the previous nor current ethical-legal frameworks have protected under-age participants adequately, facilitated child participation or promoted research with this population.

## **Chapter Two:**

### **The institutional and normative framework for regulating health research with children as established by international law and ethical codes**

In the preceding chapter, the background to this thesis was presented. It described the importance of health research in developing evidence-based interventions and of involving children in such research; discussed the competing interests that need to be balanced during the regulation of research; identified the key legal complexities with regulating research with children; and gave an overview of the current ethical-legal framework for regulating research in South Africa. The chapter concluded by arguing that in South Africa, neither the previous nor the current ethical-legal frameworks have protected under-age participants adequately, facilitated child participation or promoted research with this population. Accordingly, law and policy reform is required to serve the interests of both children and science. Thus law and policy reform must be grounded in the well-established principles described in international law and ethical codes.

This chapter describes: the historical context which has informed the development of the international ethical-legal framework; the interface between ethics and law; and the rationales used to justify the regulation of health research. The most significant documents in international humanitarian and human rights law and ethical codes for the regulation of research, the key characteristics of well-functioning ethical-legal frameworks (institutions and norms) and a model for classifying ethical-legal systems are also described. The chapter concludes with comments on the nature of the protections found within the institutional and normative framework in international law and ethical guidelines and how they can be used

to inform the critique of our current ethical-legal framework, and the development of law reform proposals.

## 2.1 Introduction

At the international level there are well-established institutional and normative principles setting out how countries and institutions should review, regulate and enforce health research standards.

### 2.1.1 *Historical context*

The legal regulation of research has had a relatively short history. Prior to the Nuremburg Code in 1946, legal restraints on health research were almost non-existent.<sup>144</sup> The regulation of research with children has an even shorter history, the Nuremburg Code, for example, being silent on this issue.<sup>145</sup> Regulation has been introduced largely as a result of public pressure on legislatures following the exposure of high profile human rights abuses. Resultantly, in the last century governments have responded by developing ethical-legal frameworks that regulate health research through substantive and procedural protections for research participants.<sup>146</sup>

Two of the most high profile abuses of the rights of research participants in clinical trials were the experiments conducted on Nazi prisoners-of-war, and the Tuskegee syphilis study in the United States of America.

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<sup>144</sup> Glanz (note 90 above) 103.

<sup>145</sup> *Ibid.* It has been argued that a literal reading of the Nuremburg Code prohibits research with children unless they can give independent consent as it makes no provision for proxy consent. Glantz argues that this oversight occurred as the drafters of the Code were not focusing on the subtleties of consent given that all the Nazi research was done without consent of any form. This omission within the Nuremburg Code has been rectified by the Helsinki Declaration which allows for proxy consent (note 41 above).

<sup>146</sup> NR Elster & RE Hoffman 'Public health research and health information' in RA Goodman, N Rothstel, RE Hoffman, W Lopez & GW Mathews (eds) *Law in Public Health Practice* (2003) 160, 161.

During the Second World War, Nazi doctors undertook widespread medical experimentation on prisoners-of-war. For example, the so-called 'freezing experiments' were performed to find the most effective way of resuscitating German pilots who had to parachute into the North Sea. Prisoners-of-war (research participants) were forced to remain outside in sub-zero conditions for nine to 14 hours, or they were coerced into tanks of ice water for up to three hours at a time. Re-warming occurred by placing them in a hot bath, or between two naked gypsy women. Many prisoners died during these resuscitation processes.<sup>147</sup>

In the Tuskegee trial, the US Public Health Service recruited poor African-American men between 1932 and 1972 into a study and allowed them to die of untreated syphilis, in order to facilitate research into the natural progression of the disease.<sup>148</sup> Even when penicillin was found to be a cheap and effective treatment for syphilis, the researchers failed to offer this treatment or disclose this information to participants.<sup>149</sup> The denial of a known therapy to research participants was exposed in the media in 1972, leading to public outrage and a series of public hearings. Ultimately, it resulted in pressure being placed on the United States government to pass the National Research Act of 1974 and federal regulations dealing with research.<sup>150</sup>

There have also been a number of high profile abuses in clinical trials involving children. For example, the infamous Nazi doctor, Josef Mengele undertook extensive medical experimentation on hundreds of sets of twins at Aushwitz concentration camp in Germany

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Also see T Taylor 'Opening statement of the prosecution, December 9, 1946' in GJ Annas & MA Grodin (eds) *The Nazi doctors and the Nuremburg Code: Human rights in human experimentation* (1992) 67, 67. The prosecutors described the cruel approach of the Nazi doctors as follows 'for the most part they are nameless dead. To their murders, these wretched people were not individuals at all. They came in wholesale lots and were treated worse than animals . . . The victims of these crimes are numbered among the anonymous millions who met death at the hands of the Nazis' *ibid* 67.

<sup>148</sup> Elster & Hoffman (note 146 above) 161.

<sup>149</sup> This took place even though other patients outside of the trial were being treated at the clinics where they were reporting for research visits. Kennedy & Grubb (note 51 above) 1714–1715.

<sup>150</sup> Elster & Hoffman (note 144 above) 162.

during the Second World War.<sup>151</sup> Dr Mengele was particularly interested in genomics and investigating which characteristics twins were born with and which they developed as a result of their environment,<sup>152</sup> In the US, the longitudinal hepatitis study that took place at Willowbrook State School in the USA from the 1950s until the 1970s is regarded as having abused the rights of a highly vulnerable group even though parental consent was obtained.<sup>153</sup> Children at this school for the mentally disabled were injected with a hepatitis virus in order to allow researchers to study the natural course of the disease. Parents wishing to enroll their children in the school (very few of such schools existed at the time) were required to agree that their child would participate in the study. The research was only stopped after a public outcry.<sup>154</sup> More recently, it was alleged that research into Trovan, a meningitis drug which was being tested on children living in Nigeria, was undertaken without appropriate consent and it resulted in 12 deaths and many more children suffering brain damage, paralysis or slurred speech.<sup>155</sup>

Research abuses have not been confined to clinical research, in recent decades a number of social science studies which have violated participants rights have been exposed in the media and academic journals.<sup>156</sup> For example, Wassenaar and Mamotte describe a study on the sexual practices of gay men undertaken during the 1970s. This was done by observing covert meetings of men in a public park. Photographs were taken of their car registrations and this information was used to trace their physical addresses in order to recruit them into

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<sup>151</sup> [http://history1900s.about.com/od/auschwitz/a/mengeletwins\\_2.htm](http://history1900s.about.com/od/auschwitz/a/mengeletwins_2.htm) [Accessed: 30 January 2014].

<sup>152</sup> *Ibid.*

<sup>153</sup> Burns (note 6 above).

<sup>154</sup> *Ibid.*

<sup>155</sup> Singh (note 10 above) 74. In *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009) a civil claim for damages was brought against the funder of the research. In this case it was further alleged that participants were not made aware that the drug was experimental.

<sup>156</sup> D Wassenaar & N Mamotte 'Ethical issues and ethical reviews in social science research' (2008) Vol 1 *Social Science and Medicine* 1, 2.

the study. Potential participants were visited at home and invited to be interviewed about their sexual behavior or practices.<sup>157</sup>

Wassenaar and Mamotte argue that this study violated ethical principles through its unjustified 'intrusive monitoring of public and private behaviour', and using this as an entry to coercive recruitment practices.<sup>158</sup>

There have also been a number of research-related scandals in South Africa. These include: the failure of an academic from the University of Witwatersrand to obtain ethical approval for breast-cancer studies that compared conventional and high doses of chemotherapy involving women who were at risk of breast cancer;<sup>159</sup> and the so-called 'Virdodene affair' in which researchers from the University of Pretoria conducted clinical trials with an industrial solvent which they claimed 'cured AIDS'. Following a public outcry, an investigation established that the researchers had proceeded without the requisite permission being obtained from either the ethics committee or the MCC.<sup>160</sup>

More recent examples of research abuses have been more complex and less overt transgressions of ethical or regulatory obligations. For example, in the late 1990s there was an international debate on whether Prevention of Mother to Child Transmission (PMTCT) studies, which included a placebo arm, were ethical given that data already existed which showed that a short course in azidothymidine (AZT) reduced the possibility of HIV transmission from mother to child. In other words, given that it had already been established

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<sup>157</sup> *Ibid.*

<sup>158</sup> *Ibid.* Wassenaar and Mamotte also list a number of other examples of high profile abuses that took place in social science studies.

<sup>159</sup> P Cleaton-Jones 'Scientific misconduct in breast cancer chemotherapy trial: Response of the University of the Witwatersrand' (2000) (Vol 355) *The Lancet* 1011, 1011.

<sup>160</sup> <http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=83156&sn=Detail>  
[Accessed: 28 May 2009].

that AZT could reduce the possibility of HIV being transmitted to the child during pregnancy and birth, and that it had been registered as a drug for this particular use, was it ethical to deny female research participants in the placebo group the possibility of preventing mother to child transmission by using AZT? Subsequently a number of on-going trials were either stopped or re-designed.<sup>161</sup>

These abuses of procedural protections and substantive rights have demonstrated that firstly, health research must be regulated by external institutions and not simply by scientists themselves. Secondly, norms and standards must be put in place in both ethical guidelines and laws, ensuring basic protections for human subjects. Thirdly, enforcement mechanisms need to be in place to ensure that rights are complied with and obligations met.

#### 2.1.2 *The two faces of research regulation – the inter-relationship between law and ethics*

The link between law and ethics in the context of health research is complex. However, for the most part, it is a symbiotic relationship. While laws impose enforceable norms, it has been argued that bioethics aims at establishing ‘morally defensible’ practices.<sup>162</sup>

Nevertheless both ethics and law have the common goal of providing rules or norms for the regulation of human conduct with regard to health research.

In the field of health research, law and ethics provide an interwoven set of norms. Firstly, where there is no clear legal rule dealing with the issue, ethical guidelines can be used to establish the obligations on researchers. Harm emanating from a failure to adhere to ethical guidelines could be actionable.<sup>163</sup> Secondly, ethics may inform policy-making and underpin

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<sup>161</sup> Heywood (note 44 above) 397.

<sup>162</sup> JN Lindemann *Moral teachings from unexpected quarters: Lessons for bioethics from social sciences and management care* (2000) 12.

<sup>163</sup> *Jansen van Vuuren and Another v Kruger* 1993 (4) SA 842 (A) 850B–J and 856B–H. In this matter the Appellate Division found that a doctor’s failure to maintain confidentiality regarding a patient’s HIV status violated the ethical guidelines of the South African Medical and Dental Council. Given that patients have a right

the approach taken by statutory institutions, for example, the MCC requires that applications to undertake clinical trials include a signed statement that the investigators will comply with the ethical norms in the Good Clinical Practice Guidelines (GCP) issued by the Department of Health and obtain ethical approval by a recognised REC.<sup>164</sup> Thirdly, in some instances ethical norms have become legal obligations, for example, the long-standing ethical rule of submitting research to an REC for review has become a legal obligation in terms of section 73 of the NHA which requires that all institutions undertaking health research establish or have access to an REC.<sup>165</sup>

## 2.2 Rationales for regulating research

Traditionally, legislatures have resisted regulating research as they have preferred not to interfere in the special relationship between doctors and patients, encroach on academic freedom, or infringe on the autonomy rights of individuals.<sup>166</sup> Accordingly, the law has played a relatively minor role in regulating health research.<sup>167</sup> However health research frequently requires the use of human volunteers who may bear some risk. Furthermore, as described above, the potential for abuse or exploitation of such volunteers may exist, particularly if regulatory systems are under-developed, lack resources or are ineffective.<sup>168</sup> Accordingly, it has been recognised increasingly that an effective ethical-legal framework is required for research regulation.

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to expect that their doctor would act ethically, the doctor could be held liable for this breach of confidentiality, *ibid.*

<sup>164</sup> Regulation 34(2) General Regulations, Medicines and Related Substances Act 101 of 1965. The GCP Guidelines have been developed to provide clear, appropriate and locally relevant standards of good clinical practice in research and to ensure that research with human participants takes place within the framework of sound scientific and ethical standards Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa (note 58 above).

<sup>165</sup> National Health Act (note 57 above).

<sup>166</sup> P Andanda *The law and regulation of clinical research* (2006) 39.

<sup>167</sup> Glanz (note 90 above) 127.

<sup>168</sup> Fisher (note 40 above) 195–197.

In this context it has been argued that the regulation of research is important for two reasons. Firstly, in order to safeguard participants from harm, ensuring that their autonomy is protected, and that they participate only with their or a proxy's informed consent.<sup>169</sup> And secondly, in order to ensure that the interests of society and of science do not outweigh the individual interests of research participants.<sup>170</sup> The Helsinki Declaration recognises that although medical progress requires research which may entail experimentation involving human subjects, the well-being of human subjects should take precedence over the interests of science and society.<sup>171</sup> Chima postulates the other purpose of research regulation as being the guidance it provides on, amongst others, the role of local RECs, informed consent procedures, standards of care, and compensation for harm.<sup>172</sup>

Nielsen, on the other hand, identifies three different functions that are served by regulating research. They are, firstly, a norm-setting function. This declares certain interests as worthy of protection against infringement, for example, the need for informed consent (or proxy consent) from all research participants. Secondly, a protective function, which balances the protected values against other interests, for example, ensuring appropriate risk standards exist in research even where the study may generate important outcomes such as a possible HIV vaccine. Thirdly, a declarative function, which establishes clarity in dealing with controversial issues, for example, setting out the position that ought to be adopted regarding research into human cloning.<sup>173</sup>

### **2.3 The International framework for research regulation**

In the post-Nuremburg period, the ethical-legal regulation of research has been an issue of concern for the international community, which has developed a number of international

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<sup>169</sup> T Hope, J Savulesen & J Hendrick *Medical ethics and the law* (2003) 193.

<sup>170</sup> *Ibid.*

<sup>171</sup> Article, 3 Helsinki Declaration (note 41 above).

<sup>172</sup> SC Chima 'Regulation of biomedical research in Africa' (2006) Vol 332 *British Medical Journal* 848, 848.

<sup>173</sup> Nielsen (note 42 above) 42.

and regional statements establishing norms and standards.<sup>174</sup> There has also been the adoption of, amongst others, the four Geneva Conventions,<sup>175</sup> the International Covenant on Civil and Political Rights (ICCPRs),<sup>176</sup> the ICESCRs,<sup>177</sup> and the Universal Declaration on the Human Genome and Human Rights (UDHGHRs),<sup>178</sup> all of which make some reference to research. There has also been one regional convention, the Convention on Human Rights and Biomedicine, which was adopted by the European Union.<sup>179</sup> Finally, although the CRC is silent on the issue of the participation of children in health research, the Committee on the Rights of the Child has issued two General Comments both of which deal in some way with the participation of children in research.<sup>180</sup>

Several international ethical codes have also been issued in recent years, including, the World Medical Association's Helsinki Declaration,<sup>181</sup> the Council for the International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research involving Human Subjects,<sup>182</sup> the World Health Organisation's Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products,<sup>183</sup> and the Good Clinical Practice

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<sup>174</sup> Hervey & McHale (note 89 above) 237.

<sup>175</sup> The Geneva Conventions deal with amongst others, informed consent, the selection of research participants and they prohibit the use of protected military personnel or civilians in biological experimentation available from <http://www.icrc.org/ihl.nsf/7c08d9b287a42141256739003e636b/44072487ec4c2131c125641e004a9977?OpenDocument> [Accessed: 9 July 2008]. See a more detailed discussion of these provisions in Andanda (note 166 above) 56–57.

<sup>176</sup> <http://www.hrweb.org/legal/cpr.html> [Accessed: 2 July 2009].

<sup>177</sup> International Convention on Economic Social and Cultural Rights (note 9 above).

<sup>178</sup> [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1881&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html) [Accessed 8 September 2008].

<sup>179</sup> [http://europatientrights.eu/biomedicine\\_convention/biomedicine\\_convention.html](http://europatientrights.eu/biomedicine_convention/biomedicine_convention.html) [Accessed: 2 July 2009].

<sup>180</sup> Convention on the Rights of the Child (note 48 above) and General Comment No. 3 (2003) HIV/AIDS and the rights of the child issued by the Committee on the Rights of the Child, available at [http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/CRC.GC.2003.3.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/CRC.GC.2003.3.En?OpenDocument) [Accessed: 8 October 2008] and General Comment No. 5 (2003) (note 9 above).

<sup>181</sup> Helsinki Declaration (note 41 above).

<sup>182</sup> CIOMS Guidelines available from [http://www.cioms.ch/frame\\_guidelines\\_nov\\_2002.htm](http://www.cioms.ch/frame_guidelines_nov_2002.htm) [Accessed: 9 July 2008].

<sup>183</sup> World Health Organisation's Good Clinical Practice Guidelines available from <http://homepage.vghtpe.gov.tw/~mre/goodexp/Fercap-Survey/WHO-GCP-1995.pdf> [Accessed: 29 June 2009].

Guidelines issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.<sup>184</sup>

Andanda posits that these international guidelines can be divided into three broad categories, those found in international:

- (i) Humanitarian law;
- (ii) Human rights law; or
- (iii) Ethical documents issued by the medical profession.<sup>185</sup>

### 2.3.1 *Protections described in international humanitarian law*

The four Geneva Conventions all make various references to research. They deal primarily with ensuring that research occurs only in limited circumstances, and with the informed consent of participants. Thus, for example, Article 12 of the First and Second Geneva Conventions provides that members of the armed forces may not be subjected to biological experiments:

Members of the armed forces and other persons mentioned in the following Article . . . shall be respected and protected in all circumstances . . . Such persons shall be treated humanely and cared for by the Parties to the conflict in whose power they may be, without any adverse distinction founded on sex, race, nationality, religion, political opinions, or any other similar criteria. Any attempts upon their lives, or violence to their persons, shall be strictly prohibited; in particular, they shall not be murdered or exterminated, subjected to torture or to biological experiments.<sup>186</sup>

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<sup>184</sup> ICH Guidelines available from <http://www.ich.org/cache/compo/276-254-1.html> [Accessed: 22 June 2009].

<sup>185</sup> Andanda (note 166 above) 55.

<sup>186</sup> Geneva Conventions (note 175 above).

These provisions, by their very nature, have limited application as they apply only to armed conflicts.<sup>187</sup> Furthermore, the Geneva Conventions do not deal expressly with the participation of child soldiers in research, given that children under the age of 15 are prohibited from fighting in armed conflicts.<sup>188</sup>

### 2.3.2 *Protections found in international human rights law*

There are several documents which form part of international human rights law, which make reference to research. They establish a limited number of substantive norms and do not create any procedural obligations relating to the need, for example, to undertake ethical review. The international legal framework also does not deal in any detail with the participation of children in health research.

#### *(i) The Nuremburg Code*

One of the most critical issues facing the court in the so-called 'doctor's trial' was the lack of established ethical and legal standards for research involving human subjects.<sup>189</sup> Given this lacuna in international guidance the judges responded by issuing the Nuremburg Code.<sup>190</sup> This Code, based on the theory of natural law,<sup>191</sup> protects the rights of research participants primarily through the doctrine of informed consent. Two of the 10 principles reflect the

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<sup>187</sup> Andanda (note 166 above) 56.

<sup>188</sup> The Convention on the Rights of The Child provides in Article 38(2) that states shall 'take all feasible measures to ensure that persons who have not attained the age of fifteen years do not take a direct part in hostilities'. Furthermore in Article 38(3) provides that '(s)tates Parties shall refrain from recruiting any person who has not attained the age of fifteen years into their armed forces. In recruiting among those persons who have attained the age of fifteen years but who have not attained the age of eighteen years, States Parties shall endeavour to give priority to those who are oldest' (note 48 above).

<sup>189</sup> Andanda (note 166 above) 49 and *United States of America v. Karl Brandt* Case No. 1 Nuremburg Military Tribunal (1946).

<sup>190</sup> Annas GJ 'Questing for Grails: Duplicity, betrayal, and self-deception in postmodern medical research' in JM Mann, S Gruskin, MA Grodin, & GJ Annas (ed) *Health and Human Rights: A Reader* (1998) 312, 315.

<sup>191</sup> Natural law is a 'law or body of laws that derives from nature and is believed to be binding upon human actions apart from or in conjunction with laws established by human authority' <http://www.thefreedictionary.com/natural+law> [Accessed: 8 July 2012].

rights of research participants<sup>192</sup> and the other eight require researchers to promote the welfare of research participants during research.<sup>193</sup> The Code also requires the research process to promote the welfare of participants before consent is secured.<sup>194</sup> The 10 principles articulated in the Nuremburg Code are as follows:

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

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<sup>192</sup> Principles 1 and 9 reflect the rights of research participants to participate in research with their informed consent and to withdraw such consent at any point, Nuremburg Code (note 11 above).

<sup>193</sup> GJ Annas & MA Grodin 'Medicines and human rights: Reflections on the fiftieth anniversary of the Doctor's Trial' in Mann, Gruskin, Grodin & Annas (eds) (note 190 above) 301, 302.

<sup>194</sup> Annas (note 190 above) 315.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.<sup>195</sup>

The Code is regarded as significant for several reasons. Firstly, it was the first international code of practice establishing principles for the regulation of health research.<sup>196</sup> Secondly, it has been the impetus for the development of other international codes dealing with health research, such as the Geneva Conventions and the Helsinki Declaration issued by the World Medical Association.<sup>197</sup> Thirdly, it has been argued that its provisions are so widely accepted

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<sup>195</sup> Nuremburg Code (note 11 above).

<sup>196</sup> CM Bassiouni, TG Baffes & JT Evrard 'An appraisal of human experimentation in international law and practice' (1981) *The Journal of Criminal Law and Criminology* 1639, 1641.

<sup>197</sup> S Perley, SS Fluss, Z Bankowski & F Simon *The Nuremburg Code: An international overview* in GJ Annas & MA Grodin (eds) *The Nazi doctors and the Nuremburg Code: Human rights in human experimentation* (1992) 149, 152–154.

that they have become part of international customary law and may be applied in both civil and criminal courts.<sup>198</sup>

Nevertheless, the Code has been criticised on a number of grounds, including: it was developed as a human rights document by judges in a criminal trial; it is silent on research involving children, healthy volunteers or mentally disabled persons;<sup>199</sup> and it makes no mention of the need for ethical review of research.<sup>200</sup> There have also been criticisms of numerous specific principles, for example, principle three, as researchers are not generally able to guarantee success.<sup>201</sup> So too with principle five, as the willingness of researchers to expose themselves to risk cannot justify an otherwise unethical study.<sup>202</sup> Finally, principle six can be faulted for requiring an evaluation of one's own research which is contrary to the more modern focus on independent ethical review.<sup>203</sup>

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<sup>198</sup> GJ Annas 'The Nuremburg Code in US courts: Ethics versus expediency' in GJ Annas & MA Grodin (eds) *ibid* 201, 201. More recently, the Nuremburg Code was found to be the bedrock of the customary international law principle that no person may participate in health research unless they have provided their informed consent *Abdullahi v. Pfizer, Inc* (note 155 above).

<sup>199</sup> *Ibid.*

<sup>200</sup> Perley, Fluss, Bankowski & Simon (note 197 above) 156.

<sup>201</sup> *Ibid.*

<sup>202</sup> *Ibid.*

<sup>203</sup> *Ibid.*

*(ii) The International Convention on Civil and Political Rights*

The ICCPRs was adopted by the United Nations in 1966 and came into operation in 1976.<sup>204</sup> The Preamble to the Convention states ‘the ideal of free human beings enjoying civil and political freedom and freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his civil and political rights.’<sup>205</sup> The 53 articles deal with amongst others: equality between men and women,<sup>206</sup> the right to liberty and security of the person,<sup>207</sup> and the right to freedom of thought, conscience and religion.<sup>208</sup> Notably, the Convention does not deal with issues relating specifically to children.<sup>209</sup>

Only one article in this Covenant deals directly with research. Article 7 provides that ‘no one shall be subjected without his free consent to medical or scientific experimentation’.<sup>210</sup> Although there is no other specific reference to research, many of the provisions in the Convention are broad and could apply indirectly to health research. For example, Article 17 deals with the right to privacy and provides that ‘(N)o one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.’ This article could be applied to a research relationship to ensure that participants’ rights are protected from the arbitrary disclosure of research information. Other rights that could be applicable to a research relationship include the right not to be subjected to torture, cruel or inhuman treatment, and the right to physical integrity, dignity and equality.<sup>211</sup> Furthermore, rights protecting vulnerable groups such as

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<sup>204</sup> J Dugard *International Law: A South African perspective* 3 ed (2005) 316.

<sup>205</sup> International Convention on Civil and Political Rights (note 170 above).

<sup>206</sup> Article 3 *ibid.*

<sup>207</sup> Article 9 *ibid.*

<sup>208</sup> Article 18 *ibid.*

<sup>209</sup> However, this gap has been dealt with by the adoption of the Convention on the Rights of the Child by the United Nations in 1989 (note 48 above).

<sup>210</sup> *Ibid.* A very similar phrase is contained within s 12 of the Constitution of the Republic of South Africa (note 2 above). This is discussed in more detail in Chapter Five.

<sup>211</sup> Nienaber (note 87 above) 146–147.

women or children could also assist in ensuring that such populations are not harmed during research.<sup>212</sup>

South Africa ratified this Convention in 1998.<sup>213</sup>

There has been criticism of the way in which Article 7 of the ICCPRs has been worded with some arguing that the use of the words 'without his free consent' implies that proxy consent for health research is not permissible as only the individual participants themselves may give consent.<sup>214</sup> This argument excludes children and other groups who do not have the capacity to consent from participating in some forms of research, such as clinical trials. However it could also be argued, using a purposive approach to interpretation, that this phrase simply means that research without consent (from the individual or an authorised representative) is not permitted.<sup>215</sup>

*(iii) International Covenant on Economic, Social and Cultural Rights*

The ICESCRs was adopted by the United Nations in 1966 and came into operation in 1976.<sup>216</sup>

It deals with socio-economic and cultural rights. Its preamble states that 'the ideal of free human beings enjoying freedom from fear and want can only be achieved if conditions are created whereby everyone may enjoy his economic, social and cultural rights, as well as his civil and political rights.'<sup>217</sup> States are required to take steps to the maximum of their available resources to progressively achieve the full realisation of the rights described in the

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<sup>212</sup> *Ibid.*

<sup>213</sup> Dugard (note 204 above) 316.

<sup>214</sup> Van Oosten (note 104 above) 7–8.

<sup>215</sup> Van Wyk (note 13 above) 46. This interpretation of the ICCPRs has been adopted in a number of other jurisdictions for example, in Australia s 4.1 of the National Statement on Research Involving Children that proxy consent may be provided, in the USA where s 46 of the 406, Code of Federal Regulations allows certain adults to provide consent on behalf of incompetent children and in Scotland where in terms of Annexure 1 of the Statutory Instrument No. 1031, 2003 proxy consent in certain circumstances is lawful. See Chapter Five for further discussion on this point.

<sup>216</sup> Dugard (note 204) above 316.

<sup>217</sup> International Convention on Economic, Social and Cultural Rights (note 9 above).

Covenant.<sup>218</sup> The 31 articles in the Covenant deal with, amongst others, the right to just working conditions,<sup>219</sup> social security<sup>220</sup> and the enjoyment of the highest attainable standard of physical and mental health.<sup>221</sup> The Covenant does not deal with issues relating specifically to children.<sup>222</sup>

The Covenant deals directly with research in only one provision, Article 15, which states that everyone has the right to ‘enjoy the benefits of scientific progress and its applications.’<sup>223</sup> As in the case of the ICCPRS, many of its non-specific provisions could nevertheless be applied to health research. For example, Article 12 outlines the right of every person to the ‘highest attainable standard of physical and mental health’ and it is argued that this could be interpreted as placing an obligation on the state to ensure that participants in clinical trials receive adequate care during and after the study.<sup>224</sup>

South Africa signed this Covenant in 1994 but has not ratified it as yet.<sup>225</sup>

#### *(iv) Universal Declaration on the Human Genome and Human Rights*

The UDHGHRs was adopted by the General Conference of the United Nations Educational, Scientific and Cultural Organisation (UNESCO) on 11 November 1997.<sup>226</sup> This Declaration

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<sup>218</sup> Article 2 *ibid*.

<sup>219</sup> Article 7 *ibid*.

<sup>220</sup> Article 9 *ibid*.

<sup>221</sup> Article 12 *ibid*.

<sup>222</sup> However, a child’s socio-economic rights are described in detail in the Convention on the Rights of the Child (note 48 above). It should be noted that the CRC was the first international instrument to incorporate civil, political, cultural, economic, political and social rights within a single convention.

<sup>223</sup> International Convention on Economic, Social and Cultural Rights (note 9 above).

<sup>224</sup> *Ibid* and Nienaber (note 87 above) 146–147.

<sup>225</sup> Dugard (note 204 above) 316. Also see <http://www.peopletoparliament.org.za/focus-areas/socio-economic-rights/resources/icescr-ratification-campaign> [Accessed: 3 January 2013]. However, it was reported in October 2012 that cabinet had agreed that South Africa ought to ratify the convention <http://www.ngopulse.org/press-release/south-africa-ratify-international-socio-economic-rights-covenant> [Accessed: 15 February 2013].

<sup>226</sup> Universal Declaration on the Human Genome and Human Rights (note 180 above).

deals with the human rights issues relating specifically to genomic research and not health research generally.

The Declaration deals with amongst others: the right of everyone to respect for their dignity and rights, regardless of their genetic characteristics;<sup>227</sup> ensuring the rights of all persons are protected, including, for example, obtaining consent before research;<sup>228</sup> outlawing discrimination due to genetic characteristics;<sup>229</sup> ensuring human rights prevail over research interests;<sup>230</sup> outlawing practices which are contrary to human dignity such as human cloning;<sup>231</sup> and encouraging states to foster genomic research whilst nevertheless considering the ethical, legal, social and economic considerations.<sup>232</sup>

This is a declaration and not a convention and is therefore not legally binding on member states of the United Nations. However it does describe the obligations that ought to be imposed on states in implementing safeguards which balance respect for human rights with the fundamental freedom to engage in genomics research.<sup>233</sup>

Despite not being legally binding, the Declaration is regarded as significant for a number of reasons including that it is the first international document which links the language of human rights to medical ethics and a controversial research issue.<sup>234</sup>

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<sup>227</sup> Article 2 *ibid.*

<sup>228</sup> Article 5 *ibid.*

<sup>229</sup> Article 6 *ibid.*

<sup>230</sup> Article 10 *ibid.*

<sup>231</sup> Article 11 *ibid.*

<sup>232</sup> Article 14 *ibid.*

<sup>233</sup> Preamble *ibid.*

<sup>234</sup> YM Barilan & M Brusa 'Human rights and bioethics' (2008) Vol 34 *J Med Ethics* 379, 379.

*(v) Convention on the Rights of the Child*

The CRC was adopted by the United Nations in 1989 and has established children's rights a core element of international law.<sup>235</sup> Wolfson argues that its significance lies in its attempt to articulate the practical implications of the best interests of the child standard.<sup>236</sup> It does this by focusing on four key principles which underlie the Convention. They are: non-discrimination; the best interests of the child; the right to life, survival and development; and respect for the views of the child.<sup>237</sup>

The CRC contains 54 articles and two Optional Protocols.<sup>238</sup> It does not specifically mention the rights of child research participants. However, it is argued that, as has been stated above in relation to the ICCPRs and the ICESCRs, many of its provisions are broad enough to permit their application to health research. For example, it includes the right to non-discrimination,<sup>239</sup> consideration of the best interests of children during decision-making,<sup>240</sup> survival and development,<sup>241</sup> of children to express their views if they are capable of doing so,<sup>242</sup> privacy,<sup>243</sup> access to information,<sup>244</sup> protection from violence or abuse,<sup>245</sup> the highest attainable standard of health,<sup>246</sup> play,<sup>247</sup> and not to be subjected to torture or cruel and inhuman treatment.<sup>248</sup>

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<sup>235</sup> J Sloth-Nielsen & BD Mezmur 'Surveying the research landscape to promote children's legal rights in an African context' (2007)(2) *African Human Rights Law Journal* 331.

<sup>236</sup> SA Wolfson 'Children's rights: the theoretical underpinning of the best interests of the child' in M Freeman & P Veerman (eds) *The ideologies of children's rights* (1992) 7.

<sup>237</sup> Convention on the Rights of the Child (note 48 above).

<sup>238</sup> *Ibid.*

<sup>239</sup> Article 2 *ibid.*

<sup>240</sup> Article 3 *ibid.*

<sup>241</sup> Article 6 *ibid.*

<sup>242</sup> Article 12, *ibid.*

<sup>243</sup> Article 16 *ibid.*

<sup>244</sup> Article 17 *ibid.*

<sup>245</sup> Article 18 *ibid.*

<sup>246</sup> Article 24 *ibid.*

<sup>247</sup> Article 31 *ibid.*

<sup>248</sup> Article 37 *ibid.*

South Africa ratified the CRC on 16 June 1995.<sup>249</sup>

Although the CRC does not itself refer to research with children, General Comment No. 3 (2003) on HIV/AIDS and the rights of the child issued by the Committee on the Rights of the Child<sup>250</sup> takes a very restrictive approach to the participation of children in research. It states in point 29:

Consistent with article 24 of the Convention, States parties must ensure that HIV/AIDS research programmes include specific studies that contribute to effective prevention, care, treatment and impact reduction for children. States parties must, nonetheless, ensure that children do not serve as research subjects until an intervention has already been thoroughly tested on adults. Rights and ethical concerns have arisen in relation to HIV/AIDS biomedical research, HIV/ADS operations, and social, cultural and behavioural research. Children have been subjected to unnecessary or inappropriately designed research with little or no voice to either refuse or consent to participation. In line with the child's evolving capacities, consent of the child should be sought and consent may be sought from parents or guardians if necessary, but in all cases consent must be based on full disclosure of the risks and benefits of research to the child. States parties are further reminded to ensure that the privacy rights of children, in line with their obligations under article 16 of the Convention, are not inadvertently violated through the research process and that personal information about children, which is accessed through research, is, under no circumstances, used for purposes other than that for which consent was given. States parties must make every effort to ensure that children and, according to their evolving capacities, their parents and/or their guardians participate in decisions on research priorities and that a supportive environment is created for children who participate in such research.<sup>251</sup>

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<sup>249</sup> The Convention came into operation on 16 July 1995, Status of ratifications of the CRC is available from [http://www.bayefsky.com/pdf/crc\\_ratif\\_table.pdf](http://www.bayefsky.com/pdf/crc_ratif_table.pdf) [Accessed: 9 July 2012].

<sup>250</sup> General Comment No. 3 (note 174 above).

<sup>251</sup> *Ibid.*

The main criticisms of this General Comment are threefold. Firstly, it focuses on HIV research instead of health research more broadly. It is important to have international guidance on health research with children and while much of the current focus is on HIV, it is not the only significant health problem facing children.<sup>252</sup> Secondly, it is unclear what is meant by the provision that children may only participate in research after interventions have been ‘thoroughly tested on adults’. For example, in a clinical trial context, it is uncertain whether this means that children may participate only after sufficient adult data has been obtained to ensure registration of the product, or at an earlier point. This is of concern as there have been numerous calls for the earlier introduction of children into clinical trials in order to ensure that they benefit from new interventions or drugs.<sup>253</sup> Thirdly, the General Comment refers only to parents or legal guardians providing proxy consent for children to participate in research. Given the social context of orphanhood in many children’s lives, particularly those in sub-Saharan Africa, this could have the unintended consequence of excluding such children from health research, if they are, for example, living with care-givers rather than parents.<sup>254</sup>

The Committee on the Rights of the Child has also made research recommendations in General Comment No. 5 of 2003.<sup>255</sup> This General Comment recommends that all states undertake research with children in order to ensure information is available on the implementation of the CRC and to allow for the ‘identification of discrimination and/or disparities in the realization of rights’.<sup>256</sup> The Committee promotes the participation of children in this research process:

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<sup>252</sup> See for example, Chapters One and Four for further discussion on the most significant health problems facing children.

<sup>253</sup> See for example, the arguments made in Abdool Karim, Khamny, Frohlich, Werner et al (note 26 above); McClure, Gray, Rybezyk et al (note 78 above) 728 and WHO/UNAIDS/AAVP Expert Group (note 140 above) 5. Also see also Chapter One for further discussion on these points.

<sup>254</sup> McClure (note 78 above) 728.

<sup>255</sup> General Comment No. 5 (2003) (note 174 above).

<sup>256</sup> *Ibid.*

The Committee emphasizes that, in many cases, only children themselves are in a position to indicate whether their rights are being fully recognized and realized. Interviewing children and using children as researchers (with appropriate safeguards) is likely to be an important way of finding out, for example, to what extent their civil rights, including the crucial right set out in article 12, to have their views heard and given due consideration, are respected within the family, in schools and so on.<sup>257</sup>

*(vi) Convention for the Protection of Human Rights and Dignity of Human Beings with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine*

The Convention for the Protection of Human Rights and Dignity of Human Beings with regard to the application of Biology and Medicine: Convention on Human Rights and Biomedicine is a regional convention adopted by the Council of Europe in 1997 ('the Convention on Human Rights and Biomedicine').<sup>258</sup> This is the only existing regional convention which deals directly with research and human rights.

The Convention on Human Rights and Biomedicine links the importance of on-going scientific developments in the fields of biology and medicine to existing human rights obligations in documents such as the ICCPRs.<sup>259</sup> It deals with, amongst others, the rights of all research participants to non-discrimination,<sup>260</sup> the primacy of human rights over science,<sup>261</sup> the right to privacy in research<sup>262</sup> and the freedom to undertake research.<sup>263</sup>

The Convention on Human Rights and Biomedicine refers to minors and persons who do not have the competence to consent independently to research. It requires that it must be

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<sup>257</sup> *Ibid.*

<sup>258</sup> Convention on Human Rights and Biomedicine (note 179 above).

<sup>259</sup> Preamble *ibid.*

<sup>260</sup> Article 1 *ibid.*

<sup>261</sup> Article 2 *ibid.*

<sup>262</sup> Article 10 *ibid.*

<sup>263</sup> Article 15 *ibid.*

demonstrated that such persons are indispensable to the research.<sup>264</sup> Furthermore, persons lacking legal competency may participate in research only if it will be of direct benefit to them.<sup>265</sup> The Convention on Human Rights and Biomedicine promotes child participation in decision-making by requiring the minor's opinion to be taken into consideration.<sup>266</sup>

The Convention on Human Rights and Biomedicine could be criticised for failing to specify when persons would lack competence to provide consent to research. Its approach to research which does not hold out the prospect of direct benefit is also unclear. Under Article 6, research which does not hold out the prospect of direct benefit to participants is prohibited with persons who cannot provide their own consent. However, under Article 17(2) such research may take place provided that, firstly, it will contribute knowledge which will help to understand the minor's condition, disease or disorder.<sup>267</sup> Secondly, if the research poses no more than a minimal risk to, and burden for, the participant.

The Convention on Human Rights and Biomedicine is binding only on countries of the Council of Europe who have signed and ratified the Convention.

### *2.3.3 International ethical codes issued by the medical profession*

There are a number of international ethical codes which deal with the regulation of health research. Although none of the ethical codes is legally binding, they create an extensive framework of accepted norms and standards for the conduct of health research with human subjects. In particular, within this framework, ethical review of all research protocols is established as a key procedural norm. These codes also create a range of substantive norms,

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<sup>264</sup> Article 17 *ibid.*

<sup>265</sup> Article 6 *ibid.*, the Convention does allow proxy consent in such circumstances.

<sup>266</sup> *Ibid.*

<sup>267</sup> Stobie, Strode & Slack (note 59 above) 190–191. The authors argue that this phrase ought to be interpreted as being broad enough to include a condition that the child is at risk of and not only existing conditions that the child might have at that point in time.

including standards on the manner and circumstances in which children can participate in research. Finally, within this framework, there is a focus on harmonising and standardising norms for clinical trials across the globe, through the issuing of the WHO's Good Clinical Practice Guidelines<sup>268</sup> and the Good Clinical Practice Guidelines issued by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.<sup>269</sup>

*(i) Declaration of Helsinki*

The Nuremberg Code was followed several decades later by the adoption of the Declaration of Helsinki (the Helsinki Declaration) by the General Assembly of the World Medical Assembly in 1964.<sup>270</sup> This Declaration has been revised several times and currently the 2008 revision is in force.<sup>271</sup> Dhai and McQuoid-Mason argue that it is an expansion of the principles articulated in the Nuremberg Code.<sup>272</sup> They submit that the Helsinki Declaration makes it clear that a physician's primary duty extends beyond the obtaining of informed consent to ensuring the well-being of the patient under his or her care.<sup>273</sup>

The stated aims of the Helsinki Declaration are to act as a common statement of key ethical principles for medical research involving human subjects, including research on identifiable human material and data.<sup>274</sup> Although the Helsinki Declaration is an ethical code it also refers to the importance of protecting the legal rights of human subjects.<sup>275</sup> Given that this is a declaration issued by the General Assembly of the World Medical Association, it is binding

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<sup>268</sup> WHO'S GCP (note 183 above).

<sup>269</sup> ICH GCP (note 184 above).

<sup>270</sup> Declaration of Helsinki (note 41 above).

<sup>271</sup> A Dhai & D McQuoid-Mason 'What is the function of Research Ethics Committees?' (editorial) (2010) Vol 3(1) *South African Journal of Law and Bioethics* 2, 2.

<sup>272</sup> *Ibid.*

<sup>273</sup> *Ibid.*

<sup>274</sup> *Ibid.*

<sup>275</sup> D Human & SS Fluss 'The World Medical Association's Declaration of Helsinki' available from <http://www.wma.net/e/ethicsunit/helsinki.htm> [Accessed: 26 June 2009].

only on its members. Nevertheless, its significance is that it is the most widely accepted international ethical guide on medical research involving human subjects. Furthermore, given its broad acceptance throughout the global medical and research communities it is possible to argue that it forms part of international customary law.<sup>276</sup> Andanda argues further that the Helsinki Declaration's significance lies in the influence that it has had globally on research legislation at a regional and national level.<sup>277</sup>

The Helsinki Declaration deals with both procedural obligations and substantive ethical norms. For example, it provides that there is a need to develop a research protocol and submit this for ethical review.<sup>278</sup> It also stresses the importance of complying with ethical norms and safeguards,<sup>279</sup> including respect for domestic legal and regulatory obligations.<sup>280</sup>

The Helsinki Declaration also requires:

- Special protection of vulnerable groups which may participate in research;<sup>281</sup>
- Research to have an appropriate risk-benefit ratio;<sup>282</sup>
- Privacy rights to be protected;<sup>283</sup> and
- Voluntary informed consent to be obtained from research participants.<sup>284</sup>

Finally, as stated above, the Helsinki Declaration requires researchers to be aware of the local ethical, legal and regulatory requirements for research on human subjects in their own countries, as well as of any applicable international requirements. Furthermore national

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<sup>276</sup> B Christie 'Doctors revise Declaration of Helsinki' (2000) Vol 321 *British Medical Journal* 913, 915. Furthermore Guidance Point 2 of the Helsinki Declaration (note 41 above) provides that other research stakeholders are 'invited' to adopt these principles.

<sup>277</sup> Andanda (note 166 above) 61.

<sup>278</sup> Guidance Points 14 and 15 Declaration of Helsinki (note 41 above).

<sup>279</sup> Guidance Point 9 *ibid.*

<sup>280</sup> Guidance Point 10 *ibid.*

<sup>281</sup> Guidance Point 17 *ibid.*

<sup>282</sup> Guidance Point 18 *ibid.*

<sup>283</sup> Guidance Point 23 *ibid.*

<sup>284</sup> Guidance Points 22 and 24 *ibid.*

ethical, legal or regulatory requirements should not be allowed to reduce or eliminate any of the protections for human subjects set out in the Declaration.<sup>285</sup>

The Helsinki Declaration has been criticised for not dealing directly with the participation of children in research. However, guidance points 17, 27 and 28 all refer to the protections that ought to be in place when the research subject does not have the capacity to give either consent or assent to the research, a provision which would obviously include certain children who lack the capacity to provide independent consent.<sup>286</sup>

*(ii) Council for International Organisations of Medical Sciences (CIOMS) Guidelines*

CIOMS is a non-governmental organisation that was established in 1949 by the WHO and the United Nations Educational, Scientific and Cultural Organisation (UNESCO). It has produced the International Ethical Guidelines for Biomedical Research Involving Human Subjects (the CIOMS Guidelines).<sup>287</sup> These Guidelines were first published in 1993. They are in essence a commentary on the Helsinki Declaration.<sup>288</sup> They were the first attempt to address ethical concerns that could arise in relation to the so-called 'internationalisation of research'.<sup>289</sup>

The CIOMS Guidelines deal with, amongst others: the special limitations on the level of risk that persons who are not competent to consent, are able to be subjected to during biomedical research,<sup>290</sup> and the equitable distribution of the burden and the benefits of research.<sup>291</sup> The Guidelines are not legally binding but their stated aim is to ensure that the principles established in the Helsinki Declaration are of use to developing countries 'in defining national policies on the ethics of biomedical research involving human subjects,

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<sup>285</sup> Guidance Point 10 *ibid.*

<sup>286</sup> *Ibid.* For other criticisms of the Declaration see Andanda (note 166 above) 62.

<sup>287</sup> International Ethical Guidelines for Biomedical Research involving Human Subjects (note 182 above).

<sup>288</sup> Andanda (note 166 above) 63.

<sup>289</sup> *Ibid.*

<sup>290</sup> Guidance Point 9 CIOMS (note 182 above).

<sup>291</sup> Guidance Point 12 *ibid.*

applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms'.<sup>292</sup> They are also more broadly applicable to the wide range of persons who may participate in health research, unlike the Helsinki Declaration which is directed at medical doctors. Andanda argues that the CIOMS Guidelines create a framework that ought to inform the development of a modern ethical-legal regulatory system at domestic level.<sup>293</sup>

The CIOMS Guidelines deal specifically with the participation of children in research in Guideline 14. This Guideline provides that:

Before undertaking research involving children, the investigator must ensure that: the research might not equally well be carried out with adults; the purpose of the research is to obtain knowledge relevant to the health needs of children; a parent or legal representative of each child has given permission; the agreement (assent) of each child has been obtained to the extent of the child's capabilities; and, a child's refusal to participate or continue in the research will be respected.<sup>294</sup>

The strength of the approach taken in the CIOMS Guidelines is that, firstly, it requires researchers to justify the inclusion of children in research. Secondly, it recognises that proxy consent may be given by more than just parents or legal guardians through the use of the words 'legal representative'. It is submitted that this is a broad concept which could include for example, care-givers.<sup>295</sup> Thirdly, it recognises the principle of child participation through its specific reference to obtaining assent from children and its focus on the rights of children to withdraw from research.

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<sup>292</sup> *Ibid.*

<sup>293</sup> Andanda (note 166 above) 63.

<sup>294</sup> *Ibid.*

<sup>295</sup> See Chapters Five and Six for more detailed discussion on who ought to have the authority to provide proxy consent for health research involving children in South Africa.

The CIOMS Guidelines have been criticised for failing to make provision for more specific issues such as sample sizes in studies, or when research ought to be undertaken.<sup>296</sup>

*(iii) World Health Organisation's Guidelines on Good Clinical Practice (WHO GCP)*

The WHO's GCP is a set of ethical guidelines regulating clinical trials. Its objective is to set globally-applicable standards for the conduct of biomedical research on human participants, and to ensure established ethical and scientific quality standards exist for the design, conduct, recording and reporting of clinical research involving the participation of human participants.<sup>297</sup> These guidelines ought to be followed by all members of the WHO.<sup>298</sup>

The WHO Guidelines state that the use of the WHO's GCP in clinical trials promotes public confidence in research, as communities are assured that the rights, safety, and well-being of research participants will be protected and respected throughout the world. At the same time, the scientific integrity of clinical research data is maintained.<sup>299</sup>

These Guidelines deal with, amongst others: requiring countries undertaking clinical trials to have an appropriate regulatory framework,<sup>300</sup> protocols to be submitted for ethical review;<sup>301</sup> and ensuring that research participants have safe and adequate medical care during the trial.<sup>302</sup> The Guidelines are not binding but in the introduction, it is recommended that countries use and adapt them into binding national standards.<sup>303</sup>

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<sup>296</sup> Andanda (note 166 above) 63.

<sup>297</sup> Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (note 182 above).

<sup>298</sup> Andanda (note 166 above) 64.

<sup>299</sup> *Handbook for Good Clinical Research* (2002), World Health Organisation available from [http://whqlibdoc.who.int/publications/2005/924159392X\\_eng.pdf](http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf) [Accessed: 26 June 2009].

<sup>300</sup> Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products Point 1.5 (note 182 above).

<sup>301</sup> Point 3.2 *ibid.*

<sup>302</sup> Point 4.1 *ibid.*

<sup>303</sup> *Ibid.* See Chapter Four for further discussion on the way in which South Africa has adopted and adapted these Guidelines.

The WHO's GCP has been criticised for failing to deal expressly with the participation of children in clinical trials, with the exception of the section on informed consent which refers briefly to children.<sup>304</sup>

*(iv) The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines*

In 1997 the ICH brought together regulators of clinical trials, from the US, Japan and Europe to develop international norms for the conduct of clinical trials.<sup>305</sup> These Guidelines, entitled the Guidelines for Good Clinical Practice E6(R1) have resulted in greater standardisation on the minimum requirements for clinical trials. Many countries have adopted and/or adapted these guidelines into local norms.<sup>306</sup> The Guidelines pay some attention to the use of children in research.<sup>307</sup> They are only of persuasive value in respect of research that can be defined as a clinical trial.<sup>308</sup>

Recently there has been some criticism of the ICH Guidelines with suggestions that they are a bronze, rather than a gold standard for clinical research.<sup>309</sup> Criticisms include:

- (i) The references to good clinical practice are misleading as they focus on the way in which trials are conducted;
- (ii) They fail to deal with some key issues in clinical trials;

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<sup>304</sup> Point 3.3 *ibid*.

<sup>305</sup> *Ibid* and <http://www.ich.org/> [Accessed: 27 January 2014].

<sup>306</sup> *Ibid*. South African has followed this international trend by adapting the ICH guidelines into the Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa (note 58 above). The 2<sup>nd</sup> ed of the SA GCP specifically provides that the principles based in the document are based on those articulated in amongst others by the ICH. Furthermore, one of the purposes of the SA GCP has been to ensure that the general principles contained in documents such as those produced by ICH are adapted for the South African context *ibid* 12. See Chapter Four for further discussion on these issues.

<sup>307</sup> *Ibid*.

<sup>308</sup> See Chapter 1 for more discussion on the definition of a clinical trial. Andanda argues (note 160 above) 65 that South Africa's Good Clinical Practice Guidelines, have been harmonised with the ICH Guidelines. See Chapter Four for more discussion on these Guidelines.

<sup>309</sup> DA Grimes, D Hubacher, K Nanda, KF Schulz, D Moher & Douglas G Altman 'The Good Clinical Practice guideline: a bronze standard for clinical research' (2005) Vol 366 *The Lancet* 172, 172.

- (iii) There are no identified authors;
- (iv) They have not been updated for more than 15 years; and
- (v) Compliance with the Guidelines entails enormous costs but no research has been conducted on whether such costs are justified.<sup>310</sup>

## 2.4 Key characteristics of effective ethical-legal frameworks

### 2.4.1 Overview

The well-established international ethical-legal norms and standards have informed the development of a number of institutions, laws, policies, guidelines and enforcement mechanisms at a domestic level. Nevertheless there are multiple views on what the key characteristics of an ideal domestic ethical-legal framework are. Elster and Hoffman argue that effective systems are based on four fundamental tenets: firstly, ethical review by an independent body; secondly, voluntary and informed consent to enrolment by participants; thirdly, protection of the privacy of participants; and fourthly, institutional assurances of compliance with regulations.<sup>311</sup> Following a more normative approach, Annas argues that effective ethical-legal frameworks are those that protect the dignity and rights of participants and promote their welfare.<sup>312</sup>

The 1997 Convention on Human Rights and Biomedicine also provides a good summary of the key elements of an effective ethical-legal framework. This Convention states that research with human participants should take place only if:

- i. there is no alternative of comparable effectiveness to research on humans;

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<sup>310</sup> *Ibid.*

<sup>311</sup> Elster & Hoffman (note 146 above) 162.

<sup>312</sup> Annas & Grodin (note 190 above) 327.

- ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;
- iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;
- iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;
- v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.<sup>313</sup>

Importantly, there has been a shift in the international norms away from a narrow focus on informed consent as reflected in the Nuremburg Code. Although consent remains one of the most important rights of research participants, an extra layer of protection has been added through the ethical-legal obligation that researchers must obtain ethical approval.<sup>314</sup> Fisher argues that this is a natural progression within the evolution of research regulation. Initially doctors were required to satisfy only themselves as to whether their research was acceptable. Following the Nuremburg Code, this responsibility shifted to individuals through the doctrine of informed consent, and has finally has been placed largely in the hands of RECs.<sup>315</sup> It is argued that this signifies a move towards a broader public policy approach in which it must be demonstrated that research is both scientifically valid and ethically acceptable, before individuals are approached and invited to be research participants. For example, it requires ethics committees to consider whether a study into a potential HIV

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<sup>313</sup> Article 16 Convention on Human Rights and Biomedicine (note 173 above).

<sup>314</sup> Fisher (note 40 above) 195–196. Also see for example, JH Jones *Bad blood: The Tuskegee syphilis experiment* (1981) 112 where it is argued that the Tuskegee experiment showed that placing the regulation of research in the hands of scientists failed to protect research participants as they could place the interests of science over those of participants. Jones argues that in the Tuskegee case ‘the consensus was that the experiment was worth doing, and in a profession whose members did not have a well-developed system of normative ethics, consensus formed the functional equivalent of moral sanction’.

<sup>315</sup> Fisher *ibid* 195–196.

vaccine which enrolls adolescents, is scientifically justified and ethical before approaching the community and inviting participants to consider volunteering. It also reflects an acceptance of both the complexities and limitations of informed consent in a context in which research participants may be influenced by a range of external factors such as gender dynamics, limited access to health care or the proposed compensation offered for participation.<sup>316</sup>

It is suggested that, although expressed differently, there is significant consensus amongst these writers and within the international law framework regarding the core elements of an ethical-legal framework. In essence, this thesis argues that effective ethical-legal frameworks require, firstly, institutions which are able to (a) create policy guidance on the most appropriate forms of research that ought to be undertaken, (b) review and regulate research (scientifically and ethically), and issue ethical norms and standards dealing with both procedural and substantive matters, (c) liaise with and involve the community, and (d) implement effective enforcement mechanisms.<sup>317</sup> Secondly, they require legally established norms which establish minimum standards for conduct of research.

#### *2.4.2 Ethical-legal institutions to regulate health research*

A range of institutional structures is required to regulate health research. At the most basic level these are primarily, a policy formulation body, a national drug regulatory authority, research ethics committees, community advisory structures, and various bodies to monitor and enforce rights.

Although the range of institutions that are required to regulate research is broadly accepted, there is lesser consensus on a number of other issues. The first is the inter-relationship

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<sup>316</sup> Fisher *ibid* 207–208 also refers to the ‘unintended pressure’ that may occur in therapeutic research, she gives as an example of patients who may consent or volunteer for research because they have an unconscious desire to be ‘good patients’. See Chapter One for a definition of therapeutic research.

<sup>317</sup> See Chapters Three, Four and Five for a discussion of the extent to which these three elements exist in South Africa. See further Chapter Six for a critique of the South African ethical-legal framework.

between the ethical-legal institutions and how to manage tensions that may exist between them, when carrying out their respective functions.<sup>318</sup> The second is managing overlapping roles between institutions, for example, the scientific validity of a clinical trial is a concern for both national drug regulatory authorities and RECs. The third is strengthening the independence of institutions which are required to review and approve research.<sup>319</sup>

*(i) Research policy formulation*

An institution is required to set the framework for research policy so as to ensure that appropriate research, which will benefit local communities and focus on priority health problems, is undertaken.<sup>320</sup> Delineating the role such institutions should play, and finding a balance between oversight and interference in the research agenda, is a complex issue. Although there is no specific right to academic freedom in international law, this remains a key human rights issue. Research should be justified for objective scientific reasons, such as addressing a key health concern for a particular population. Nevertheless the line separating science and political policy-making can become blurred. For example, in South Africa during the Mbeki era, scientific arguments were used to promote a particular AIDS denialist agenda resulting in the government denying women early access to prophylaxis which could have prevented mother to child transmission of HIV.<sup>321</sup> This approach was in part based on

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<sup>318</sup> For example, it has been argued that a key problem in South Africa is that there is no joint forum at which the MCC, RECs and the National Health Research Committee are able to meet and discuss common issues. Furthermore given some overlapping roles this could lead to conflict: Strobe, Slack & Mushariwa (note 94 above) 599. See Chapters Six and Seven for further discussion on this issue.

<sup>319</sup> For example, there was extensive criticism of interference by the former Minister of Health Dr Tshabala-Msimang in the work of the MCC, *Mail and Guardian* 8 August 2003. See Chapter Six for further discussion on this point.

<sup>320</sup> For example, in Ethiopia, the Ethiopian Science and Technology Commission is empowered by law, in terms of Proclamation 7/1995 to formulate science and technology policies. CJ Grant, M Lewis & A Strobe 'The ethical-legal regulation of HIV vaccine research in Africa: A study of the regulation of health research in Botswana, Ethiopia, Kenya, Tanzania and Uganda to determine their capacity to protect and promote the rights of persons participating in HIV vaccine research' (2006), African AIDS Vaccine Programme.

<sup>321</sup> Heywood M 'Preventing mother to child HIV transmission in South Africa: Background, strategies and outcomes of the Treatment Action Campaign case against the Minister of Health' (2003) Vol 19 *South African Journal of Human Rights* 278, 311. Also see E Cameron 'Legal and human rights responses to the HIV/AIDS

arguments that insufficient operational research had been conducted on implementing PMTC programmes.<sup>322</sup>

Many writers have attempted to articulate the parameters of acceptable research. For example, it has been argued that research should not be allowed if it is likely to result in the discovery of knowledge that is inappropriate for human beings to process. Or, when such knowledge may be misused in human hands, for example, if it could be used to develop or perfect instruments for killing or injuring human beings. Alternatively, if the research is not being conducted properly, is unfair to participants, or the risks are so great that they outweigh the benefits to participants or society.<sup>323</sup> In a similar vein, Shapiro and Spece suggest that certain scientific questions should not be explored as the knowledge gained by the research may present serious social dilemmas, could be put to improper use, the technology developed may have harmful effects or the new knowledge may threaten our existing values and way of life.<sup>324</sup> These remain on-going debates. Although a number of countries have legislated on some of these issues through, for example, prohibitions on human cloning,<sup>325</sup> in many instances it remains the prerogative of bodies setting the research policy agenda, research priorities or RECs to establish whether such research will in the circumstances be ethical.

This thesis argues that there ought to be an ethical-legal institution which sets research policy and that this body should engage with a range of stakeholders in policy formulation. Holman and Dutton suggest that the public ought to participate in the development of

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epidemic' (2006) 1 *Stell LR* 38, 44 for a discussion of the scientific arguments raised by AIDS denialists which suggested that there was no evidence for the international public health approach to HIV.

<sup>322</sup> *Ibid.*

<sup>323</sup> C Cohen 'When may research be stopped?' (1977) Vol 269 *New England Journal of Medicine* quoted in MH Shapiro & RG Spece *Cases, materials and problems in bioethics and the law* (1981) 118.

<sup>324</sup> *Ibid* 97. See Chapter Four for a discussion of the South African institutions which regulate research.

<sup>325</sup> See for example, s 57(1) National Health Act (note 57 above) prohibits reproductive cloning of a human being in South Africa.

research policies as it has a democratic right to participate in social policy formulation, its participation ensures that the public interest is reflected in the research agenda, and that public participation is essential to the practice and development of modern science.<sup>326</sup> Such institutions should therefore have mandates to involve the public broadly in developing research policies.

*(ii) National drug regulatory authorities*

A national drug regulatory structure which has the over-arching function of regulating the registration and use of medicines. It ought to, amongst others, regulate clinical trials researching medicines intended for use on humans or animals. Such a body should: evaluate the scientific quality of the proposed research, approve research in conjunction with ethics review bodies, monitor such research and intervene should deviations from the approved protocol occur.<sup>327</sup>

There is a complex inter-relationship between national drug regulatory authorities and ethics committees. Although it is submitted that ideally national drug regulatory authorities ought to work with ethics committees in regulating health research and in particular clinical trials, the WHO has identified three different models of the way in which they operate in practice.<sup>328</sup> The first approach is one in which the regulation of clinical trials is undertaken solely by the national drug regulatory authority.<sup>329</sup> For example, in Uganda, the National Drug Authority is established by the National Drug Policy and Authority Act of 1993 and its functions, as per section 5, include dealing with the development and regulation of pharmacies and drugs in the country (which includes approving new drugs) and preparations

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<sup>326</sup> HR Holman & DB Dutton 'A case for public participation in science policy formulation and practice' ((1978) Vol 51 *Southern Californian Law Review* 1505, 1508.

<sup>327</sup> For example, the Tanzania Food and Drugs Authority is responsible for regulating clinical trials of drugs in Tanzania. CJ Grant (note 86 above).

<sup>328</sup> S Ratanawijitrasin and E Wondemagegnehu (2002) Effective drug regulation: A multi-country study World Health Organisation Geneva Switzerland.

<sup>329</sup> *Ibid.*

for inclusion on the national formulary of drugs, granting certificates of approval for clinical trials on drugs, approving the national list of essential drugs and supervising revisions of the list in a manner approved by the Minister, establishing and revising professional guidelines and disseminating information to health professionals and the public, and providing advice and guidance to the Minister and bodies concerned with drugs on the implementation of the national drug policy.<sup>330</sup>

The second model is one in which the regulation of clinical trials is done by both a national drug regulatory authority and an ethics committee.<sup>331</sup> For example, in South Africa the MCC can only approve a clinical trial that has already received ethical approval by a local ethics committee.<sup>332</sup> In terms of the third model clinical trials are regulated solely by local ethics committees.<sup>333</sup> For example, in the Netherlands an ethics committee at the trial site regulates the conduct of the research.<sup>334</sup>

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<sup>330</sup> CJ Grant (note 87 above). A full description of the role and functions of the South African national drug regulatory authority is set out in Chapter Four. Also see Ratanawijitrasin and Wondemagegnehu *ibid* where they list Estonia, Malaysia, Tunisia, Venezuela and Zimbabwe as using this model for the structuring of their drug regulatory authority.

<sup>331</sup> *Ibid.*

<sup>332</sup> See Chapters Three and Four for a detailed discussion on this point.

<sup>333</sup> Ratanawijitrasin and Wondemagegnehu (note 328 above). The authors cite the Netherlands as an example of this approach.

<sup>334</sup> *Ibid.*

*(iii) Research ethics committees*

Ethical review bodies should exist within research and other institutions with the capacity to review protocols.<sup>335</sup> Ethics committees should provide third party review of research protocols in order to minimise possible conflicts of interests, protect research participants and avoid the exploitation of vulnerable individuals or communities.<sup>336</sup> O’Grady argues that research ethics committees (or institutional review boards as they are called in the US) are at the ‘core’ of the system for protecting research participants’ rights.<sup>337</sup> They were established by institutions to provide independent review of research conducted by that institution in order to assess whether it was ethical and whether researchers faced any conflicts of interests in conducting the proposed study.<sup>338</sup> One of the most important functions of RECs is to protect human research participants.<sup>339</sup>

It is argued that such bodies should operate within a national framework in which standardised procedures govern review and the composition of ethics committees; where an accreditation mechanism exists, and a national body monitors their composition, training, review process and reporting requirements.<sup>340</sup> Finally, such bodies should be aware of the

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<sup>335</sup> Fischer (note 40 above) postulates that independent scrutiny of research protocols by an ethical review committee has received international recognition in the Helsinki Declaration. Furthermore well-informed research ethics committees are an essential protection for research participants 234.

<sup>336</sup> NE Kass, AA Hyde, A Ajuwon, J Appiah-Poku, N Barsdorf, DE Elsayed, M Mokhachane, B Mupenda, P Ndebele, G Ndossi, Bornwell Sikateyo, G Tangwa & P Tindana ‘The structure and function of research ethics committees in Africa: A case study’ (2007) Vol 4(1) *PLoS Medicine* 0026, 0026.

<sup>337</sup> C Grady ‘Do IRBs protect human research subjects?’ (2010) Vol 304(1) *JAMA* 1122, 1122. Nevertheless given the growth in research ethics there has been increasing debate on how RECs can provide effective ethics review of research. L London, A Kagee, K Moodley & L Swartz (note 163 above) 286. One of the key issues being debated regarding the effectiveness of ethical review is the question of the role of RECs in relation to legal issues, with some arguing that RECs must as part of ethical review assess whether a study is legal. Others submit that the question of whether a study meets legal requirements is an institutional and researcher obligation, not an REC one: see for example TM Douglas ‘Ethics committees and the legality of research’ (2007) Vol 33 *J Med Ethics* 732.

<sup>338</sup> *Ibid.*

<sup>339</sup> Wassenaar & Mamotte (note 156 above) 1.

<sup>340</sup> Recent research on the ethical-legal frameworks in Cameroon, Malawi, Nigeria, Rwanda and Zambia found that differing approaches were taken to national research ethics committees. Firstly, one country, Zambia, had no national ethics structure. Secondly, in two countries, Malawi and Rwanda, the national structure acted as a

local context and appreciate the potential vulnerability of proposed research volunteers in light of local socio-economic and cultural factors.<sup>341</sup>

It has been argued that ethics in research was ‘... born in scandal and reared in protectionism’.<sup>342</sup> Many attribute the development of the norm requiring review by an REC to the outcry created by an article written by an American academic Henry Beecher, who exposed human rights abuses in 22 scientific experiments being undertaken with human participants in the USA at the time.<sup>343</sup> In his seminal 1966 article published in the *New England Journal of Medicine* he recommended that institutions undertaking health research set up committees to review proposed research in order to address these types of abuses of research participants.<sup>344</sup>

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‘super’ ethics committee by undertaking the actual reviewing of protocols. Thirdly, in two countries, Cameroon and Niger, the national ethics committee played an oversight and regulatory role by accrediting and monitoring local ethics committees, P Andanda, P Awah, P Ndebele, O Onigbogi, D Udatinya & M Mwondela ‘The ethical and legal regulation of HIV Vaccine research in Africa: Lessons from Cameroon, Malawi, Nigeria, Rwanda and Zambia’ (2011) Vol 10(4) *African Journal of AIDS Research* 451, 452.

<sup>341</sup> For example the British Medical Association recommends that ethical review committees should consider factors such as the participant’s knowledge of the complaints procedures within the trial and whether special steps have been taken to protect vulnerable populations. Fischer (note 40 above) 105–107. For another example of the role culture plays in the informed consent process see L Richter, G Lindegger, Q Abdool Karim & N Gasa *Guidelines for the Development of Culturally Sensitive Approaches to Informed Consent for Participation in HIV vaccine related Trials, UNAIDS Discussion Document* (1999). Also see Chapter Four for a more detailed discussion of the legal framework for ethical review in South Africa.

<sup>342</sup> C Levine ‘Has AIDS changed the ethics of human subject’s research?’ (1990) 16 *Law, Medicine and Health Care* 167, 170.

<sup>343</sup> Dhali & McQuoid-Mason (note 271 above) 2. Key concerns identified by Beecher included, effective treatment was being withheld, experimental treatment being researched despite severe side-effects, known harmful treatment was being given to participants to facilitate the study of side-effects and some procedures were done without consent.

<sup>344</sup> *Ibid.*

*(iv) Community advisory structures*

Growing attention is being paid to the importance of community advisory boards in health research.<sup>345</sup> There is also increasing international debate on the nature of public participation in science.<sup>346</sup> Consequently, it is becoming an international norm that in large community-based studies, some form of structure is established to facilitate engagement between researchers and the communities in which they will be conducting the study.

It has been argued that community participation is important as ‘consultation, collaboration, and dynamic interaction between communities and researchers are seen as key to increasing participants’ and communities’ sense of ownership of research, commitment to research success, and to implementation of research-based programmes’.<sup>347</sup> Much of this relatively new focus on community participation was initiated following a recommendation by the National Institute of General Medical Sciences in the United States that researchers obtain community input into all phases of research.<sup>348</sup> This includes the involvement of the community in all levels of ethical decision-making.<sup>349</sup> This approach is in addition to the recommendation that research ethics committees include community members or lay persons on their committees.<sup>350</sup>

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<sup>345</sup> P Reddy, D Buchanan, S Sifunda, S James & N Naidoo ‘The role of community advisory boards in health research: Divergent views in the South African experience’ (2010) Vol 7(3) *Journal of Social Aspects of HIV/AIDS* 1, 1.

<sup>346</sup> L Swartz & A Kagee ‘Community participation in AIDS Vaccine trials: Empowerment or science?’ (2006) Vol 63 *Social Science and Medicine* 1142, 1142.

<sup>347</sup> *Ibid* 1142–1143.

<sup>348</sup> *Ibid*.

<sup>349</sup> *Ibid*.

<sup>350</sup> See for example, s 4.1 GCP (note 58 above). which provides that an ethics committee must be ‘representative of the communities it serves’. Furthermore such committees should have ‘at least two lay persons, who have no affiliation to the institution, are not currently involved in medical, scientific or legal work and are preferably from the community in which the research is to take place’.

Reddy et al argue that historically, communities were involved in research for three distinct reasons.<sup>351</sup> Firstly, social scientists pioneered ‘participatory action research’ which aimed at using community engagement through research to achieve social change. In this approach community engagement was used to develop more effective interventions.<sup>352</sup> Secondly, following strong advocacy from HIV-related interests groups, community advisory boards were set up to liaise between researchers and the community in HIV treatment research in the USA.<sup>353</sup> These community groups played a strong role in monitoring the research process. Thirdly, there has been a move towards establishing community advisory boards in order to protect participants by involving the community in the consent processes, amongst others:

community participation ensures that communities are not exploited . . . this ethical requirement entails: developing partnerships among researchers, policy makers and the community; involving community partners in identifying health problems; assessing the value of the research; planning, conducting, and overseeing the research; integrating the results into the health care system; respecting the community’s values, culture, and social practices; and ensuring that communities benefit from the research. Thus CABs are perceived primarily in an ethical role.<sup>354</sup>

It has been suggested that community organisations could play six distinct roles in biomedical research. These are: acting as an interface between the researchers and the community; facilitating access to vulnerable communities who may ordinarily be included in research; acting as collaborators with the research team; acting as a check to ensure the research is being planned and implemented in a manner that serves the best interests of the local community; acting as advocates for the adoption of research findings as local policy;

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<sup>351</sup> Reddy, Buchanan, Sifunda, James & Naidoo (note 345 above) 2.

<sup>352</sup> *Ibid.*

<sup>353</sup> *Ibid.*

<sup>354</sup> *Ibid.*

and acting as a distribution channel to assist researchers with the delivery of effective interventions.<sup>355</sup>

Ensuring that community advisory structures achieve these roles is difficult, and key issues include ensuring representivity, and addressing non-sectarianism, financial and other agendas within the structure. Bhan et al allude to these and other issues facing community liaison structures including possible conflicts of interests between the community organisations and the researchers, accountability of the structure to the broader community, relationships with elected local government officials and maintaining transparency.<sup>356</sup> Similar views are expressed by Swartz and Kagee who argue that one of the complexities of the notion of community participation is the assumption that if there are high levels of awareness amongst communities, and opportunities to be involved in the study, this will increase the numbers of persons who volunteer to participate in the trial. They submit that given this context community participation is not just driven by a social good of encouraging active engagement in research but also aims at improving research objectives such as the recruitment and retention of participants in the study.<sup>357</sup>

While good science is needed to contribute to building human rights, in order to achieve the best in both fields, we need to recognize some potential contradictions along the way.<sup>358</sup>

#### *(v) Monitoring and enforcement mechanisms*

Ideally, a range of monitoring and enforcement mechanisms needs to exist. This should include a structure with the ability to issue ethical codes, namely a national ethics structure and a national regulatory body to regulate research on new medical products.

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<sup>355</sup> A Bhan, JA Singh, REG Upshur, PA Singer & AS Daar 'Grand challenges in global health: Engaging civil society organisations in biomedical research in developing countries' (2006) *PloS Medicine* Vol 4(9), 1456, 1458.

<sup>356</sup> *Ibid* 1457. See Chapter Four for further discussion on this issue.

<sup>357</sup> Swartz & Kagee (note 346 above) 1143.

<sup>358</sup> *Ibid* 1146.

Paragraph 15 of the Helsinki Declaration states that RECs should monitor ongoing studies, and it places an obligation on the researchers to provide monitoring information to the committee, and in particular, information about any serious adverse events. Monitoring of research is important because ethical approval cannot on its own ensure the protection of research participants. Klitzman argues that an REC can monitor research through, firstly, the review of applications for renewal of ethical approval at regular points.<sup>359</sup> Secondly, monitoring informed consent processes.<sup>360</sup> Thirdly, examinations of whether there has been adherence to protocols and, fourthly, investigations into unapproved activities.<sup>361</sup>

Civil and criminal laws should also be available to enforce research participants' rights. Singh argues that we need to see enforcement mechanisms broadly; they are not merely to enforce the rights of research participants, but they can also be a 'useful mechanism to reverse irrational ideology-driven science policy and decision-making'.<sup>362</sup>

Criminal law could be used to remedy a situation where participants have not given their consent, or where they have been induced by fraudulent means to enter the study.<sup>363</sup> For example, charges of assault could be laid if a researcher wilfully failed to obtain consent, or fraud if they deliberately misled a potential participant.<sup>364</sup> Nevertheless, the criminal law can generally only be used in very restrictive circumstances where there is proof beyond a

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<sup>359</sup> Ethical approval will be given for an express period, for example 12 months, at the end of this period an application for ethical renewal must be made and the matter is put before the committee for reconsideration, personal communication, Professor Wassenaar, 3 July 2012.

<sup>360</sup> R Klitzman 'Views and experiences of IRBs concerning research integrity' (2011) Fall *Journal of Law, Medicine and Ethics* 514, 514.

<sup>361</sup> *Ibid.*

<sup>362</sup> Singh (note 10 above) s 72. Singh gives as one example, the use of the courts by the University of KwaZulu-Natal to challenge an irrational refusal by the MCC to register a clinical trial which was investigating whether providing HIV positive and breastfeeding mothers with the drug Nevirapine would reduce the possibility of mother to child transmission of HIV *ibid* s 77.

<sup>363</sup> DJ McQuoid-Mason 'Legal aspects of medical practice' in MA Dada & DJ McQuoid-Mason (eds) *Introduction to Medico-legal Practice* (2001) 3, 7.

<sup>364</sup> *Ibid.*

reasonable doubt that a researcher intentionally harmed a participant.<sup>365</sup> The 1946 trial of 23 German doctors charged with war crimes and crimes against humanity, for the experimentation carried out on prisoners-of-war during the Second World War, is to date the most high profile criminal trial regarding research abuses. It resulted in the documentation one of the most extreme examples of the role doctors can play in research abuses and criminal activity.<sup>366</sup> At the conclusion of the trial, 15 defendants were found guilty and seven were executed.<sup>367</sup> No criminal charges were laid against researchers in the Tuskegee clinical trial.<sup>368</sup> Given the nature of modern research regulation in terms of which researchers must obtain ethical and other forms of approval, it can be argued that the possibility of intentional harm to research participants has been reduced.

There are a number of different ways in which civil law could be used to hold a researcher liable for wrongful acts during research. Firstly, contract law can be used to ensure that investigators meet all their obligations to the participant as set out in the informed consent form.<sup>369</sup> It is also possible that contract law could be used to compel researchers to continue to supply a research participant with a particular therapy. In other words an interdict could be applied for to order them to act positively if they are failing to comply with obligations in the informed consent document (the contract). Secondly, the law of delict could also be utilised to enable participants to claim damages should they suffer harm or an injury as a result of the negligent actions of researchers, for example, the inappropriate disclosure of participants' identities in public documents.<sup>370</sup> In the Tuskegee trial, research participants

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<sup>365</sup> *Ibid.*

<sup>366</sup> Annas & Grodin (note 190 above) 301–302.

<sup>367</sup> *Ibid* 302.

<sup>368</sup> Kennedy & Grubb (note 51 above) 1715.

<sup>369</sup> See also Singh (note 10 above) s 72.

<sup>370</sup> See for example, *NM and Others v Smith and Others (Freedom of Expression Institute as Amicus Curiae)* 2007 (5) SA 250 (CC) in which three women claimed their rights to privacy and dignity had been infringed when their names were published in a biography of a prominent politician, Ms Patricia de Lille. The women had been assisted by De Lille in making a complaint to the ethics committee at the University of Pretoria when they had safety concerns about a clinical trial they were participating in which was being run at the University's academic

successfully used the civil law to sue the Public Health Service for compensation.<sup>371</sup> Singh argues that the civil law could be used to sue researchers for amongst others, a lack of informed consent, and breaches of confidentiality, emotional distress, fraud, and faulty-product liability.<sup>372</sup> He argues further that the civil law has been used to hold a wide range of parties to the research relationship liable including researchers, institutions<sup>373</sup> which host the research, RECs,<sup>374</sup> consultants advising the study<sup>375</sup> and sponsors of the research.<sup>376</sup> Thirdly, complaints to professional associations should be possible, for example, if researchers are doctors it should be possible to report them to the appropriate governing body.<sup>377</sup>

Finally, besides laws placing obligations on researchers and sponsors of research, ethical-legal institutions are required to enable participants to enforce their rights. These should include amongst others, institutions with a mandate to regulate research such as RECs, or drug regulatory authorities, as well other statutory bodies such as human rights

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hospital. This assistance offered by Ms De Lille in resolving their ethical complaint about the study was used as an example of her HIV activism in the book. The Constitutional Court held at para 45 that the women had an expectation of privacy in this situation and that there was no compelling public interest in the disclosure of their names and HIV status. Furthermore, this amounted to a wrongful publication of a private fact which resulted in a breach of their right to privacy, para 67. The women were each awarded R35 000 in damages, para 82. See also Singh *ibid* where several examples of civil claims against researchers are described.

<sup>371</sup> Kennedy & Grubb (note 51 above) 1715.

<sup>372</sup> Singh (note 10 above) s 72.

<sup>373</sup> Singh argues that institutions can be held liable through the common law doctrine of vicarious liability, *ibid* s 72. He cites the examples of *Berman v Fred Hutchinson Cancer Center* Case No. C01-0727L (BJR), August 8, 2002 United States District Court Western District of Washington at Seattle and *Kus v Sherman Hospital* 1995. 268 Ill.App.3d 771 where institutions were successfully held liable for the unlawful actions of their staff, *ibid*.

<sup>374</sup> Singh submits that members of the RECs should not be held liable in their personal capacity, *ibid* s 73.

Furthermore courts have provided very little guidance on the circumstances in which RECs can be held liable for wrongdoing relating to the approval or monitoring of research, *ibid*.

<sup>375</sup> Although Singh submits no consultant advising a study on ethical issues has been successfully sued for damages, two cases before the US courts have named bioethicists as defendants, this indicates that there may well be liability if wrongfulness could be demonstrated, *ibid* s 74.

<sup>376</sup> *Ibid* s 74.

<sup>377</sup> For example, the Tanzanian Medical Association has the power to discipline any of its members who contravene its code of ethics. Grant (note 87 above) argues that this means that medical doctors undertaking research in Tanzania could be disciplined if they acted unethically.

commissions. These bodies should have the power for example, to order that researchers discontinue the trial if there are significant adverse effects resulting from the study.

#### 2.4.3 *Ethical-legal norms and standards dealing with procedural and substantive issues*

Both ethical and legal norms are required in order to regulate research. Our Good Clinical Practice Guidelines provide the following rationale for having such norms and standards:

The purpose of these guidelines is to ensure that clinical trials conducted on human participants are designed and conducted according to sound scientific and ethical standards within the framework of good ethical practice. Compliance with these standards provides the public with assurance that the rights, safety and well-being of participants are protected and that the clinical trial data are credible.<sup>378</sup>

In the post Nuremberg Code era, ethical guidelines governing research have been considered an essential component of the package of safeguards that should exist to protect research participants.<sup>379</sup> Building on the principles articulated in the Nuremberg Code the Helsinki Declaration provides that researchers should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements.<sup>380</sup> Furthermore, no national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set out in the Declaration.<sup>381</sup>

Ethical standards should also be developed to regulate the ethical conduct of the researchers by national research ethics bodies, ministries of health or professional bodies regulating health care workers and researchers. Nielsen argues that codes of conduct describing key

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<sup>378</sup> Although these guidelines are only binding on clinical trials it is argued that the points made are of general relevance: GCP (note 58 above).

<sup>379</sup> Andanda (note 166 above) 233.

<sup>380</sup> Declaration of Helsinki (note 41 above).

<sup>381</sup> *Ibid.*

ethical standards for health professionals can be an important protection that promotes a high scientific standard.<sup>382</sup> However, given that not all health researchers or members of a research team may be registered with a professional council, for example, field workers collecting data cannot be disciplined by such bodies if they are not registered health professionals, there are limitations to this approach.<sup>383</sup> Nevertheless, it is argued that to ensure consistency ethical guidelines should be utilised by all bodies that review research. Furthermore, national guidelines should be based on accepted international ethical norms regarding research as well as be cognisant of the local context. Recent research in Botswana, Ethiopia, Kenya, Tanzania and Uganda found that all five countries had norms and standards setting out the process for ethical review. However, there was less information on the extent to which committees follow this guidance.<sup>384</sup>

Nienaber argues that as in most cases ethical guidelines are not legally enforceable, they should be supported by the introduction of domestic laws dealing with research.<sup>385</sup> Accordingly, it is argued that an ideal legal framework should have laws describing the rights of research participants, and the obligations on the state, researchers and sponsors to protect these rights. The preceding section has described many of the rights of research participants which are recognised in international law.<sup>386</sup> If countries do not have research-specific laws, Nienaber submits that research participants could use the rights in their domestic constitutions which protect for example, rights to equality, privacy and dignity:<sup>387</sup>

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<sup>382</sup> Andanda (note 166 above) 41.

<sup>383</sup> Field workers are generally not health professionals. See s 2.5 below on the classification of ethical-legal frameworks where the issue of regulation by professional councils is discussed in more detail. Also see Chapter Six where the limitation of this approach is discussed.

<sup>384</sup> Grant (note 87 above).

<sup>385</sup> Nienaber (note 87 above) 159.

<sup>386</sup> It has been argued that international documents focus on consent and the way research participants should be involved in a trial or study, London, Kagee, Moodley & Swartz (note 156 above) 287.

<sup>387</sup> *Ibid.* Nienaber also notes that two constitutions in the Southern African region have specific references to the right to participate in research only with informed consent, namely, Malawi and South Africa. Nienaber (note 87 above) 161.

self-evidently, the goal of clinical research is the promotion of human health and human well-being. Human rights, as embodied in domestic human rights instruments, define and advance human well-being; a rights-based approach to research participation delivers a conceptual and a practical framework by which to assess the process.<sup>388</sup>

If constitutional or statutory protection does not exist, then, at a minimum, countries should utilise common law protections that preclude research participants being involved in research without informed consent, amongst other rights. Research within the Southern and East African region has found that there are very limited examples of research-specific laws setting norms and standards for health research, and protecting the rights of research participants. In such contexts the rights of research participants are generally drawn from laws and policies conferring broad rights, such as the right to security of the person and the right to privacy.<sup>389</sup> This approach has obvious disadvantages including a lack of clarity as to how such a general principle applies to research.<sup>390</sup> Furthermore, research-specific issues such as the setting of appropriate levels of risk that participants, particularly vulnerable groups such as children, can be exposed to are not found in general legal principles of the law or in laws relating to medical treatment.

There are, however, many examples of research-specific legislation in developed countries. Many of these establish key ethical norms as legal obligations. An example is the Code of Federal Regulations (Title 45, Part 46: Protection of Human Subjects) in the United States which deals with research with human subjects.<sup>391</sup> This Code sets minimum standards for research, such as that research must be approved by an Independent Review Board<sup>392</sup> and

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<sup>388</sup> *Ibid.*

<sup>389</sup> *Ibid.*

<sup>390</sup> See Chapter Six for further discussion on this point.

<sup>391</sup> <http://ohsr.od.nih.gov/guidelines/45cfr46.html> [Accessed 2 May 2011].

<sup>392</sup> *Ibid.*, point 646.109. In the US as stated above the term IRB is used as opposed to Research Ethics Committee.

researchers must obtain informed consent from the participants or their legally authorised representative.<sup>393</sup>

*(i) Informed consent*

Informed consent is based on the principle of respect for a person's autonomy.<sup>394</sup> Its historical roots are in the Nuremberg Code and the subsequent Helsinki Declaration.<sup>395</sup> The central role that it plays in protecting research participants has been described in the preceding section detailing research rights in international law.<sup>396</sup> Wendler and Grady describe the over-arching purpose of informed consent as being:

(i) informed consent serves at least two purposes. First, the requirement for informed consent allows competent individuals to decide whether participation in research is consistent with their interests. This goal implies that individuals should understand the information they need to determine whether participation in a given study is consistent with their interests. Second, informed consent allows individuals to decide for themselves whether they will enroll in the study in question. For this purpose, potential participants should be provided with the information they want to decide whether to enroll in the study.<sup>397</sup>

Informed consent is widely accepted as a process rather than an event.<sup>398</sup> As such, there are several components to the concept and a series of steps need to be taken to obtain valid

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<sup>393</sup> *Ibid* point 646.116.

<sup>394</sup> K Lee, PL Havens, TT Sato, GM Hoffman & SR Leuthner 'Assent for treatment: Clinician knowledge, attitudes and practices' (2006) Vol 118 *Paediatrics* 723, 724.

<sup>395</sup> London et al (note 156 above) 288.

<sup>396</sup> In *Abdullahi v. Pfizer, Inc* (note 155 above) a US court held that the norm 'prohibiting non-consensual medical experimentation on human subjects has become firmly embedded and has secured universal acceptance in the community of nations' and thus can be considered to be part of international customary law.

<sup>397</sup> D Wendler & C Grady 'What should research participants understand to understand that they are participants in research?' (2008) Vol 22(4) *Bio-ethics* 203, 205.

<sup>398</sup> Guidance Point 4 CIOMS Guidelines (note 182 above).

consent for research to be both ethical and legal. It has been argued that the threshold elements of consent include the ability to consent and voluntariness.<sup>399</sup>

The ICH Good Clinical Practices guidelines list 20 items of information that research participants ought to be informed of during the consent process, including the risks, potential benefits, expenses and duration of the study.<sup>400</sup> These Guidelines highlight, by making it the first item, the importance of potential volunteers being aware that they are participating in research.<sup>401</sup> The CIOMS guidelines list 26 factors that must be covered in the informed consent process. Again, the first item is that individuals must understand they are being invited to volunteer to participate in research.<sup>402</sup>

In some types of research, there are specific complexities regarding consent, for example, with focus group discussions. Tolich argues that obtaining informed consent may be complex as the group discussion could generate new questions or discussion points which were not part of the research plan and accordingly, consent would not have been given for these aspects of the group discussion.<sup>403</sup> In order for the consent to be comprehensive, researchers must be aware of the nature of the study and address such possibilities in the consent process.

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<sup>399</sup> London et al (note 156 above) 288.

<sup>400</sup> Wendler & Grady (note 397 above) 204.

<sup>401</sup> *Ibid.*

<sup>402</sup> *Ibid.* Wendler and Grady argue that there is an obligation to ensure that participants understand that they are part of a study therefore 'potential participants should understand: that they are being invited to contribute to a project designed to benefit others in the future; that the investigators will rely on the participants' efforts for the purpose of gathering knowledge that may help others; and the extent to which participating in the study will alter what participants do and what happens to them' *ibid* 206.

<sup>403</sup> M Tolich 'The principle of caveat emptor: Confidentiality and informed consent as endemic ethical dilemmas in focus group research' (2009) Vol 6 *Bioethical Inquiry* 99, 103.

Where children do not have the capacity to consent to research they should nevertheless provide assent to it. Lee et al argue that assent from children shows respect for them and enables them to be given information on their illness and to start developing the capacity to consent which they will require as adults.<sup>404</sup> The American Academy of Pediatrics published a position paper on assent in 1995. It states that there are four elements to assent, namely, helping children reach an age-appropriate understanding of their illness, ensuring there is awareness of the nature of the proposed treatment, assessing the child's level of understanding, and ascertaining whether they give their agreement to the procedure.<sup>405</sup>

*(ii) Privacy, confidentiality, dignity and equality*

International law provides that everyone has a right to privacy with Article 17 of the ICCPRs stating that '(n)o one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation'.<sup>406</sup> Although this is not specific to health research it is submitted that it would protect research participants from unlawful disclosures of confidential information. Furthermore, a number of international ethical codes provide that research participants are entitled to privacy when they participate in research.<sup>407</sup>

It is argued that the right to privacy in the context of health research means the participants are entitled to (a) any information which they disclose during the research process or the fact that they participated in the study to be kept confidential. This includes ensuring that any results from the study are not directly linkable to the research participants even after their death.<sup>408</sup>

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<sup>404</sup> Lee et al (note 394 above) 724.

<sup>405</sup> *Ibid.*

<sup>406</sup> International Convention on Civil and Political Rights (note 175 above).

<sup>407</sup> Guidance Point 6 Declaration of Helsinki (note 41 above) and Guidance Points 4 and 5 CIOMS (note 182 above).

<sup>408</sup> Tolich (note 403 above) 101.

In some research contexts, there are specific issues regarding confidentiality, for example, within a focus group discussion, researchers cannot guarantee that other participants will keep information private even if urged to do so:

Researchers may promise participants confidentiality without acknowledging how difficult it may be in practice to achieve this when there are few formal restrictions on (focus) group members divulging information mentioned inside the group to others outside the group.<sup>409</sup>

Accordingly, the consent form should specify that although researchers can guarantee that they will not divulge personal information about the research participant, they cannot provide this same guarantee on behalf of other members of the focus group.<sup>410</sup> The leading foreign case regarding the limitations of confidentiality within a medical relationship is *Tarasoff v Regents of the University of California*.<sup>411</sup> In this matter the court held that a psychologist was negligent for failing to warn a third party at risk of harm.<sup>412</sup> It could be argued that based on the principles established in the *Tarasoff* case the right to privacy within research may be limited in some situations.<sup>413</sup>

The rights to dignity and equality are also well established in international law.<sup>414</sup> However, fewer documents link these rights to research participation. The right to dignity is referred to in both the Helsinki Declaration and the CIOMS Guidelines.<sup>415</sup> However, the centrality of this

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<sup>409</sup> *Ibid* 100.

<sup>410</sup> *Ibid*.

<sup>411</sup> [17 Cal. 3d 425, 551 P.2d 334, 131 Cal. Rptr. 14](#) (Cal. 1976). In this matter a university student disclosed to his psychologist that he intended to kill his former girlfriend. The psychologist informed the campus security who detained him briefly but released him as he appeared rational. The girlfriend was never warned of this danger and was subsequently murdered by the ex-boyfriend.

<sup>412</sup> *Ibid*.

<sup>413</sup> See Chapter Five where the obligation to mandatorily report neglect or abuse of research participants is discussed in more detail.

<sup>414</sup> Articles 10, 2 and 3 International Convention on Civil and Political Rights (note 175 above).

<sup>415</sup> Guidance Point 2 Helsinki Declaration (note 41 above) and Guidance Point 4 CIOMS (note 182 above).

right was only recently recognised with the adoption of the International Declaration on the Human Genome and Human Rights.<sup>416</sup> It is argued that the right to dignity within the context of health research means the right to be treated with respect and not simply as a means to a scientific end.

None of the key international ethical codes refer directly to the right to equality.

However, it is argued that it is indirectly recognised through it being a core element of the ethical principle of justice. It is argued that the right to equality within research means that (a) participants may not be unfairly excluded from research on arbitrary grounds such as race or gender, and (b) certain populations being recruited into studies should not disproportionately bear the burdens of research.

### *(iii) Risk standards*

Research to improve the health and well-being of individuals and society often requires research participants to be exposed to some risks or burdens that they would not otherwise face in their daily lives.<sup>417</sup> Although research participants accept these risks through the informed consent process, it is an international ethical norm dictated by public policy considerations that requires the risks to be appropriate given that in many instances participants will accept them altruistically for the benefit of others.<sup>418</sup> Weijer submits that risk standards serve two purposes, firstly they enable ethics committees to establish which protocols will require greater scrutiny and secondly, they establish an upper limit of risk that they may not be exceeded.<sup>419</sup>

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<sup>416</sup> DG Kirchhoffer & K Dierick 'Human dignity and consent in research biobanking' (2012) Vol 5(2) *South African Journal of Law and Bioethics* 75, 75.

<sup>417</sup> Wendler & Grady (note 397) above) 203.

<sup>418</sup> *Ibid.* Weijer argues that a key failing of RECs is their focus on informed consent rather than risk standards, see C Weijer 'The ethical analysis of risk' (2000) Vol 28 *Journal of Law, Medicine and Ethics* 344, 344.

<sup>419</sup> *Ibid* 355.

Despite agreement on this basic principle Nelson et al submit that there are four key areas of divergence. These are: (a) the permissible level of risk, as this varies according to different legal jurisdictions; (b) identifying common terms that can be used to describe the permissible level of risk, for example minimal risk or negligible risk; (c) agreeing on how these terms are interpreted<sup>420</sup> and (d) establishing whether research which does not provide a direct benefit to the child but will develop generalisable knowledge is to be permitted.<sup>421</sup>

## 2.5 Classifying ethical-legal frameworks

Classifying ethical-legal frameworks is important as it enables comparisons of various systems or models for regulating health research. This in turn enables the identification of the key characteristics of various systems including the extent to which they protect participants, promote participation and facilitate research. It also illustrates the advantages and disadvantages of using the law to regulate health research.

Nielsen argues that there are four possible forms of ethical-legal frameworks. These range from those with low levels of regulation or self-regulation, to highly regulated systems in which legislation establishes substantive protections and procedural obligations.

Nielsen's first form of an ethical-legal framework is the individual control model or the private ordering approach. This model is based on self-regulation. There is no legal regulation of health research in this model. In terms of this model, responsible persons and institutions make autonomous choices. This leaves the protection of participants in their own hands. The obvious limitation of this approach, identified by Nielsen, is that it leaves

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<sup>420</sup> The interpretation of the term 'minimal risk' has been subject to intense international debate. In particular, there have been arguments for an against interpreting this term in a relative veruses an international standard. See amongst others D Wendler 'Three steps to protecting paediatric research participants from excessive risks' (2006) September *PLoS* 1 – 5, S Shah, A Whittle, B Wiltford, G Gensler and D Wendler 'How do Institutional Review Boards apply the federal risks and benefit standards for paediatric research?' (2004) Vol 291(4) *JAMA* 476 – 482 and RM Nelson, LL Lewis, K Struble and SF Wood 'Ethical and Regulatory Considerations for the Inclusion of Adolescents in HIV Biomedical Prevention'(2010) Vol 54 *J Acquir Immune Defic Syndr* 18. 19.

<sup>421</sup> Nelson *ibid*.

vulnerable participants open to abuse as it may be difficult for them to understand the long-term consequences of their choices, especially in cases of urgent health needs. Furthermore, in this model there are no norm-setting guidelines.<sup>422</sup> Leenen argues further that self-regulation absolves the state of its responsibilities to protect the fundamental rights of its citizens by requiring private rule-making.<sup>423</sup> In summary, this model offers low levels of protection, but it facilitates research.

The second model is the professional control model or the professional ordering approach. In terms of this model regulation occurs primarily through professional councils; in other words, this approach is based on regulation by peers who monitor whether researchers are acting in accordance with their professional code of ethics. Again, in terms of this model there is no direct regulation of research by the law. This model emphasises ethical procedures and norm setting.<sup>424</sup> A problem with this model is that in many instances, not all researchers or members of the research team are required to register with professional councils. Thus should research participants wish to lay a complaint regarding the conduct of a non-professional member of the research team they would have to complain to the institution hosting the study.<sup>425</sup> In some instances there have also been complaints of professional associations showing bias towards their members when resolving disputes regarding professional malpractice, given their vested interests in protecting the profession at large.<sup>426</sup> Although not discussed by Nielsen, it is possible that the regulations imposed by

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<sup>422</sup> *Ibid.*

<sup>423</sup> HJJ Leenen 'Health law and health legislation: Possibilities and limits' (1998) *International Digest of Social Medicine and Health Law* 80, 81.

<sup>424</sup> Nielsen (note 42 above) 42.

<sup>425</sup> In Kenya and Ethiopia this issue has been dealt with by requiring all staff working on clinical trials to register with the science and technology council. However research by Grant, Lewis and Strode could not establish whether these two councils could take disciplinary action against such staff. The problem with this approach is that it also does not deal with irregularities that may occur at the hands of staff within social science studies: Grant, Lewis and Strode (note 320 above).

<sup>426</sup> See for example the submission on the Health Profession's Amendment Bill (B10–2005), AIDS Law Project (ALP) available from <http://www.alp.org.za/pdf/Parliament/Health%20Professions%20Amendment%20Bill%20-%202006%20-%20ALP.pdf> [Accessed 1 July 2009]. In this submission the ALP (now renamed Section 27) argue

the large funders of health research such as the National Institutes of Health in the US could also be seen as a form of professional ordering as this is a form of control exercised by a state or an international organisation.<sup>427</sup> Obligations imposed by funders would have to be met alongside any local obligations in the country where the health research was being conducted.<sup>428</sup> Whilst the funders of research would not have the power to discipline researchers they could stop or withdraw funding for a project and thus exert considerable power over researchers. The second model offers some protection and remains facilitative of research.

The third model is the cautious regulatory approach. This is a model in which there is a level of legal regulation by the state within the ethical-legal framework. This model envisages laws and policies issued by the state which regulate certain normative aspects of health research, as well as laws establishing an institutional framework such as ethical committees which are tasked with approving and monitoring research. This model is protective of participants and does not prevent research that meets the normative standards set by the state. This approach is generally regarded as the ideal approach.

The final model is one which takes a prohibitive approach. This model is an extension of the cautious regulatory approach. It is a system in which there is a high level of regulation by the state through legislation which not only sets norms and establishes regulatory institutions but prohibits certain kinds of research. This model also includes penalties for non-compliance.<sup>429</sup> Although it has many strengths in that it creates an ethical-legal framework

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that the South African Health Professions Council has been ineffective in disciplining its members. See Chapter Six for further discussion on this issue.

<sup>427</sup> The NIH website indicates for example, that applicants for a NIH grant will have to comply with certain ethical obligations set by the US government [http://grants.nih.gov/grants/compliance/42\\_CFR\\_50\\_Subpart\\_F.htm](http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm) [Accessed: 30 January 2013].

<sup>428</sup> *Ibid.*

<sup>429</sup> Nielsen (note 42 above) 45–49. Examples of ethical-legal frameworks falling into this category include, the United States, the United Kingdom and Australia. See Andanda (note 160 above) for a more detailed discussion of these frameworks 66–77.

enforced by law, its weakness is that it may fall into the danger of over-regulating research, thus impinging on academic freedom and the discovery of new knowledge.<sup>430</sup> In summary, this model is highly protective but is also obstructive of research.

## 2.6 Conclusion

There are some criticisms of the value of the international ethical-legal framework. Nienaber argues that it provides very little protection as it is not directly enforceable.<sup>431</sup> Furthermore, compliance is dependent on professional sanction and other non-legal enforcement measures.<sup>432</sup> Resultantly, she submits that other than 'a refusal to fund or a refusal to publish unethical research, there is little to guard against unethical research conducted by unscrupulous agencies'.<sup>433</sup> Furthermore, Annas and Grodin have articulated three lessons from the Nuremburg trials of Nazi doctors, which can also be considered to be a broader critique of the current international ethical-legal framework. They posit that:

- (i) Ethical guidelines are in many instances not enforceable;
- (ii) Violations of human rights do occur in human experimentation; and
- (iii) There is no effective international mechanism for promulgating and enforcing basic medical ethics and human rights principles.<sup>434</sup>

In conclusion, however, this thesis argues that despite the fragility of the international framework as a system of law in itself, it nevertheless provides a framework which can be used to describe and develop the key elements of effective systems for regulating health research at domestic level. The international ethical-legal framework sets out a number of key institutions which ought to exist in order to ensure that an appropriate research agenda

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<sup>430</sup> See Chapter Three for further discussion on how the South African ethical-legal framework can be classified in terms of this framework.

<sup>431</sup> Nienaber (note 87 above) 145.

<sup>432</sup> *Ibid.*

<sup>433</sup> *Ibid.*

<sup>434</sup> Annas & Grodin (note 190 above) 309.

is established, the scientific quality of research is assured, ethical review of protocols takes place, there is community engagement, and rights are enforced. At a normative level, the international guidance clearly establishes norms regarding consent, privacy, dignity, enjoying the benefits of research, and protection against unfair discrimination. There are also well-established ethical norms regarding the participation of children within health research.

The international framework has evolved over the last 60 years, with the role of ethical-legal institutions becoming more prominent of late. In particular, there has been a shift from a purely normative focus to one in which there is now a significant role for drug regulatory authorities and ethics committees. Simultaneously, institutions that will be necessary to ensure public participation in research and setting the research agenda are emerging. The international ethical-legal framework is incomplete with many gaps. It also faces key challenges as scientific knowledge develops exponentially, raising new and more complex issues for regulatory frameworks. Advocacy is needed to promote an international covenant protecting the rights of research participants. Nevertheless, the international framework is of value in regulating health research with children as it provides guidance (albeit in a limited way) on the protection of research participants, facilitating their involvement in research and promoting child participation.

## Chapter Three:

### **The development of the current South African ethical-legal framework for regulating health research with children**

The preceding Chapter discussed the institutional and normative framework for regulating health research, which has been established by the international community. It contextualised the international norms for research regulation by briefly discussing the history of research regulation, including two key events which prompted the development of protective research norms, namely, the exposure of medical experimentation on prisoners of war by Nazi doctors and the Tuskegee syphilis trial in the USA. The ethical-legal norms that have been established through international humanitarian and human rights law and ethical codes were set out. Based on these norms the preceding Chapter argued that the key characteristics of well-functioning ethical-legal frameworks are firstly, institutions which are able to (a) create a policy framework, (b) review and regulate research, (c) issue ethical norms and standards dealing with both procedural and substantive issues, (d) liaise with the community and (d) enforce research participants' rights. Secondly, it submitted that effective ethical-legal frameworks have legally established norms which create minimum standards for conducting health research. The Chapter concluded with a theoretical model of how ethical-legal frameworks can be classified.

This Chapter describes the evolution of the South African ethical-legal framework through three distinct legislative phases, namely, the situation:

- (i) Prior to the adoption of the NHA (first phase);<sup>435</sup>
- (ii) Following the partial implementation of the NHA (second phase); and
- (iii) Currently, following the full implementation of the NHA (third phase).

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<sup>435</sup> National Health Act (note 57 above).

Using the key institutional and normative characteristics of well-functioning ethical-legal frameworks described in Chapter Two as benchmarks, this Chapter briefly describes and critiques the first two phases of the ethical-legal framework for regulating health research in South Africa.<sup>436</sup> It does this by describing the key institutions, setting out any ethical-legal norms and classifying the frameworks in terms of Nielsen's model.<sup>437</sup> Both phases are critiqued using the three themes underlying this thesis, namely, the extent to which they protect child research participants, promote child participation and facilitate health research.<sup>438</sup> The Chapter concludes with general comments on the nature of the evolution of the ethical-legal framework and its implications for research with children.

### 3.1 Introduction<sup>439</sup>

Medical research in South Africa dates back to the 1860s.<sup>440</sup> Early scientific work was conducted primarily by the Veterinary Research Institute, in Onderstepoort and the South African Association for the Advancement of Science.<sup>441</sup> The first academic journal dealing with medical issues was the *South African Medical Record* which published original scientific articles between 1903 and 1926.<sup>442</sup> During the twentieth century the state began to invest more funding in medical research and established, amongst others, the South African Institute of Medical Research, the MRC and HSRC.<sup>443</sup>

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<sup>436</sup> The current phase of the ethical-legal framework is described in Chapters Four (institutional aspects) and Five (normative elements). It is critiqued in Chapter Six.

<sup>437</sup> Nielsen's model is described in more detail in Chapter Two.

<sup>438</sup> See Chapter One for a full description of these three concepts.

<sup>439</sup> This Chapter is based to a limited extent on previous work by the author in Strode, Slack & Mushariwa (note 94 above) 598–601. In this article, Strode, as the first author prepared the first draft of the article and her co-authors provided inputs on that version when assisting in completing the piece.

<sup>440</sup> BJ Barker 'A Short General History of the MRC' available from <http://www.mrc.ac.za/history/history.pdf> [Accessed: 18 June 2012].

<sup>441</sup> Singh & Strode (note 45 above).

<sup>442</sup> *Ibid.*

<sup>443</sup> Barker (note 440 above).

It has been submitted that during the Apartheid era state-funded health research aimed at achieving:

two primary considerations: (a) the desire to improve the health of white citizens; and (b) the desire to improve the health of non-white citizens, but primarily only in so far as their health posed a threat to white citizens, or threatened to undermine the national economy. As such, health research in the country was motivated by economic considerations and not humanitarian ones.<sup>444</sup>

Initially, research was unregulated. However, in the last 50 years the ethical-legal framework has evolved through three phases from high levels of self-regulation to a highly sophisticated, institutional and normative framework which describes procedural and substantive protections for research participants.

## **3.2 The ethical-legal framework prior to the National Health Act**

### *3.2.1 Overview*

Prior to the NHA there was no formal, legally established ethical-legal framework for regulating health research.<sup>445</sup> In essence, in this first phase of the development of the ethical-legal framework the focus was on self-regulation, with many researchers and research institutions not being under any statutory obligation to, for example, submit research for ethical review, unless they were undertaking clinical trials or the research was conducted by or on behalf of the MRC.<sup>446</sup>

### *3.2.2 Institutional framework*

The only two institutions established by law which dealt with ethical-legal matters related to the regulation of health research were the MCC, created in terms of the Medicines and

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<sup>444</sup> *Ibid.*

<sup>445</sup> Pope (note 93 above) 170.

<sup>446</sup> Strode, Slack & Mushariwa (note 94 above) 599.

Related Substances Act<sup>447</sup> (the ‘Medicines Act’), and the MRC’s REC.<sup>448</sup> There were, however, a number of other statutory institutions which played a varying degree of roles in the informal ethical-legal framework as is illustrated by Table 3 below. These included the HSRC as the largest statutory body undertaking social science research,<sup>449</sup> the South African Medical and Dental Council which had the authority to regulate and discipline its members (medical practitioners) undertaking health research<sup>450</sup> and the courts. Finally, although they were not specifically required to do so by statute, a number of institutionally based RECs were voluntarily established.<sup>451</sup>

**Table 3: The institutional framework prior to the National Health Act**

<b>Institutions establishing research priorities</b>	<b>Institutions reviewing and regulating health research</b>	<b>Institutions issuing ethical norms and standards</b>	<b>Institutions liaising with the community on research issues</b>	<b>Institutions enforcing research participants rights</b>
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<sup>447</sup> Medicines and Related Substances Act 101 of 1965, s 35(1)(xxxix) read with the General Regulations (note 164 above) *Government Gazette*, 10 April 2003, No. 24727, R510 and Act 58 of 1991.

<sup>448</sup> The MRC was established by the South African Medical Research Council Act 19 of 1969 and later by the Medical Research Council Act 58 of 1991.

<sup>449</sup> Human Sciences Research Act (note 62 above). The objectives of the HSRC were to promote research and the development of knowledge in the field of human sciences, s 2A and 3 *ibid*. See Chapter One for the definition of social science research as contained in the current Human Sciences Research Council Act *ibid*. The HSRC does not have a regulatory function as is evident from s 2 of its Act, which describes its objectives as being, amongst others, to '(a) initiate, undertake and foster strategic basic research and applied research in human sciences, and to gather, analyse and publish data relevant to developmental challenges in the Republic, elsewhere in Africa and in the rest of the world, especially by means of projects linked to public sector oriented collaborative programmes; (b) inform the effective formulation and monitoring of policy and to evaluate the implementation of policy; (c) stimulate public debate through the effective dissemination of fact-based results of research; (d) help build research capacity and infrastructure for the human sciences in the Republic and elsewhere in Africa; (e) foster and support research collaboration, networks and institutional linkages within the human sciences research community; (f) respond to the needs of vulnerable and marginalised groups in society by researching and analysing developmental problems, thereby contributing to the improvement of the quality of their lives; and (g) develop and make publicly available new data sets to underpin research, policy development and public discussion of the key issues of development, and to develop new and improved methodologies for use in their development'.

<sup>450</sup> Health Professions Act 56 of 1974.

<sup>451</sup> The first University to create an REC was the University of Witwatersrand which did so in 1966 K Moodley & M Landon 'Health research ethics committees in South Africa: 12 years into democracy' (2007) Vol 8(1) *BMC Medical Ethics* 1, 1.

MRC HSRC	MCC MRC's REC	NCC MRC's REC Medical and Dental Council	No statutory institutions existed	MCC MRC's REC Institutional RECs Medical and Dental Council Courts
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*(i) Institutions establishing research priorities*

In the first phase of the ethical-legal framework there was no statutory body with the express mandate of setting national research priorities for all forms of health research in South Africa. However, both the HSRC and the MRC were required to advise their respective ministers of research priorities in their fields of research. The HSRC was required to advise the Minister of National Education on 'research priorities' relating to human sciences<sup>452</sup> whilst the MRC was required to advise the minister assigned to this function of 'the determination of policy and national priorities regarding research' and on the 'development, promotion, implementation and co-ordination of research on a national basis'.<sup>453</sup>

*(ii) Institutions reviewing and regulating health research*

The only regulatory bodies in this first phase of the ethical-legal framework were the MCC, the MRC's REC and other institutional RECs.

One of the primary functions of the MCC was to provide for the registration of medicines and related substances.<sup>454</sup> Although the Medicines Act didn't deal directly with the conduct of clinical trials it was given the authority to register medicines only if it was satisfied with their application for registration following 'any investigation or enquiry which it may consider

<sup>452</sup> S 2A(b) Human Sciences Research Act (note 62 above).

<sup>453</sup> S 20 Medical Research Council Act (note 448 above).

<sup>454</sup> Preamble, Medicines and Related Substances Act (note 447 above).

necessary'.<sup>455</sup> It is argued therefore that the broad mandate of the MCC included the regulation of clinical trials which preceded the registration of a medicine or medical product.<sup>456</sup> In this context it is submitted that one of the regulatory functions of the MCC was to ensure that clinical trials were scientifically valid given the stipulations that were set out in the General Regulations accompanying the Medicines Act.<sup>457</sup>

No RECs were expressly required to be established by law although the MRC, a statutory body established to use 'research, development and technology transfer, to promote the improvement of the health and the quality of life of the population of the Republic'<sup>458</sup> was required to 'establish ethical directives' and 'ensure that they were complied with by MRC staff'.<sup>459</sup> It could be argued that this placed an obligation on the MRC Board to ensure that research or experimentation with humans or animals undertaken by MRC staff or persons on behalf of the MRC was regulated and controlled. Thus although not expressly provided for, it appears that the MRC was under an indirect statutory obligation to establish an REC.<sup>460</sup> Furthermore, even though no other research institutions were required to set up RECs, many were obliged to if they wished to conduct clinical trials because in order to register a clinical trial with the MCC, ethical approval was required from a recognised REC.<sup>461</sup> Accordingly, many institutions voluntarily established RECs for both clinical trials and social science studies and required researchers (employees or contractors) conducting research on their

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<sup>455</sup> General Regulations, Medicines and Related Substances Act, Regulation 15(3)(a) (note 164 above).

<sup>456</sup> Strode, Slack & Mushariwa (note 94 above) 599.

<sup>457</sup> *Ibid.* Although see also below, regarding the requirement in the General Regulations, Medicines and Related Substances Act that researchers obtain ethical approval before approaching the MCC (note 164 above).

<sup>458</sup> S 3 Medical Research Council Act (note 448 above).

<sup>459</sup> S 17(1) *ibid.*

<sup>460</sup> The MRC complied with this obligation by establishing an REC in 1970. Furthermore in its Guidelines on ethics for medical research: General Principles (Book 1), which was first issued in 1977, it provided that research on healthy volunteers and patients must be subject to independent ethical review by an REC (note 12 above).

<sup>461</sup> Regulation 34(2), General Regulations issued in terms of the Medicines and Related Substances Act (note 164 above).

behalf to obtain ethical clearance.<sup>462</sup> Far fewer social science research institutions established RECs or required researchers to obtain ethical approval for studies with human participants with, for example, the HSRC did not require ethical approval for all its work until after the partial implementation of the NHA.<sup>463</sup>

*(iii) Institutions to issue ethical norms and standards*

Both the MCC and the MRC had the statutory authority to issue norms and standards regulating health research.<sup>464</sup> The MRC issued ethical guidelines in 1977, 1987, 1993 and 2003.<sup>465</sup> The most recent, the Guidelines on ethics for medical research: General Principles (Book One), were informally regarded as national ethical guidelines as no other widely used set of ethical guidelines issued by a statutory body existed.<sup>466</sup>

A similar statutory duty was placed on the Medical and Dental Council in terms of the Health Professions Act which empowered the Council to, amongst others, issue ethical codes to guide the professional conduct of their members.<sup>467</sup> Any registered doctor, dentist or psychologist undertaking research would be required to comply with such ethical codes.<sup>468</sup> Unlike the MRC, the HSRC's empowering legislation did not require it to establish an ethics

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<sup>462</sup> Moodley & Landon (note 451 above) 1.

<sup>463</sup> The HSRC only established an REC in 2003, personal communication, Professor Wassenaar, Chair, HSRC Research Ethics Committee, 14 May 2012.

<sup>464</sup> The General Regulations accompanying the Medicines and Related Substances Act (note 164 above) described in some detail the obligations on researchers conducting clinical trials. This included for example, in Regulation 34(2) that the application to the MCC must include: the trial protocol; the investigator's brochure which includes the background information on the product to be tested; the curriculum vitae of all investigators; a signed statement by all investigators that they will comply with the Good Clinical Practice Guidelines (GCP) issued by the Department of Health; a copy of the informed consent document; and ethical approval by a recognised REC. The first set of GCP guidelines was issued by the Department of Health in 2000. An updated version was completed and issued in 2006, Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa (note 58 above). Whilst s 17 of the MRC Act (note 448 above) required the MRC to 'establish ethical directives' which it did by developing ethical guidelines.

<sup>465</sup> Medical Research Council (2003) Guidelines on ethics for medical research: General Principles (Book 1) (note 12 above).

<sup>466</sup> Van Oosten (note 104 above) 7–8.

<sup>467</sup> SA Strauss *Doctor, patient and the law* 3 ed (1980) 369.

<sup>468</sup> *Ibid.*

committee, to issue ethical directives for social science research or to ensure that ethical standards were enforced.<sup>469</sup>

*(iv) Institutions to facilitate communication between researchers and the community*

No institutions were required to be established to provide a forum for liaison between researchers and the community during this phase of the ethical-legal framework, and none were voluntarily set up.

*(v) Institutions to enforce research participants rights*

A number of both research-specific and other institutions existed which could potentially be used to enforce research participants' rights including:

- (a) The MCC could act against researchers who failed to comply with the obligations set out in the General Regulations;<sup>470</sup>
- (b) The MRC REC was able to act against researchers either employed by it or those undertaking work on its behalf, for failing to comply with its ethical guidelines;<sup>471</sup>
- (c) Any institutionally-based REC could act against its employees who failed to comply with their ethical guidelines. They could also refer the matter to the institution for further disciplinary steps;<sup>472</sup>
- (d) The Medical and Dental Council could act against any of its members for unprofessional or unethical conduct during research;<sup>473</sup> and
- (e) Courts could adjudicate on any criminal or civil complaint regarding the unethical or illegal conduct of a researcher.<sup>474</sup>

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<sup>469</sup> S 2A(a) provided for example, that the HSRC was required to 'promote, support and co-ordinate research' (note 67 above). It is submitted that this cannot be interpreted as implying a regulatory function on the HSRC.

<sup>470</sup> General Regulations accompanying the Medicines and Related Substances Act (note 164 above).

<sup>471</sup> S 17 MRC Act (note 4480 above).

<sup>472</sup> It is possible to argue that the failure to comply with ethical guidelines was a breach of a workplace rule and accordingly was a form of misconduct for which an employee could be dismissed in terms of s 188(1)(a)(i) of the Labour Relations Act 66 of 1995.

<sup>473</sup> Health Professions Act (note 450 above).

There was only one statutory obligation regarding the monitoring of research in order to protect research participants' rights, namely, researchers conducting clinical trials had to submit regular progress reports to the MCC.<sup>475</sup> The MRC Guidelines did not require progress reports but clearly indicated that the REC had an on-going oversight role for the duration of the research.<sup>476</sup> Furthermore, although not required by law, many institutional ethical guidelines required RECs to monitor research that they had approved.<sup>477</sup>

Obligations also existed in the MRC and GCP Guidelines regarding research-related injuries. Both provided that if research participants were harmed as a direct result of research participation they were entitled to compensation.<sup>478</sup>

Finally, there were a number of institutions which did not have a research-specific mandate but which could have been used to enforce research participants' rights. This included, for example, the Medical and Dental Council which had disciplinary powers over its members (doctors, dentists and psychologists).<sup>479</sup>

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<sup>474</sup> See Chapter Four for a more detailed discussion on the circumstances in which the criminal or civil law could be used to hold a researcher liable for inappropriate or harmful conduct relating to research.

<sup>475</sup> Regulation 34(5)–(6) General Regulations (note 164 above).

<sup>476</sup> 10.3 MRC Book One (note 12 above).

<sup>477</sup> For example, the MRC's ethical guidelines on Ethics for Medical Research (Book 1) provide in 10.2 that research ethics committees have a critical role to play in monitoring research and that their responsibilities 'continue whilst the research is in progress' *ibid*. However, outside of research conducted by the MRC this was not a legal requirement.

<sup>478</sup> The MRC's Book One *ibid* provided in point 10.6 that participants should be compensated if they were injured during the research. They recommended that researchers obtain professional indemnity insurance to cover this possibility. Furthermore, if a participant suffered a 'significant injury' they would be entitled to compensation regardless of whether or not there was negligence or legal liability on the part of the researchers, 10.6.2.2 *ibid*. The GCP Guidelines in point 4.11 (note 58 above) provide that researchers must obtain comprehensive insurance to cover any possible research-related injuries. Furthermore 'compensation should be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under a trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial'.

<sup>479</sup> Health Professions Act (note 450 above).

### 3.2.3 Normative framework

There was no comprehensive normative framework for regulating research in the first phase of the ethical-legal framework. However, there were some limited references to research norms contained in a number of different statutes. None of these norms dealt expressly with the participation of children in health research. The laws included the:

- (i) Medicines Act which described the regulation of clinical trials;<sup>480</sup>
- (ii) South African Medical Research Council Act which contained some norms regarding research undertaken by the MRC;<sup>481</sup>
- (iii) Human Tissues Act<sup>482</sup> which regulated the removal, use of and import/export of human bodies, blood, tissues and gametes from living or deceased persons, including research on such material;<sup>483</sup> and
- (iv) The common law relating to everyone's personality rights which could be applied to research.<sup>484</sup>

It can be argued that these legal norms required, firstly, that informed consent be obtained from research participants before enrolment in a study.<sup>485</sup> Secondly, ethical approval had to be obtained for all clinical trials and research conducted by the MRC. Thirdly, authorisation was required from the MCC for clinical trials.<sup>486</sup> Figure 1 below shows the procedural obligations prior to the NHA.

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<sup>480</sup> Medicines and Related Substances Act (note 429 above).

<sup>481</sup> Medical Research Council Act (note 450 above).

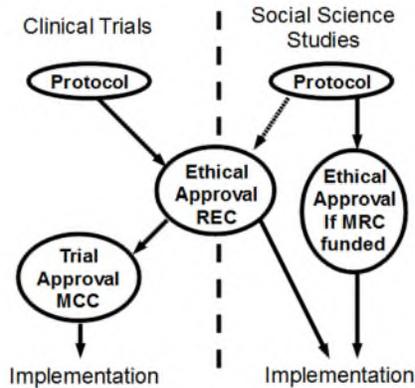
<sup>482</sup> Act 65 of 1983. This Act has been repealed by the NHA (note 57 above).

<sup>483</sup> *Ibid* s 18, 19, 24 and 25.

<sup>484</sup> Stobie, Strode & Slack (note 59 above) 194.

<sup>485</sup> Before 1996 this was not an express requirement in our law. S 12 of the Constitution of the Republic of South Africa (note 2 above) was the first general obligation to ensure that consent was obtained before health research. See Chapters One and Five for further discussion on this point. However, s 18(b) Human Tissues Act 65 of 1983 required consent to any research on blood, human tissues or gametes. Nevertheless it is argued that given the fundamental right to autonomy in terms of the common law, researchers would be required to obtain consent from potential participants.

<sup>486</sup> General Regulations accompanying the Medicines and Related Substances Act (note 164 above) and the MRC Act (note 450 above).



**Figure 1: The ethical-legal framework prior to the implementation of the National Health Act**

Fourthly, MRC researchers were required to comply with the ethical guidelines issued by the MRC.<sup>487</sup> These dealt expressly with the participation of children in health research.<sup>488</sup> Researchers conducting clinical trials were required to comply with the GCP issued by the Department of Health which included research participant protections.<sup>489</sup> It has been argued that these requirements indirectly resulted in some ethical norms being legally

<sup>487</sup> S 17(1) Medical Research Council Act *ibid*. There are currently five MRC books dealing with ethical issues (note 9 above) they include; Book 1: Guidelines for medical research: General Principles, Book 2: Guidelines on ethics for medical research: Reproductive biology and genetic research, Book 3: Guidelines on ethics for medical research: use of animals in research, Book 4: Guidelines on Ethics for Medical Research: use of Biohazards and Radiation, Book 5: Guidelines on Ethics for Medical Research: HIV Vaccine Trials, available from [www.mrc.ac.za](http://www.mrc.ac.za) [Accessed: 2 June 2008].

<sup>487</sup> Before 1996 this was not an express requirement in our law. S 12 of the Constitution of the Republic of South Africa (note 2 above) was the first general obligation to ensure that consent was obtained before health research. See Chapters One and Five for further discussion on this point. However, s 18(b) Human Tissues Act (note 467 above) required consent to conduct any research on blood, human tissues or gametes. Nevertheless it is argued that given the fundamental right to autonomy in terms of the common law, researchers would be required to obtain consent from potential participants.

<sup>487</sup> General Regulations accompanying the Medicines and Related Substances Act (note 164 above).

<sup>488</sup> MRC Book One (note 12 above).

<sup>489</sup> Regulation 34(2) Medicines and Related Substances Act (note 164 above). The GCP Guidelines were developed to provide clear, appropriate and locally relevant standards of good clinical practice in research and to ensure that research with human participants takes place within the framework of sound scientific and ethical standards (note 58 above).

enforceable.<sup>490</sup> Fifthly, only authorised institutions who had obtained permits were allowed to import or export any blood, blood product or gamete for research purposes.<sup>491</sup>

Child-specific ethical norms were established in the GCP Guidelines of 2000 and Book One issued by the MRC. These focused on consent, risk standards and limiting the nature of research or trials in which children could participate. Differing approaches were taken by both sets of guidelines on all three issues. Firstly, with regard to consent, the GCP Guidelines did not provide for independent consent by children in any circumstances whilst the MRC allowed independent consent by children over 14 in therapeutic research (this could include clinical trials) (See Table 4 below).<sup>492</sup>

**Table 4: Comparison between the approach taken by GCP and the MRC (Book One) on consent to research participation in research by children**

	GCP (2000)	MRC Book One
<b>Consent</b>	Consent from parents or legal guardians and assent from children	Consent from parents for non-therapeutic research Consent from the child over the age of 14 for therapeutic research, parental consent if below 14 Assent from children if unable to consent

Secondly, in terms of risk standards the GCP Guidelines (2000) specified no express limit on the permissible level of risk in research which holds out the possibility of direct benefit to

<sup>490</sup> In essence this approach argued that the courts would look to ethical guidelines to establish the standard of behaviour expected from health professionals, see for example, *Jansen van Vuuren and Another NNO v Kruger* (note 157 above) 854G–H where the Appellate Division held that patients had a right to expect that their doctors would abide by the ethical guidelines issued by their professional body. Given that this meant that health professionals could be held delictually liable for failing to comply with ethical guidelines it has been argued that these ethical codes were indirectly legally enforceable.

<sup>491</sup> Ss 24 and 25 Human Tissue Act (note 487 above).

<sup>492</sup> The MRC justified this approach by providing that therapeutic research could be equated to medical treatment and as children could consent independently to medical treatment from the age of 14 in terms of s 39(4) of the Child Care Act 74 of 1983, they could in turn also consent to therapeutic research from the age of 14, point 5.3.1.2.1, MRC Book One (note 12 above).

child participants. However, if the study posed more than a minor increase over minimal risk, then the risks had to be justified by the benefits to participants.<sup>493</sup> In research which did not hold out the prospect of direct benefit a study could not pose more than a minor increase over minimal risk. Furthermore, the risks had to be justified by the generalisable knowledge that would be generated by the study.<sup>494</sup> On the other hand, the MRC's Book One provided that so-called therapeutic research could not pose any more than an everyday risk for children.<sup>495</sup> In other words, it could not pose more than small chance of a 'trivial reaction, remote chance or serious injury/death'.<sup>496</sup> With so called non-therapeutic research it could not pose more than a negligible risk of harm (See Table 5 below).<sup>497</sup>

**Table 5: Comparison between the approach taken by GCP and the MRC (Book One) on the issue of risks standards in research involving children**

	Therapeutic research	Non-therapeutic research
<b>GCP (2000)</b>	No express limit on the allowable level of risk  If the study posed more than a minor increase over minimal risks to be justified by the benefits to participants	A study could not pose more than a minor increase over minimal risk  Risks to be justified by the generalisable knowledge generated by the study
<b>MRC (Book One)</b>	Express limit on allowable level of risk – no more than the everyday risk of harm	Express limit on allowable level of harm – no risks or no more than negligible risk

Finally, the two sets of guidelines differed with regard to the nature of the research that children could participate in, with the MRC limiting so-called therapeutic research to studies

<sup>493</sup> Stobie, Strode & Slack (note 59 above) 206–207.

<sup>494</sup> *Ibid.*

<sup>495</sup> *Ibid* 192–193.

<sup>496</sup> *Ibid.*

<sup>497</sup> *Ibid.* See Chapter Two for a more detailed discussion on the international debates on the meaning of the term minimal risk.

which took the form of treatment, and so-called non-therapeutic research to observational and non-intervention research.<sup>498</sup>

### 3.2.4 *Classifying the ethical-legal framework prior to the adoption of the National Health Act*

Using Nielsen’s approach, as described in Chapter Two, on the classification of ethical-legal frameworks<sup>499</sup> it is argued that given the lack of a comprehensive institutional or normative ethical-legal framework, South Africa’s ethical-legal regime prior to the NHA could be regarded as falling between the professional control model and the cautious regulatory approach. The system had elements of the professional control model as bodies like the Medical and Dental Council which regulated doctors, dentists and psychologists could have been used to discipline the unethical conduct of health professionals conducting health research. On the other hand elements of the cautious regulatory approach existed as both the MCC and the MRC had certain statutory obligations to regulate research, issue norms and standards and ensure compliance with them. However, given that these norms applied only to some forms of health research, the framework also did not completely fit into the cautious regulatory approach (See Table 6 below).

**Table 6: Applying Nielsen’s model to South Africa’s ethical-legal framework prior to the National Health Act**

Model	Key elements	Application to South Africa
Professional control model	Regulation of researchers by professional bodies	The Medical and Dental Council and other similar bodies had the authority to discipline members who acted unethically in health research
Cautious regulatory approach	Legal regulation of research through institutions such as RECs	The MCC had legal powers to regulate clinical trials

<sup>498</sup> *Ibid.*

<sup>499</sup> See Chapter Two for a detailed description of Nielsen’s model.

		MRC RECs had the authority to regulate MRC research Institutional ethical guidelines existed and limited legal provisions
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### 3.2.5 Critique of the ethical-legal framework prior to the adoption of the National Health Act

The ethical-legal framework before the adoption of the NHA was limited, fragmented and inconsistent in its approach to children. Elements of the framework were overly protective and, for example, certain ethical guidelines excluded almost all clinical trials with children.<sup>500</sup> Other parts of the framework were very permissive as the lack of legal regulation meant, for example, that social science studies did not require ethical approval. Overall, protection was weak as ethical norms were not directly enforceable and did not apply to all studies. There were no special obligations regarding health research involving children, except for those established in ethical guidelines.<sup>501</sup> Child participation was recognised in ethical guidelines which required assent from children without the capacity to consent, and independent consent from children in certain circumstances.

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<sup>500</sup> See the above discussion on the MRC's Book One (note 12 above) which prohibited all forms of non-therapeutic research with children which were interventional in nature. Very few clinical trials are not interventional as generally they are testing a new drug, intervention or therapy. See the definitions of a clinical trial in Chapter One.

<sup>501</sup> Stobie, Strode & Slack (note 59 above) 196.

**Table 7: The extent to which the first phase of the ethical-legal framework protected and promoted child participation whilst facilitating research with children**

Protection	Child participation	Research facilitation
Weak	Recognised as a principle through assent and consent procedures	Ranged between excluding research with children and allowing research in any circumstances

*(i) Institutional framework*

In first stage of the development of our ethical-legal framework, the institutional arrangement for regulating research was weak. Firstly, the framework lacked key institutions to set research policy, to provide ethical review, issue ethical standards or to facilitate community engagement in research. Secondly, it focused largely on regulating a narrow sector of health research, namely, clinical trials.<sup>502</sup> The flagship institution in the ethical-legal framework was the MCC which was primarily responsible for setting the scientific standards in clinical research.<sup>503</sup> A key social science institution, the HSRC was not required to regulate social science research.<sup>504</sup> Thirdly, there was some overlap between the respective regulatory roles of RECs and the MCC on ethical issues which resulted in some uncertainty. For example, the scientific validity of a clinical trial was clearly a concern for the MCC, which had to be satisfied that the research was methodologically valid and would produce reliable data.<sup>505</sup> Likewise it is a key ethical principle that research must be scientifically valid. In the past the MCC's approach of encroaching on ethical policy standards as part of its review of clinical trials caused conflict, for example, many researchers were outraged when it required that phase one HIV vaccine trial participants had to have 12 years education in order to be eligible to participate in such a study.<sup>506</sup> This was also contrary to the MRC ethical guidelines which required research participants to have understanding as part of the consent process

<sup>502</sup> Strode, Slack & Mushariwa (note 94 above) 599.

<sup>503</sup> *Ibid.*

<sup>504</sup> HSRC Act (note 62 above).

<sup>505</sup> S 35(i)(xxxix) Medicines and Related Substances Act (note 429 above).

<sup>506</sup> Personal communication, Dr Efthymia Vardas, 5 February 2004.

but did not stipulate that they had to have a particular educational standard.<sup>507</sup> Fourthly, the institutional framework was fragmented in the sense that there was no mechanism to coordinate the work of the MCC, RECs, MRC and the HSRC.

Finally, monitoring and enforcement mechanisms were generally weak as few institutions had a legal mandate to protect and promote the rights of research participants.<sup>508</sup> Where mechanisms did exist, they focused on, for example, the submission of reports to the MCC. Furthermore, given that ethical review was not required for many forms of social science research, not all research was scrutinised or monitored. This meant, for example, that participants had to use the civil law if they wished to bring an action against researchers who had conducted health research illegally by not obtaining consent for participation, as the ethical guidelines only provided for compensation for harm where a physical injury occurred.

*(ii) Normative framework*

Prior to the adoption of the NHA the norms and standards regulating research were limited, with almost no statute on this issue and no national ethical guidelines.<sup>509</sup> Furthermore, where legal norms did exist most were not established in research-specific laws.<sup>510</sup> Nevertheless, research participants did have protections such as the right to informed consent, privacy and protection from harm. The implications of this limited legal framework was firstly, there was no legal obligation on researchers who were not conducting clinical trials or performing work for the MRC to obtain ethical approval.<sup>511</sup> Thus, for example, a

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<sup>507</sup> Strode, Slack & Mushariwa (note 94 above) 600. Ironically, this would mean for example, that President Jacob Zuma would not qualify to be a research participant in an HIV vaccine study.

<sup>508</sup> *Ibid* 600.

<sup>509</sup> Although as stated above, some writers such as Van Oosten (note 104 above) argued that the MRC Guidelines ought to be regarded as national ethical guidelines 7.

<sup>510</sup> Strode, Slack, Grant & Mushariwa (note 114 above) 225 and Stobie, Strode & Slack (note 59 above) 194. See Chapter Four for a more detailed discussion on this point.

<sup>511</sup> S 17 Medicines and Related Substances Act (note 429 above). Regulations accompanying the Act provide that an application to the MCC for approval of a clinical trial must include a copy of ethical approval by an REC.

qualitative study into the experiences of children growing up in child-headed households was not required by law to obtain ethical approval even though it could pose some risk for participants. Secondly, given the lack of explicit legal provisions, academic writers and RECs often had to apply the general principles relating to medical treatment or the norms established in ethical guidelines to a research context.<sup>512</sup> There were two problems with this. One, the research relationship is different in its nature and objectives to a therapeutic one, for example, it is difficult to equate so-called non-therapeutic research to medical treatment. Two, ethical guidance had not been completely harmonised.<sup>513</sup> Furthermore, this inconsistent approach resulted in RECs taking divergent approaches to key issues, such as the age at which children could consent independently to participation in health research.

### **3.3 The ethical-legal framework following the partial implementation of the National Health Act**

#### *3.3.1 Overview*

The second stage of the development of the ethical-legal framework commenced with the implementation of parts of the NHA.<sup>514</sup> Chapter Nine of the NHA created a formal ethical-legal framework for the first time in South Africa. The parts of this Chapter which came into operation on 2 May 2005 included:<sup>515</sup>

- (i) A number of key institutions, which set the policy agenda, establish norms and standards, review and regulate individual studies;

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Although there was no legal obligation to obtain ethical approval, many institutions and sponsors of research required the research protocol to be reviewed.

<sup>512</sup> Strode, Slack & Mushariwa (note 94 above) 600.

<sup>513</sup> In particular there was a lack of harmonisation around the issue of the permissible level of risk in non-therapeutic research. Also see Stobie, Strode & Slack (note 59 above) 194 and Chapter One for an example of the different approaches by RECs on the issue of independent consent by adolescents.

<sup>514</sup> *Government Gazette* No. 27503 (note 95 above).

<sup>515</sup> *Ibid.*

- (ii) Legally enforceable norms in ethical guidelines which established substantive and procedural guidelines for the conducting of health research;<sup>516</sup> and
- (iii) Monitoring and enforcement mechanisms through RECs and the NHREC.

Significantly, the new ethical-legal framework was inclusive as it regulated both clinical trials and social science studies. The second stage of the development of the ethical-legal framework did not however include the implementation of legal norms regulating when and how health research with children may be conducted. This was the case despite the promulgation of the Children's Act which made provision for numerous health rights for children, but did not address the rights of child research participants.<sup>517</sup>

### 3.3.2 *Institutional framework*

The NHA created a number of new institutions to regulate and support health research, including the National Health Research Committee (NHRC), the National Health Research Ethics Council (NHREC) and RECs. These institutions together with the pre-existing MCC create a comprehensive institutional framework for health research. The institutional framework introduced in 2005 is our current ethical-legal framework as no significant changes having been introduced in the last seven years. Accordingly, it is discussed in detail in Chapter Four of this thesis which describes the current institutional framework for regulating health research.

### 3.3.3 *Normative framework*

The normative framework changed between the first and second stages of the development of the ethical-legal framework in two significant ways. Firstly, the Bill of Rights in the final Constitution contained a specific provision on consent to research.<sup>518</sup> The nature of this right

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<sup>516</sup> See Chapter 5 for a detailed description of these legal norms.

<sup>517</sup> Strode, Slack & Essack (note 143 above) 247.

<sup>518</sup> S 12(2)(c) Constitution of the Republic of South Africa (note 2 above).

is discussed in Chapter Five. Secondly, the NHA gave the newly-created NHREC the power to issue national ethical guidelines which RECs and researchers were obliged to follow.<sup>519</sup> This ushered in a new era in which national ethical norms and standards could be developed by the NHREC.

Section 72 of the NHA creates a national system of ethical review by providing for the establishment of the NHREC.<sup>520</sup> One of the key functions of the NHREC is norm setting. The Council is required to issue guidelines on both the functioning of ethics committees as well as ethical norms and standards for health research.<sup>521</sup> Acting in terms of this function the NHREC issued national ethical guidelines entitled Ethics in Health Research: Principles, Structures and Processes.<sup>522</sup> The Guidelines require researchers to be mindful of four key ethical principles; respect for human beings, beneficence, non-maleficence and justice.<sup>523</sup> The Guidelines have a dedicated section on minors and children which details, amongst others, the appropriate risk levels and consent requirements.<sup>524</sup> Furthermore, they instruct RECs to pay special attention when approving research with vulnerable groups such as children.<sup>525</sup>

The section below only discusses the norms established by the national ethical guidelines issued by the NHREC in 2004 and the 2006 revised version of the GCP Guidelines.<sup>526</sup> It does not deal with the constitutional principles or any other part of the normative framework which remains in place today as these are set out in detail in Chapter Five. This section simply articulates the norms that governed informed consent to child research during the

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<sup>519</sup> S 72(5)(2) National Health Act (note 57 above).

<sup>520</sup> *Ibid.* See Chapter Four for a detailed description of the NHREC's role and functions.

<sup>521</sup> S 72(6)(a) and (c) *ibid.*

<sup>522</sup> NHREC Guidelines (note 56 above). It recommends that the Guidelines be used by 'investigators, ethical review committees, administrators, health-care practitioners, policy-makers, and community representatives'.

<sup>523</sup> *Ibid.*

<sup>524</sup> *Ibid.* See Chapter Four for further discussion on this point.

<sup>525</sup> *Ibid.*

<sup>526</sup> Good Clinical Practice Guidelines (note 58 above).

second stage of the ethical-legal framework, which have now been replaced, through the implementation of sections 11, 16 and 71 of the NHA.<sup>527</sup>

During this period, given the state's failure to implement explicit legal guidance on consent to health research, the key legislative and common law principles relating to informed consent to medical treatment and the principles established in ethical guidelines were used as a framework for determining when consent to health research would be lawful.<sup>528</sup>

Informed consent has a positive element, the recognition of the rights of individuals to act as autonomous agents.<sup>529</sup> This ensures that a patient's or research participant's rights to self-determination and freedom of choice are respected and it encourages rational decision-making through enabling them to weigh and balance the various options.<sup>530</sup> Consent also has a negative element in the sense that it can operate as a defence for health care providers or researchers, as persons who willingly consent to a harmful act or activity cannot claim that a delict has been committed against them.<sup>531</sup> If the principle is to operate as a defence the following must exist, namely, the patient or research participant should:

- (i) Have knowledge of the nature and extent of the harm or risk involved;<sup>532</sup>
- (ii) Appreciate and understand the nature of the harm or risk,<sup>533</sup> and

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<sup>527</sup> The current normative framework established by ss 11, 16 and 71 of the National Health Act (note 57 above) is set out in Chapter Five.

<sup>528</sup> The NHREC is required to set norms and standards for conducting research on humans and animals. Acting in terms of this section the NHREC has issued national ethical guidelines (note 56 above). The Guidelines also apply to the military and national research institutions. Furthermore given that s 73 of the NHA provides that RECs must approve health research that meets the ethical standards of their committee it has been argued by Smit that this is a reference to the standards established in the national ethical guidelines: Smit (note 34 above). It is submitted that this makes ethical guidelines indirectly legally enforceable.

<sup>529</sup> G Lindegger & L Richter 'HIV vaccine trials: critical issues in informed consent' (2000) Vol (96) *South African Journal of Science* 313, 315. The doctrine of informed consent was introduced into South African law in the case of *Castell v de Greef* reflecting a shift from medical paternalism to patient autonomy (note 142 above) 426B.

<sup>530</sup> P Carstens & D Permain *Foundational principles of South African Medical Law* (2007) Butterworths: Durban, South Africa 875.

<sup>531</sup> McQuoid-Mason (note 363 above) 8. This is the principle of *volenti non fit injuria* (to one consenting no harm is done).

<sup>532</sup> *Ibid.*

<sup>533</sup> *C v Minister of Correctional Services* 1996 (4) SA 292 (T) 301B.

- (iii) Voluntarily consent to the harm or assume the risk.<sup>534</sup>

Furthermore the person consenting must have legal capacity.<sup>535</sup> These four requirements for valid consent to medical treatment are used as a framework for the discussion below.

- (i) *Provide research participants with knowledge of the nature and extent of the risks involved in the research*

The common law required the patient to have knowledge of the nature and extent of the risks involved in the procedure for the consent to be valid.<sup>536</sup> However, there was no express legal guidance on the nature and extent of the information that ought to be provided to research participants. In applying this principle relating to medical treatment to health research, Van Oosten argued that it placed an obligation on researchers to inform participants or persons consenting, in layperson's language, of the nature, scope, consequences, risks, dangers, complications, benefits, disadvantages and prognosis as well as any alternatives.<sup>537</sup>

The NHREC's national ethical guidelines listed the information that should be given to research participants. It required participants to be informed of, amongst others:

- The investigators' qualifications;
- Their responsibilities as participants;
- The foreseeable risks or discomforts;
- The benefits to the participants or to others (during and after the research);
- Alternative procedures or courses of treatment;
- The extent to which confidentiality will be maintained;

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<sup>534</sup> *Esterhuizen v Administrator, Transvaal* 1957 (3) SA 710 (T) 722.

<sup>535</sup> McQuoid-Mason (note 363 above) 8.

<sup>536</sup> *Ibid.*

<sup>537</sup> Van Oosten (note 104 above) 6 and C van Wyk (note 13 above) 'Clinical trials, medical research and cloning in South Africa' 7.

- Whether the research has been approved by an REC;
- Contact details of the REC;
- Whether compensation will be given for research-related injuries;
- The consequences of any injury, including medical treatments that will be provided;  
and
- Who to contact in the event of a research-related injury.<sup>538</sup>

Similar requirements were contained in the GCP Guidelines regulating clinical trials.<sup>539</sup> Both the GCP and the NHREC Guidelines required the information to be provided in a culturally sensitive manner.<sup>540</sup> With regard to social science research the HSRC ethical guidelines did not deal specifically with the nature of the information that ought to be provided to research participants.<sup>541</sup>

*(ii) Appreciating and understanding the risks of the research*

It is argued that research participants had to appreciate and understand the nature of the harm or risk associated with research participation.<sup>542</sup> Ethical guidelines were silent on this point. However, the courts have viewed knowledge and understanding as inter-twined but distinct concepts:

(l)t must be clearly shown that the risk was known, that it was realised, and that it was voluntarily undertaken. Knowledge, appreciation, consent – these are the essential elements;

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<sup>538</sup> NHREC Guidelines (note 56 above) 4–5.

<sup>539</sup> Guidelines for Good Clinical Practice (note 58 above).

<sup>540</sup> *Ibid* 11 and NHREC Guidelines (note 56 above) 4.

<sup>541</sup> Code of Research Ethics, Human Sciences Research Council, available from [www.hsrc.ac.za](http://www.hsrc.ac.za) [Accessed: 9 February 2010].

<sup>542</sup> *Waring & Gillow Ltd v Sherborne* 1904 TS 340 at 344 cited with approval in *Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as Amicus Curiae)* 2005 (1) SA 509 (TDP) 515G–H.

but knowledge does not invariably imply appreciation, and both together are not necessarily equivalent to consent.<sup>543</sup>

The requirement of 'appreciation' implies more than mere knowledge ..... (the patient) must also comprehend and understand the nature and extent of the harm or risk.<sup>544</sup>

Courts take a factual approach to establishing whether appreciation exists.<sup>545</sup> With regard to children they consider subjective and objective factors including age, knowledge, experience, judgment and personal circumstances.<sup>546</sup> Nevertheless, establishing whether a research participant appreciates the risks associated with research is clearly a complex issue, as Lindegger and Richter describe:

understanding is an elusive concept, and it is not a simple matter to gauge the nature and level of understanding that someone has of a concept, an event or process. While it may be relatively easy to evaluate the adequacy of information disclosed (eg, showing information on a videotape) it is far more difficult to assess how the information and its implications are truly understood.<sup>547</sup>

In practice, clinical trials invariably assess understanding by requiring research participants to pass basic tests usually in the form of short questions that ask whether certain

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<sup>543</sup> *Ibid.*

<sup>544</sup> *Ibid* 515I–J.

<sup>545</sup> For example, in *C v Minister of Correctional Services* (note 533 above) the court found that a prisoner had been aware that he was to be tested for HIV and that he had a right to refuse the test yet, nevertheless, appreciation did not exist as required by the Department of Correctional Services' own norms regarding consent to HIV testing. Relevant factors included: the prisoner had been given information on the test in a group whilst waiting in a line in the passage way; he had not been given an opportunity to consider and reflect on the information; the right to refuse the test was not expressed to him individually; and the information was not provided by a person who had been trained in pre-test counseling, 300E–F and 304A–E. Likewise the criminal courts in assessing, for example, whether children may be held responsible for criminal conduct (as they have criminal capacity) have required that the child show an appreciation of wrongfulness and an ability to act in accordance with that appreciation, J Burchell & J Milton *Principles of Criminal Law* 3 ed (2005) 368 .

<sup>546</sup> Burchell & Milton *ibid.*

<sup>547</sup> Lindegger & Richter (note 511 above) 315.

statements are, for example, true or false.<sup>548</sup> There has been considerable debate about the most appropriate method of assessing understanding<sup>549</sup> and it has been submitted that this approach of testing how much information has been retained does not establish understanding but is instead an assessment of short-term memory of technical and product-related information.<sup>550</sup>

*(iii) Express agreement to the risk of research participation*

Van Oosten has submitted that research participants have to clearly express their intention to participate in the study, and their consent has to extend to all aspects of the research and its consequences.<sup>551</sup> The NHREC Guidelines provided that generally consent is required however it may be given, verbally or in writing. In certain limited circumstances consent does not need to be obtained, However, prior approval of the REC must be obtained for research where consent is to be waived.<sup>552</sup> GCP required informed consent but did not specify whether this should always be in writing.<sup>553</sup>

Consent was required to be given freely and voluntarily. Ethical guidelines required careful consideration of subtle coercive factors that may influence voluntariness, particularly in the case of children who may be more vulnerable due to their youth and inexperience.<sup>554</sup>

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<sup>548</sup> G Lindegger, C Milford, C Slack, X Xaba & M Quayle 'Assessing understanding for HIV vaccine trial participation in South Africa' (2006) Vol 43 *Acquired Immune Deficiency Syndrome* 560, 560.

<sup>549</sup> *Ibid* 560. It appears that less of a focus has been placed on assessing the understanding of participants in social science research. This may be due to the lower levels of risk that it often poses.

<sup>550</sup> Lindegger & Richter (note 511 above) 315.

<sup>551</sup> Van Oosten (note 104 above) 30.

<sup>552</sup> NHREC Guidelines (note 56 above) 4.

<sup>553</sup> GCP (note 58 above) 11.

<sup>554</sup> There may be many factors that could impact on voluntariness, for example, Lindegger & Richter (note 511 above) 314 refer to social desirability which is the tendency for research participants to behave and respond in a manner in which they think is expected of them. They will therefore try to be a 'good' research subject by complying with researcher demands. Social desirability clearly impacts on the ability of the research participant to act autonomously.

Furthermore, both the NHREC Guidelines and GCP state that participants should not be prejudiced by their refusal to participate in, or continue with, a study.<sup>555</sup>

*(iv) Capacity*

Consent had to be given by a person who is legally capable of consenting.<sup>556</sup> The capacity of minors to participate in legal transactions is limited, in order to protect them from their lack of intellectual or cognitive ability, inexperience and social or emotional immaturity.<sup>557</sup>

In the second phase of the development of the ethical-legal framework there was a wide divergence of views of when, if ever, children had the capacity to consent independently to health research and in the event that they did not have the capacity, who could provide proxy consent on their behalf.<sup>558</sup> In this phase children become legal majors at the age of 18 rather than 21<sup>559</sup> and from this point onwards the law provided them with the ability to make legally-binding decisions.<sup>560</sup>

There were three uncertainties regarding consent in this phase of the ethical-legal framework: firstly, when did children have the capacity to consent independently to health research? Secondly, if children did not have the capacity to consent, who could consent on their behalf? Thirdly, if children did not have the capacity to consent, when did they have the capacity to assent?

(a) Capacity to consent independently to health research

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<sup>555</sup> NHREC Guidelines (note 56 above) 5 and GCP (note 58 above) 11.

<sup>556</sup> Van Oosten (note 104 above) 14. Carstens and Permain argue that legal capacity refers to competence and functional ability to make certain decisions, Carstens & Permain (note 529 above) 879,

<sup>557</sup> *Ibid.*

<sup>558</sup> Strobe, Slack & Essack (note 143 above) 247.

<sup>559</sup> S 17 Children's Act (note 4 above).

<sup>560</sup> T Davel 'General principles' in CJ Davel & A Skelton (eds) *Commentary on the Children's Act* (2007) 26.

The ethical guidelines, generally, provided a flexible approach as to when children would have the capacity to consent independently to all health research except clinical trials. The NHREC Guidelines stated that consent for children to participate in health research must be obtained from the parents or legal guardian in all but exceptional circumstances. However, where children are ‘competent to make the decision’ they may consent alongside their parents.<sup>561</sup> Adopting a similar approach, the HSRC Guidelines on the participation of children in research provided that consent for children over the age of 12 should be obtained from the parents or legal guardian ‘wherever possible’.<sup>562</sup> GCP did not allow independent consent by children.<sup>563</sup> A more restrictive approach to independent consent was taken by the MRC’s ethical guidelines, as described above.<sup>564</sup> Nevertheless, the role of the MRC Guidelines was less important during this period given that the NHREC Guidelines were regarded as the national ethical guidelines.<sup>565</sup>

A number of academic authors explored the issue of ‘exceptional circumstances’ and articulated arguments for when children could independently consent to research (See Table 8 below). Some applied the principles relating to the capacity to consent to medical treatment to therapeutic health research.<sup>566</sup> Accordingly, they argued that children from the

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<sup>561</sup> NHREC Guidelines (note 56 above) 5.2.

<sup>562</sup> Points 1.3–1.4 HSRC’s Code of Research Ethics (note 541 above). The guidelines provide where the child is under the age of 12 proxy consent is mandatory.

<sup>563</sup> GCP (note 58 above) 17.

<sup>564</sup> See s 3.2.3 above for a more detailed discussion of the content of the MRC’s Book One. This approach sparked debate on the issue of whether proxy consent may be given for children to participate in non-therapeutic health research. Arguments have been made that proxy consent to so-called non-therapeutic research is *contra bonos mores* as parents do not have the capacity to consent to children participating in research which holds no direct benefit for them. This approach has been discredited in recent years. See Chapter One for more discussion on this point.

<sup>565</sup> See for example, Andanda (note 166 above) 79–80 where she argues that the MRC Guidelines were subservient to the NHREC ones during this period. See also Smit (note 34 above) who argues that the ethical standards referred to in the NHA are those issued by the NHREC 15.

<sup>566</sup> Van Wyk (note 13 above) 40–41. The NHREC Guidelines define therapeutic research as ‘interventions directed to the wellbeing of the individual or community involved’ and non-therapeutic research is defined as ‘interventions not directed to the benefit of the individual but rather towards improving scientific knowledge or technical application’ (note 56 above).

age of 14 who had the capacity to consent to medical treatment in terms of the Child Care Act could consent to so-called therapeutic research without assistance.<sup>567</sup> Others used a competence argument as a way of establishing the ability of older children to act unassisted. This was supported by the NHREC Guidelines which provided that children may consent independently when they are ‘competent to make the decision’.<sup>568</sup> The NHREC Guidelines also allow children who have reached puberty to consent independently if (a) the research poses no more than minimal risk for the child participants, (b) the REC is convinced that it is unlikely that parents, guardians or the community from which the children are drawn would object to independent consent, and (c) this exceptional approach has been justified in the protocol.<sup>569</sup> Finally, arguments have been made for independent consent on the basis of the level of risk in the study, it being submitted that research which does not hold out the prospect of direct benefit but which carries no risk at all should be an exceptional circumstance, and children should be able to participate without parental consent.<sup>570</sup>

**Table 8: Independent consent from children for health research in the second phase of the ethical-legal framework**

Research to which children cannot consent to independently	Research to which children may consent independently
Clinical trials Research where the REC does find ‘exceptional circumstances’ exist Social science research with children under 12	All other forms of health research provided: <ul style="list-style-type: none"> <li>• Research found to fall within ‘exceptional circumstances’ by an REC. The child is competent and the               <ul style="list-style-type: none"> <li>○ Research poses no more than minimal risk</li> <li>○ Notion of independent informed</li> </ul> </li> </ul>

<sup>567</sup> *Ibid.* This approach was reflected in the MRC’s Book One (note 12 above). During the second phase of the ethical-legal framework the Children’s Act (note 4 above) came into operation and as a result the age of consent to medical treatment dropped to 12 provided the child had ‘sufficient maturity’, see s 129 Children’s Act. This did not in any way change the nature of this argument just the age of consent to medical treatment and accordingly the age of consent to therapeutic research.

<sup>568</sup> NHREC Guidelines (note 56 above) 5.2.

<sup>569</sup> Van Oosten (note 104 above) 19. Pope (note 93 above) 170 submits, albeit within the context of HIV prevention research, that as it is never necessary for a child to participate in research. RECs should not be lulled in allowing adolescents to participate independently. A strong argument is made for independent consent in Singh, Abdool Karim, Abdool Karim, Mlisana et al (note 78 above) 0001.

<sup>570</sup> For example, a study of the eating habits of children whilst watching TV.

	<p style="text-align: center;">consent is acceptable within the community</p> <ul style="list-style-type: none"> <li>○ This approach has been justified</li> <li>• The child is over the age of 12 or can be classified as an adolescent for the purposes of social science research</li> <li>• Study is classified as therapeutic and the child is over 14</li> <li>• The research is non-therapeutic in nature and poses no risks</li> </ul>
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The ethical guidelines also dealt with the issue of children refusing to consent or participate in health research, the general principle being that no children should be forced into research participation and their refusal must be respected.<sup>571</sup> Furthermore, like adults, children may withdraw from the research at any point.<sup>572</sup> In a slightly different approach, Van Oosten argued that where the child did not wish to participate despite parental consent, the overriding consideration would be the best interests of the child.<sup>573</sup>

#### (b) Proxy consent for child participation in research

Ethical guidelines take different approaches to proxy consent for research participation. The NHREC Guidelines require proxy consent from parents or legal guardians,<sup>574</sup> while GCP requires consent from a parent or guardian, failing which a care-giver providing long-term care for the child may provide consent.<sup>575</sup> Pope suggests that where adolescents do not have parents or legal guardians the High Court as the upper guardian of all minors should be approached to provide consent if this is in the best interests of the minor.<sup>576</sup>

#### (c) Assent for child participation in research

<sup>571</sup> Point 5.2 NHREC Guidelines (note 56 above).

<sup>572</sup> Points 1.3 and 1.4 HSRC Code of Research Ethics (note 541 above).

<sup>573</sup> Van Oosten (note 104 above) 19–20.

<sup>574</sup> NHREC Guidelines (note 56 above) 5.2.

<sup>575</sup> GCP (note 58 above) 2.3.1.

<sup>576</sup> Pope (note 93 above) 170.

Assenting to health research is an important way in which children, even those without capacity, can participate in research-related decisions. Ethical guidelines require assent from children who do not have the capacity to consent independently. In other words, even when children do not have the capacity to consent they nevertheless need to be involved in the consent process through researchers obtaining their assent to the research.<sup>577</sup> The NHREC Guidelines provide that where RECs are of the view that child participants are capable, their assent to the research should be obtained.<sup>578</sup> GCP similarly also require assent from children participating in clinical trials.<sup>579</sup> This reflects the principle of child participation as set out in section 10 of the Children's Act.<sup>580</sup>

### *3.3.4 Classifying the ethical-legal framework following the partial implementation of the National Health Act*

The ethical-legal framework following the partial implementation of the NHA was one in which there was a strong institutional framework. These institutions ensured:

- (i) A policy framework mandating research within priority areas is undertaken in the public sector;
- (ii) Research was regulated by institutions with the power to review and approve research on ethical and scientific grounds; and
- (iii) Norms and standards for research were established.

However, the normative framework was less developed as norms and standards existed but largely in ethical guidelines rather than in law. There were also a range of monitoring and enforcement mechanisms. In this context it is possible to argue that South Africa's ethical-legal framework could be classified as falling within the cautious community control model

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<sup>577</sup> This is a reflection of the principle of child participation. See Chapters One and Five for further discussion on this point.

<sup>578</sup> NHREC Guidelines (note 56 above) 5.2.1.

<sup>579</sup> GCP (note 58 above) 2.3.1.2.

<sup>580</sup> See Chapter One for a more detailed discussion on the principle of child participation.

as described by Nielsen (See Table 9 below).<sup>581</sup> In terms of this model research was regulated, RECs had statutory authority and research participants were protected by some non-research specific laws and ethical guidelines.

**Table 9: Applying Nielsen’s model to South Africa’s ethical-legal framework with the partial implementation of the National Health Act**

Model	Key elements	Application to South Africa
Cautious regulatory approach	Legal regulation of research through institutions such as RECs	The NHA created a policy framework for ensuring relevant health research NHREC given the responsibility of creating a national framework for RECs and ethical review The MCC and RECs were required to regulate all health research Norms and standards were established in ethical guidelines and to a lesser extent in general laws

### 3.3.5 Critique of the ethical-legal framework following the partial implementation of the National Health Act

There were a number of problems with the ethical-legal framework which existed whilst the NHA was only partially implemented, including: firstly, the provisions relating to research were contained in various different pieces of legislation.<sup>582</sup> Secondly, there was no child-specific research legislation in operation.<sup>583</sup> This was despite the introduction of the new Children’s Act during this period which described a number of other children’s health rights.<sup>584</sup> Thirdly, there were inconsistent approaches to applying general legal principles to research particularly in areas in which the general principles to medical treatment could not

<sup>581</sup> See Chapter Two for a full discussion of the nature of Nielsen’s model.

<sup>582</sup> Strobe, Slack & Mushariwa (note 94 above) 600.

<sup>583</sup> Pope (note 93 above) 168. S 71 of the National Health Act (note 57 above) does deal directly with the participation of ‘minors’ in health research, see Chapter Five. See Chapter Six for further discussion on the conflict between the NHA and the Children’s Act (note 4 above).

<sup>584</sup> See Chapter Five for a full discussion on the relevant provisions in the Children’s Act.

be applied easily.<sup>585</sup> Fourthly, although the ethical guidelines<sup>586</sup> deal expressly with the participation of children in research by describing the circumstances and the manner in which children may participate, these are not completely harmonised.<sup>587</sup>

Finally, during the second phase, the ethical-legal framework became more protective of child research participants as the new institutional framework strengthened the regulation and enforcement of research participants’ rights. Nevertheless, it also continued to facilitate research as the norms established in ethical guidelines were flexible enough to ensure that the merits of each study could be individually considered by an REC. The system however failed to adequately recognise the importance of child participation according to their evolving capacity as, whilst the Children’s Act clearly described the ages at which children may consent to various health interventions such as HIV testing and medical treatment, it was silent on consent to health research.<sup>588</sup> The ethical principles regarding obtaining consent or assent from children did however enable them to participate in the informed consent process.

**Table 10: The extent to which the second phase of the ethical-legal framework protected and promoted child participation whilst facilitating research with children**

Protection	Child participation	Research facilitation
Strong	Strong through consent and assent processes but undermined by a lack of consistency regarding independent consent	Strong

<sup>585</sup> Stobie, Strode & Slack (note 59 above) 194. For example, the general principles relating to medical treatment could not be easily applied to so-called non-therapeutic research.

<sup>586</sup> NHREC Guidelines (note 56 above). GCP (note 58 above) and MRC Book One (note 12 above).

<sup>587</sup> Stobie, Strode & Slack (note 59 above) 197–198. See s 3.2.3 above where examples of the lack of harmonisation are given in a comparison between the GCP and the MRC’s Book One in relation to consent and risk standards when the research involves children.

<sup>588</sup> Children’s Act (note 4 above). See Chapters Five and Six for more discussion on these issues.

### **3.4 The current ethical-legal framework following the full implementation of the National Health Act**

#### *3.4.1 Overview*

In the third stage of the development of the ethical-legal framework, sections 11 and 71 of the NHA were operationalised on 1 March 2012 by a notice in the *Government Gazette*.<sup>589</sup> This completed the development of a comprehensive ethical-legal framework for regulating health research in South Africa. This was done through the NHA describing a number of norms for the way in which health research ought to be conducted, including health research with minors. Although draft regulations to accompany this section were published for public comment in 2007 and again in 2013, to date they have not been finalised.<sup>590</sup> The operationalisation of section 71 in particular reflects a shift in the ethical-legal framework to a particularly restrictive approach to research regulation in which the discretion is removed from RECs and the focus is on the protection of research participants, especially minors, by limiting the circumstances in which minors can participate in research.<sup>591</sup>

#### *3.4.2 Institutional framework*

The current institutional framework is described in detail in Chapter Four. This institutional framework creates three layers of control within the ethical-legal framework. Firstly, policy controls through the NHRC which ensures that research focuses on our priority health problems. Secondly, regulatory controls by the MCC, the NHREC and institutionally-based RECs which ensure that research is reviewed and approved by appropriate, independent

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<sup>589</sup> *Government Gazette* No. 35081 (note 95 above).

<sup>590</sup> Regulation No. R135, 23 (note 13 above). A further set of regulations, presumably based on the public comments and dated 2009 are available on the NHREC website, see <http://www.nhrec.org.za/wp-content/uploads/2009/09/human.pdf>. No record could be found of these draft regulations having been finalised and published in the *Government Gazette*. A further revision of the draft regulations was published on the 29 May 2013 for public comment (note 13 above).

<sup>591</sup> S 71 National Health Act (note 57 above) uses the term 'minors' rather than children. More detailed discussion on the implications of the use of this term is contained in Chapter Five. A critique of this approach is contained in Chapter Six.

bodies. Thirdly, community liaison, albeit more informally, through community advisory groups or bodies.

### 3.4.3 Normative framework

The current normative framework was created by amongst others, section 12 of the Constitution,<sup>592</sup> sections 11, 16 and 71 of the NHA and various sections of the Children's Act.<sup>593</sup> It is set out in Chapter Five of this study. The new normative framework is highly restrictive and even though children or minors are not excluded per se from participating in health research, there is a strong focus on protection through restriction of circumstances in which children may participate in research.

### 3.4.4 Classifying the current ethical-legal framework

Using Nielsen's model for classifying ethical-legal frameworks, it is submitted that the current ethical-legal framework falls within the community control model - prohibitive approach as all elements of this model exist.<sup>594</sup> Firstly, there is a high level of regulation of health research through statutory bodies.<sup>595</sup> Secondly, highly restrictive legal norms exist which prohibit certain forms of health research, such as so-called non-therapeutic research, with minors unless ministerial consent is obtained.<sup>596</sup> Thirdly, the legal norms are in direct conflict with well-established ethical norms. And fourthly, penalties exist for non-compliance with the legal norms<sup>597</sup> (See Table 11 below).

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<sup>592</sup> Constitution of the Republic of South Africa (note 2 above).

<sup>593</sup> Children's Act (note 4 above).

<sup>594</sup> Nielsen (note 42 above). See Chapter Two for a more detailed discussion of this model.

<sup>595</sup> See Chapter Four for a detailed discussion of the current institutional framework which includes bodies such as the MCC, NHREC, NHRC and RECs.

<sup>596</sup> For example, s 71(1)(b) NHA (note 57 above) provides that health research may only be conducted with the written consent of the human subject. This excludes certain forms of research which were allowable under the ethical guidelines such as studies on the care given to trauma patients in hospitals. See Chapter Five for a more detailed discussion of the nature of these restrictive legal norms contained in s 71 of the National Health Act (note 57 above) and a critique of them in Chapter Six.

<sup>597</sup> For example, the NHREC has the power in terms of s 72(6)(f) of the NHA *ibid*, to 'institute such disciplinary action as may be prescribed, against any person found in violation of any norms and standards, or guidelines

**Table 11: Applying Nielsen’s model to South Africa’s current ethical-legal framework**

Model	Key elements	Application to South Africa
Community control model or prohibitive approach	High level of regulation Legislation prohibiting certain kinds of research Penalties for non-compliance	Strong institutional framework for regulating research through policy controls, ethical and scientific review and enforcement mechanisms Highly restrictive legal norms in place

### 3.5 Conclusions

In the three stages of the evolution of the ethical-legal framework, South Africa has moved from a very low level of regulation (professional control model) to a highly restrictive and overly regulated approach (the community control model) in a period of approximately 30 years (See Table 12 below).

**Table 12: Development of the current ethical-legal framework**

Ethical-legal framework prior to the NHA	Ethical-legal framework following the partial implementation of the NHA	Current ethical-legal framework following the full implementation of the NHA
Framework lacked institutions and legally binding norms	A strong institutional framework created and enabled the development of legally binding ethical norms	Strong institutional framework and legal norms for when and how research with children is to take place
Stage One: professional control model	Stage Two: professional control model and cautious regulatory model	Stage Three: community control model prohibitive approach

In the first phase of the ethical-legal framework there were low levels of protection as a formal ethical-legal framework for regulating all forms of health research was non-existent in South Africa. There were, however, obligations on researchers conducting clinical trials and those working for or on behalf of the MRC. With all other forms of health research the system was largely based on voluntary compliance with institutional guidelines and the personal integrity of researchers. In the absence of a range of statutory institutions or well-

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set for the conduct of research in terms of the Act’. Subsection (e) allows the NHREC to refer any violation of an ethical rule to a statutory body it is argued that this is an enforcement mechanism for non-compliance with the norms in the ethical-legal framework. See Chapter Four for a more detailed discussion on this issue.

established ethical-legal norms, research participants were vulnerable to exploitation. In this phase there was also uncertainty regarding the legality of the participation of children in so-called non-therapeutic research. In this period children were involved to some extent in research decision-making as ethical guidelines provided for their participation in the informed consent process. Given the lack of regulation, there was a strong focus on research facilitation.

With the partial implementation of the NHA the system became more formalised and protective as statutory institutions were established with the power to regulate health research. Child participation continued through the ethical norms on consent and assent and, given the flexible nature of ethical norms, research with children was facilitated.

With the third phase of the ethical-legal framework since the full introduction of the NHA, the framework has been completed and formalised. It has become highly protective, particularly of child research participants. However, it is of real concern that the norms in the NHA are so highly protective that they are out of step with other legislation and the principles in ethical guidelines.<sup>598</sup> The new norms undermine child participation by requiring mandatory parental consent and act as a barrier to the conduct of child research. It appears that the pendulum has thus swung from being under-protective to being over-protective.<sup>599</sup>

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<sup>598</sup> For example, s 129 Children's Act (note 4 above) allows proxy consent to be provided by a care-giver for medical treatment rather than limiting this authority to parents or guardians. See Chapter Six for a more detailed critique of this approach.

<sup>599</sup> Friedman Ross (note 91 above) 2–3. The author argues that few countries have managed to maintain a balance between protection of participants and the facilitation of research.

## **Chapter Four:**

### **The current institutional framework for regulating health research with children**

The preceding Chapter examined the evolution of our ethical-legal framework through three distinct legislative phases. It described how prior to the adoption of the NHA the ethical-legal framework was predominantly based on the principle of self-regulation. There were a few institutions tasked with regulating research and norms, and where they existed, were enabled by a range of different laws which did not have general application. The system could not be neatly classified in terms of Nielsen's framework and thus it was argued that it straddled both the professional control and the cautious regulatory systems. The protection of child research participants was generally weak. There was however some scope for child participation through older children providing informed consent unassisted and assent being obtained from children whose parents or guardians were providing proxy consent. Research was facilitated under this system due to the low levels of formal regulation.

The Chapter also set out how in the second phase of the development of the ethical-legal framework the institutional framework was strengthened through partial implementation of the NHA and the creation of the NHRC and NHREC as statutory bodies. Obligations were also placed on all institutions conducting health research to establish or have access to an REC. In this phase the NHREC was given the statutory authority to issue ethical guidelines, which it did and these dealt specifically with participation of children in health research. This enhanced the normative framework by establishing national ethical standards on when and how children could participate in health research. The Chapter argued that this second phase of the ethical-legal framework could be classified as falling into the cautious regulatory system as described by Nielsen in her models. In this phase the ethical-legal framework was

more protective of child research participants however, it also continued to facilitate both child participation and health research.

Chapter Three also touched on the third phase of the development of the ethical-legal framework by giving an overview of the current system regulating health research with children. In this third phase legal norms setting standards for when and how research with children can be conducted were introduced through operationalisation of sections 11 and 71 of the NHA. This completes the ethical-legal framework as both institutions and norms are now in place.

The Chapter concluded with comments on how South Africa has moved from low-level regulation to a highly restrictive and overly regulated approach to health research. It argued that this occurred behind the scenes and without proper public discourse on the issue.

This Chapter contains a detailed description of the current institutional arrangements within the ethical-legal framework. Based on the arguments made in Chapter Two that effective ethical-legal systems require firstly, institutions and secondly, norms and standards in order to regulate health research, this Chapter reviews the current institutional framework while Chapter Five examines the current normative framework established by both law and ethical guidelines.

The Chapter looks at the institutions which are able to (a) create a policy framework, (b) establish a national system for regulating research ethics, (c) undertake ethical review at an institutional level, (d) engage with the community, and (e) implement effective monitoring and enforcement mechanisms. Accordingly, it begins with the parameters of the current ethical-legal framework for regulating health research, examining the types of health research that are subject to regulation. Then follows a description of the role and functions of each institution, namely, the NHRC, the MCC, the NHREC, RECs and CAGs. It also discusses

the range of bodies that are tasked with monitoring research as well as those capable of enforcing research-related rights. It concludes with a description of the procedural obligations placed on key research stakeholders. It also makes provisional comments on both the strengths and weaknesses of the institutional framework for regulating health research in South Africa.

#### **4.1 Introduction**

Prior to the adoption of the NHA, given that there was no overall ethical-legal framework for regulating health research, there were no formal legislative parameters setting out what types of health research ought to be regulated. There were however some specific obligations in the Medicines Act applicable to clinical trials, and others in the MRC Act relating to research undertaken or funded by the MRC.<sup>600</sup> These did not however effectively describe health research and the obligations that ought to be placed on the various research stakeholders.

The parameters of the current ethical-legal framework for health research are set by three key concepts used in the NHA. These concepts delineate (a) what forms of health research fit within the ethical-legal framework, and (b) under which circumstances researchers must meet obligations described in the NHA.

Firstly, the term ‘health research’ is defined in section 1 of the NHA. This is an exceptionally wide term and creates the over-arching framework for the type of activities to be regulated by the ethical-legal system. Section 1 defines health research as research which contributes to knowledge in various health-related fields:

(A)ny research which contributes to knowledge of – (a) biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision, of health care

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<sup>600</sup> This point is discussed in detail in Chapter Three.

services; (c) human pathology, (d) the cause of disease, (e) the effects of the environment on the human body, (f) the development or new application of pharmaceuticals, medicines and related substances, and (g) the development of new applications of human technology.<sup>601</sup>

It is submitted that there are two key elements to this definition. Firstly, the research activity must aim at knowledge production. The NHA does not define ‘research which contributes to knowledge’ but the national ethical guidelines issued by the NHREC define it as a ‘systematic investigation to establish facts, principles or knowledge’:<sup>602</sup>

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-intrusive 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.<sup>603</sup>

Secondly, the research must fit within the ambit of one of the fields mentioned in (a)–(g) of the definition. The listed areas seem to cover most aspects of health research except possibly studies into human rights or health law.

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<sup>601</sup> S 1 National Health Act (note 57 above). A similar definition of research is found in s 1 of the Human Sciences Research Council Act (note 62 above). This Act describes research as ‘the generation, preservation, augmentation and improvement of knowledge by means of scientific investigation and methods in the field of the human sciences’.

<sup>602</sup> NHREC Guidelines (note 56 above).

<sup>603</sup> This definition of health research is set out in the US National Commission for the Protection of Human Subjects; it is quoted with approval in the NHREC Guidelines *ibid*.

The manner in which health research is defined with the focus on contributing knowledge towards our understanding of various aspects of health means that even studies involving the broader social aspects of health, such as the TV-watching habits of teenagers, could be included. It is argued that given the wide definition of 'health research' it includes studies without the direct involvement of living participants.<sup>604</sup> The term is used in the following sections of the NHA which deal with research regulation:

- (i) Sections 69 and 70 which require the NHRC to determine the health research priorities for public sector or state-funded research;
- (ii) Section 72 which describes the role and functions of the NHREC vis-à-vis the ethical issues involved in health research; and
- (iii) Section 73 which places obligations on institutions conducting health research establish or have access to an REC.

This very broad definition of health research means that the legislature intended most forms of health research to (a) fall within national research priorities, (b) be regulated by the NHREC, and (c) be submitted for ethical review.<sup>605</sup>

The second key term which defines some of the obligations in the ethical-legal framework is 'research or experimentation on a living person'. This is a particular form of health research which requires additional scrutiny or protection. This phrase is used in section 71 of the NHA and it limits the norms contained in that section to research on or with human subjects. The NHA does not define this phrase. However, the NHREC ethical guidelines describe a research participant as 'a living individual or group of individuals about whom a researcher conducting research obtains data through intervention or interaction with the person or identifiable

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<sup>604</sup> *Ibid* 59.

<sup>605</sup> The only exception being record reviews by health care providers at health care establishments as these do not require ethical approval s 16(2) National Health Act (note 57 above). See Chapter Six for further discussion on this point.

private data'.<sup>606</sup> Given that this definition of the phrase refers to research involving an interaction with a living person it excludes epidemiological research or bio-medical research on tissue or blood samples as such do not involve an 'intervention or interaction with the person'. The obligations on researchers conducting health research on human subjects are:

- (a) Obtaining written consent from the participants;
- (b) Complying with prescribed norms;
- (c) Therapeutic research with minors must be in their best interests, consent must be obtained from their parents/legal guardians, and from the minors if they have understanding; and
- (d) Non-therapeutic research with minors must obtain consent from their parents/legal guardians, from the minors if they have understanding, and the Minister of Health.<sup>607</sup>

By limiting these norms to studies which involve 'living persons' the legislature did not intend to impose these additional obligations on, for example, record reviews or the annual HIV prevalence study on pregnant women. However, this has the unintended consequence of excluding this type of research from certain participant protections such as requiring researchers to ensure that privacy is maintained regarding all information collected during the study.

The third key phrase setting the parameters of the ethical-legal framework within the NHA refers to a 'health service for research or experimental purposes'.<sup>608</sup> Again, this is a particular type of health research, namely, research into an experimental health service. Health service is defined in section 1 of the NHA as '(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution; (b)

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<sup>606</sup> NHREC Guidelines (note 56 above) 59.

<sup>607</sup> S 71 National Health Act (note 57 above).

<sup>608</sup> S 11 *ibid.* S 16(2) provides that if the information on a user is anonymous written consent is not required. See Chapter Five for a more detailed discussion of this point.

basic nutrition and basic health care services contemplated in section 28(l)(c) of the Constitution; (c) medical treatment contemplated in section 35(2)(e) of the Constitution; and (d) municipal health services'. The phrase is, amongst others, used in Chapter Two of the NHA and it delineates when special steps must be taken to protect users<sup>609</sup> of health services because the health service they are receiving is experimental in nature or forms part of a study. Thus again, it requires additional protection due to the nature of and the place where the research is being conducted. There is some overlap between a health service which is experimental and research or experimentation on a living person. In other words, in many instances the obligations in section 71 and those in Chapter Two of the NHA would apply to a study. Table 13 below shows the obligations in the NHA which flow from each term and how they cascade downwards, with health research which forms part of a health service having to comply with the most obligations.<sup>610</sup>

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<sup>609</sup> The drafters of the National Health Act elected to use the term 'user' rather than patient. A user is defined in s 1 as 'the person receiving treatment in a health establishment, including those receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is— (a) below the age contemplated in section 39(4) of the Child Care Act, 1983 (Act No. 74 of 1983), "user" includes the person's parent or guardian or another person authorised by law to act on the first mentioned person's behalf; or (b) incapable of taking decisions, "user" includes the person's spouse or partner or, in the absence of such spouse or partner, the person's parent, grandparent, adult child or brother or sister, or another person authorised by law to act on the first mentioned person's behalf' *ibid*.

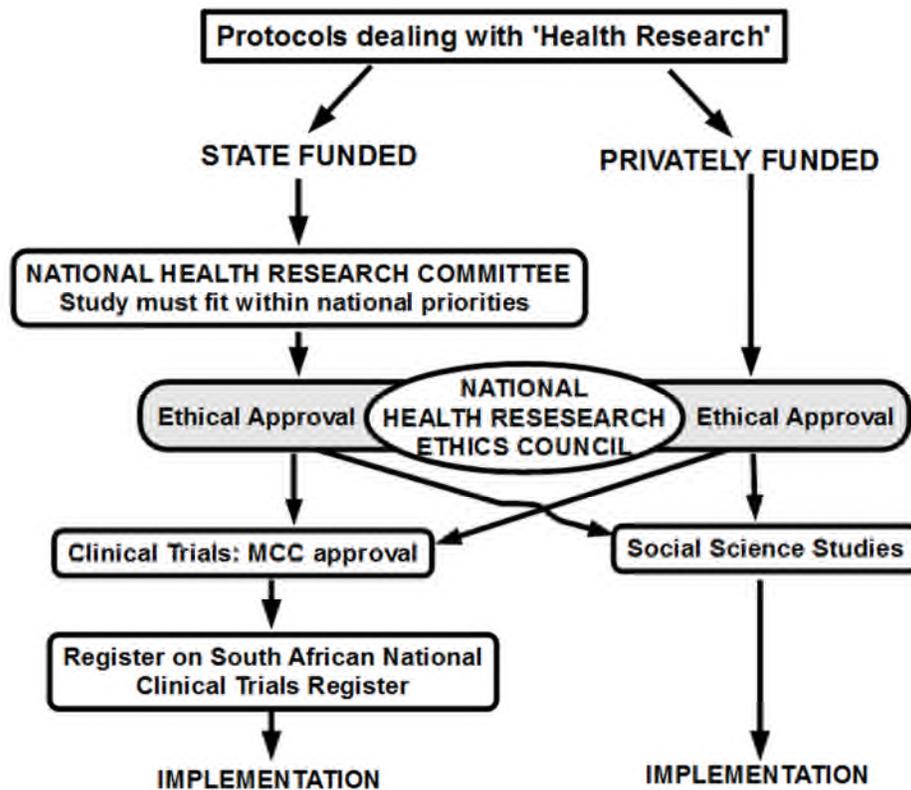
<sup>610</sup> There are a number of other instances in which the NHA refers to obligations on researchers and institutions regarding specific forms of health research however, it is argued that these provisions are specific in nature and do not help delineate the parameters of the ethical-legal framework. For example, s 16 *ibid* refers to the circumstances in which record reviews for research purposes may be undertaken by health care providers.

**Table 13: The parameters of the ethical-legal framework for health research and the corresponding obligations on researchers in terms of the NHA**

<b>Health research – research which contributes to knowledge in various health-related fields</b>	
<p>All health research must:</p> <ul style="list-style-type: none"> <li>• Fit within national health research priorities (if undertaken by the public sector)</li> <li>• Comply with obligations set by the NHREC</li> <li>• Be submitted for ethical review</li> </ul>	
<b>Health research which includes ‘research or experimentation on a living person’</b>	<b>Health research which forms part of a ‘health service for research or experimental purposes’</b>
<p>All health research with human subjects must be with:</p> <ul style="list-style-type: none"> <li>• Written consent</li> <li>• Adherence to prescribed obligations</li> </ul> <p>If the health research is considered therapeutic and it enrolls minors it must:</p> <ul style="list-style-type: none"> <li>• Be in their best interests</li> <li>• Obtain consent from their parent/guardian and the minors themselves if they have understanding</li> </ul> <p>If the health research is considered non-therapeutic and it enrolls minors it must:</p> <ul style="list-style-type: none"> <li>• Obtain consent from the Minister of Health</li> <li>• Obtain consent from the minors’ parents/guardians, and the minors themselves if they have understanding</li> </ul>	<p>All health research which forms part of a health service can only be undertaken if:</p> <ul style="list-style-type: none"> <li>• The user is informed that the health service is experimental</li> <li>• Consent has been obtained from the user, their health care provider, the head of the health establishment and the REC</li> </ul>

#### **4.2 The institutional framework for regulating research**

The current ethical-legal framework consists of a wide range of statutory and non-statutory institutions all of which play a role in regulating health research.



**Figure 2: The current ethical-legal framework**

#### 4.2.1 Policy making bodies: the National Health Research Committee

Prior to the implementation of Chapter Nine of the NHA there was no statutory body mandated to develop national health research priorities. However, the two national statutory research institutions, the HSRC and the MRC, were required by their empowering legislation to advise government of an appropriate research agenda in their respective fields.<sup>611</sup>

<sup>611</sup> The HSRC was required to advise the Minister of National Education on 'research priorities' relating to the human sciences s 2A(b) Human Sciences Research Act (note 62 above) and the MRC was required to advise the minister assigned to this function of 'the determination of policy and national priorities regarding research' and on the 'development, promotion, implementation and co-ordination of research on a national basis': s 20 Medical Research Council Act (note 448 above).

The NHA changed this situation with the establishment of the National Health Research Committee (NHRC).<sup>612</sup> This is a committee appointed by the Minister of Health after consulting with the National Health Council.<sup>613</sup> The NHA defines the role of the NHRC as being to:

- (a) determine the health research to be carried out by public health authorities;
- (b) ensure that health research agendas and research resources focus on priority health problems;
- (c) develop and advise the Minister on the application and implementation of an integrated national strategy for health research; and
- (d) co-ordinate the research activities of public health authorities.<sup>614</sup>

The NHA provides the Committee with a wide mandate to ensure that public health authorities undertake research on priority health problems and that research activities are co-ordinated. However, health research undertaken by the private sector is not required to conform with the policy framework established by the NHRC.<sup>615</sup>

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<sup>612</sup> S 69 National Health Act (note 57 above).

<sup>613</sup> Established in terms of s 70 of the National Health Act *ibid*. The NHRC's role as the over-arching body required to set the research agenda must be seen in relation to the on-going role of the HSRC in terms of s 4(1)(b) of the HSRC Act (note 62 above) to advise the Minister of Science and Technology on various issues relating to social science research. It should be noted that the term social science research is broader than that of health research. The MRC also continues to have an advisory function regarding research priorities: see note 598 above.

<sup>614</sup> *Ibid*.

<sup>615</sup> Although private sector research agencies do not need to focus their research on the priority areas identified by the NHRC they must comply with other regulatory obligations such as obtaining ethical approval. In Chapter Six it is argued that the ethical principle of justice which requires 'fairness in the treatment of individuals and communities and the equitable distribution of the burdens and benefits of research' requires RECs to ensure that their research will be relevant to the participants and their communities: GB Tangwa 'Ethical principles in health research and review process' (2009) Vol 1125 *Acta Tropica* 52, 56. It is argued that this indirectly requires the private sector to work in priority research areas.

The composition and functioning of the NHRC is detailed in its Regulations.<sup>616</sup> Regulation 3(1) provides that the NHRC is to be made up of at least four persons including; one person with 'extensive experience and knowledge of health research', a person representing the Department of Health, an individual representing the community and someone with knowledge of the law.<sup>617</sup> The NHRC must meet at least four times a year<sup>618</sup> and make decisions on the basis of a simple majority.<sup>619</sup> Persons aggrieved with decisions made by the Committee may appeal to the Minister of Health<sup>620</sup> who is required to establish an appeals committee to deal with the matter.<sup>621</sup>

In terms of the NHRC's core mandate of establishing research priorities, section 70 of the NHA requires it to take into account five factors when developing a national research agenda. These include:

- (a) the burden of disease;
- (b) the cost-effectiveness of interventions aimed at reducing the burden of disease;
- (c) the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities;
- (d) the health needs of vulnerable groups such as women, older persons, children and people with disabilities; and
- (e) the health needs of communities.<sup>622</sup>

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<sup>616</sup> Regulations relating to the Establishment of the National Health Research Committee, *Government Gazette* No. 33575, 23 September 2010.

<sup>617</sup> *Ibid.*

<sup>618</sup> Regulation 6(3) *ibid.*

<sup>619</sup> Regulation 7(1) *ibid.* An appeal must be lodged within 60 days of the person having become aware of the adverse decision having been taken against them.

<sup>620</sup> Regulation 10 *ibid.*

<sup>621</sup> Regulation 10(3) *ibid.* The Appeals Committee must consist of at least three members of the NHRC. It must be chaired by a person with knowledge of the law and at least two other members both with expertise in research ethics.

<sup>622</sup> S 70(2) National Health Act (note 57 above).

In 2001 an interim body, which preceded the Committee, produced the Health Research Policy in South Africa which was intended to be a preliminary document articulating some of the policy principles which ought to underpin the development of research priorities.<sup>623</sup> To date, the 2001 Health Research Policy in South Africa has not been revised or replaced.<sup>624</sup> This policy aims at ensuring that all stakeholders ‘promote research that contributes to the improvement of human health and welfare in South Africa.’<sup>625</sup> Accordingly, its goals are to:

- (i) Develop a national health research system that contributes to equitable health development;
- (ii) Promote innovation in health and health-related service delivery;
- (iii) Through research, advance knowledge that underpins health and equitable, quality health care;
- (iv) Develop a co-ordinated, well-funded agenda for research;
- (v) Nurture talent and develop capacity to conduct research and utilise its findings; and
- (vi) Encourage uptake of research-based knowledge into the health care system.<sup>626</sup>

The Policy requires all government-funded health research bodies to provide the NHRC with annual business plans and reports. These should state how their work fits in with national research priorities. The policy identified the NHRC’s role as being to use this information to advise government on the gaps, synergies and overlaps that exist as well as on the appropriateness of the work, budget, achievements and emphases.<sup>627</sup> The Policy proposes further that Provincial Health Research Committees should be established to co-ordinate public sector research, manage the setting of research priorities and review research reports

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<sup>623</sup> Department of Health Research Policy in South Africa (note 7 above).

<sup>624</sup> *2011 National Health Summit Report*, Department of Health available from <http://www.doh.gov.za/docs/reports/2012/summitreport.pdf> [Accessed: 14 August 2012].

<sup>625</sup> *Ibid* para 2.2.

<sup>626</sup> *Ibid* para 2.3.

<sup>627</sup> *Ibid* para 3.3.7.

within provinces.<sup>628</sup> Read with the NHA this policy document has created a framework for the establishment of research priorities in South Africa. However, recently there have been calls for the development of a white paper on health research which could be used as the basis for broader consultations on the revision of the 2001 policy.<sup>629</sup>

Since 1994 the Department of Health has facilitated four national conferences with stakeholders to develop research priorities.<sup>630</sup> These conferences have identified national research priorities, applying an Essential National Health Research Model (ENHR).<sup>631</sup> Using this model, the leading causes of Disability Adjusted Life Years (DALYs) were identified in 2002 and 2006.<sup>632</sup> Table 14 below identifies some of the leading health problems affecting children, extrapolated from the ranking of all priority health problems in South Africa (with their overall ranking reflected).

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<sup>628</sup> *Ibid* para 3.3.3. This appears to have been done in some provinces at least: see for example, the Terms of Reference for the Provincial Health Research Committee of the Department of Health, KwaZulu-Natal, available from <http://www.kznhealth.gov.za/research/tor.pdf> [Accessed: 19 August 2012]. It should be noted that research conducted by the Department of Health must also obtain approval in accordance with the Department of Health Policy Framework for the Ethics Approval and Endorsement of Health Research by National Department of Health (2012) available from <http://www.doh.gov.za/docs/policy/2012/researchethics.pdf> [Accessed: 18 February 2013].

<sup>629</sup> 2011 National Health Summit Report (note 624 above).

<sup>630</sup> Conferences were held in 1996, 2002, 2006 and 2011 Department of Health, 2006. 2<sup>nd</sup> National Conference on Priority Setting for Health Research, available from <http://www.nhrc.org.za/wp-content/uploads/2009/08/2ndNatConferenceonPrioritySettingsaddlestitch.pdf> [Accessed: 6 March 2012] and 2011 National Health Summit Report (note 624 above).

<sup>631</sup> This model promotes the development of research priorities following (a) a review of key health concerns and the identification of Disability Adjusted Life Years (DALYs), (b) stakeholder consultation and (c) analysis of this data *ibid*.

<sup>632</sup> The most significant DALYs affecting children in 2006 were (in order of significance); HIV and AIDS, homicide and violence, TB, road traffic accidents, diarrhoea, disease, low birth weight and protein energy malnutrition *ibid*,

**Table 14: Leading conditions affecting child health extrapolated from the leading causes of DALYs: 2006<sup>633</sup>**

Condition	Ranking
HIV and AIDS	1
Injuries (all causes)	2
Diarrhoea	4
Peri-natal and neonatal mortality	5
Nutrition	6
Orphans and child-headed households	9
Malaria	13

*Source: Adapted from Department of Health (2006)*

This data, amongst others, was used to develop the 2006 South African Research Prioritisation Framework.<sup>634</sup> Within the broad areas targeted by the framework, four areas impact on child health, namely, nutrition, child health, reproduction (including teenage pregnancy, contraception and abortions) and infections/immunity.<sup>635</sup> The framework recommends that research be carried out on these key issues from the perspective of basic science, clinical, social science, health systems, public health and policy reform.<sup>636</sup> The most recent conference was held in 2011, and like the previous conferences it aimed to identify the research priorities to support national health outcomes.<sup>637</sup> One of the four key national health outcomes was child specific, that of reducing maternal and child mortality rates.<sup>638</sup> Several research priorities supporting this objective were adopted by the summit.<sup>639</sup>

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<sup>633</sup> The numbering in this table is not consecutive as the data on children has been extrapolated from the ranking of health problems affecting the whole population.

<sup>634</sup> *Ibid.*

<sup>635</sup> *Ibid.*

<sup>636</sup> *Ibid.*

<sup>637</sup> 2011 National Health Summit Report (note 624 above). The four national health outcomes the state wanted to achieve were increasing life expectancy, reducing maternal and child mortality rates, combating HIV/AIDS and tuberculosis and strengthening the effectiveness of the health system *ibid.*

<sup>638</sup> *Ibid.*

<sup>639</sup> The summit agreed that priority should be given to research that (a) generates a better understanding of neonatal infections, (b) ascertains the HIV profile in children under the age of five, (c) determines the impact of vaccines on promoting child health, and (d) instigates why 40 per cent of child deaths occur outside of healthcare facilities *ibid.*

#### 4.2.2 Regulatory bodies: National drug regulatory authority: the Medicines Control Council

In terms of section 2(1) of the Medicines and Related Substances Act<sup>640</sup> (the Medicines Act) the MCC is established as a statutory body.<sup>641</sup> It is given the authority to exercise powers and perform functions conferred upon or assigned to it by the Medicines Act.<sup>642</sup> One of the primary functions of the MCC is to 'provide for the registration of medicines and related substances, intended for human and animal use'.<sup>643</sup>

The MCC is to be made up of not more than 24 members who are appointed by the Minister of Health for a five-year term.<sup>644</sup> The Minister of Health designates one member to be the Chairperson of the Council and another to be its Vice-Chairperson.<sup>645</sup> A majority of its members must be present at each meeting for there to be a quorum.<sup>646</sup> A decision of the MCC is lawful if a majority of the members present at the meeting vote in favour of that decision.<sup>647</sup>

The MCC has a statutory obligation to ensure that drugs available in South Africa are safe, efficacious and of good quality. Furthermore, the decision to register a drug must be in the interests of the public.<sup>648</sup> The Medicines Act does not deal directly with the conduct of

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<sup>640</sup> Medicines and Related Substances Act (note 429 above).

<sup>641</sup> S 2(3) recognises the MCC as a juristic body *ibid*.

<sup>642</sup> *Ibid* s 2(1).

<sup>643</sup> Preamble *ibid*. Accordingly, no person may sell medicines that are not registered s 14(1) *ibid*.

<sup>644</sup> Ss 3–4 *ibid*. In terms of s 4(2) of the Medicines Act (note 164 above) it is possible for members to serve two five-year terms on the MCC *ibid*.

<sup>645</sup> S 5(1) *ibid*.

<sup>646</sup> S 8(1) *ibid*.

<sup>647</sup> S 8(3) *ibid*. This seems to imply that the decision requires a majority of those present provided that there is a quorum. If there is no clear majority the Chairperson of the meeting is given the deciding vote, *ibid*.

<sup>648</sup> *Ibid* s 15(3)(a). The process that must be followed in registering a medicine is set out in s 15. This provides that an application for registration must be made to the registrar of the MCC in the prescribed manner. This application is submitted to the MCC for consideration. If the MCC approves the registration of the medicine then the registrar is required to register it. Section 15(2)(b) allows for an expedited registration process if a medicine is on the Essential Drugs List or 'if it is in the opinion of the Minister essential for national health' *ibid*.

clinical trials,<sup>649</sup> but the MCC is given the authority to register medicines if it is satisfied with the application for registration, following ‘any investigation or enquiry which it may consider necessary’.<sup>650</sup> In other words, it is submitted that the broad mandate of the MCC to register medicines includes the regulation of clinical trials which may precede the registration of a medicine or medical product.<sup>651</sup> In this regard the MCC’s role is to ensure that clinical trials are scientifically valid and provide the information necessary for establishing valid registration of the product for use in South Africa.

Regulations accompanying the Medicines Act detail the obligations on sponsors and principal investigators regarding the control and conduct of clinical trials. They provide:

- (i) Application for authorisation to conduct a clinical trial must be made to the MCC on a standard form;<sup>652</sup>
- (ii) The application must include: the trial protocol; the investigator’s brochure which includes the background information on the product to be tested; the curriculum vitae of all investigators; a signed statement by all investigators that they will comply with the GCP Guidelines issued by the Department of Health; a copy of the informed consent document; and ethical approval by a recognised REC;<sup>653</sup>
- (iii) The trial protocol must at a minimum set out the number of human subjects to be involved in the trial, the name of the principal investigator, who must be an

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<sup>649</sup> NHREC Guidelines (note 56 above) 56. These Guidelines define a clinical trial as a preplanned, usually controlled clinical study to determine the safety, efficacy or optimum dosage schedule (if appropriate) of one or more diagnostic, therapeutic, or prophylactic drugs, devices or interventions in humans selected according to predetermined criteria of eligibility. Also see Chapter One for further definitions of a clinical trial.

<sup>650</sup> General Regulations, Medicines and Related Substances Act, Regulation 15(3)(a) (note 158 above).

<sup>651</sup> S 35(1)(xxxix) Medicines and Related Substances Act (note 429 above).

<sup>652</sup> Regulation 34(1) General Regulations, Medicines and Related Substances Act (note 164 above).

<sup>653</sup> Regulation 34(2) *ibid*. The GCP Guidelines have been developed to provide clear, appropriate and locally relevant standards of good clinical practice in research and to ensure that research with human participants takes place within the framework of sound scientific and ethical standards. Guidelines for Good Clinical Practice in the Conduct of Clinical Trials with Human Participants in South Africa 2 ed (note 57 above).

appropriately qualified person who is resident in South Africa, and any other information required by the MCC;<sup>654</sup>

- (iv) Clinical trials must be conducted in accordance with good clinical practice guidelines issued by the MCC from time to time;<sup>655</sup>
- (v) Reports must be submitted to the MCC every six months, and 30 days after the completion of the clinical trial;<sup>656</sup>
- (vi) The MCC may request additional information, inspect a clinical trial site, and withdraw authorisation for a trial if it believes that the safety of trial subjects is compromised, or the scientific reasons for conducting the trial have changed;<sup>657</sup>  
and
- (vii) Medicines used in the clinical trial must be properly labelled so that it is clear to participants that the drugs are experimental and not registered with the Council.

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Associated to the role of the MCC in regulating clinical trials is the South African National Clinical Trials Register (SANCTR). Sponsors or principal investigators are required to register clinical trials with SANCTR. This is a database of all clinical trials managed by the Department of Health. Application for a unique identifying number for the trial must be made after obtaining ethical approval. Clinical trials may not commence without registration on SANCTR.<sup>659</sup> The register aims to provide the public with information on current clinical trials with human participants. The register describes a trial's purpose, who can participate, where the trial is located, and contact details of staff. The Department of Health maintains that the benefits of a clinical trial register include: that it serves to promote collaboration among

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<sup>654</sup> Regulation 34 (3) *ibid.*

<sup>655</sup> Regulation 34(4) *ibid.*

<sup>656</sup> Regulation 34(6) *ibid.*

<sup>657</sup> Regulation 34(7) *ibid.*

<sup>658</sup> Regulation 34(8) *ibid.*

<sup>659</sup> <http://www.sanctr.gov.za> [Accessed: 19 May 2008]. This is regardless of whether they are trials funded by the state or the private sector.

researchers, the private sector and the community through the sharing of research information; it assists people to identify clinical trials that they can volunteer for; it reduces duplication of research efforts, promotes the best use of limited funds, and contributes to global efforts to reduce disease.<sup>660</sup>

Although there is nothing specific to children in the Medicines Act or its accompanying regulations, the GCP Guidelines refer to the manner and circumstances in which children may be enrolled in clinical trials.<sup>661</sup> The GCP Guidelines provide that proxy consent is required for clinical trial participation by children.<sup>662</sup> Proxy consent can be provided by a parent or guardian, failing which a ‘care-giver providing long term care for the child’ can act on their behalf.<sup>663</sup> The GCP Guidelines do not place any explicit limits on the permissible level of risk in so-called therapeutic research with children. However, if the study poses more than a minor increase over minimal risk, then the risks must be justified by the benefits to participants.<sup>664</sup> In so-called non-therapeutic research a study should not pose more than a minor increase over minimal risk. Furthermore, the risks have to be justified by the generalisable knowledge that would be generated by the study.<sup>665</sup>

#### 4.2.3 Regulatory and norm setting bodies: National Health Research Ethics Council (NHREC)

Prior to the promulgation of the NHA there was no national framework for regulating RECs. Section 72 of the NHA has changed this by ensuring that local RECs form part of a national system of ethical review by providing for the establishment of the NHREC. The Minister of

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<sup>660</sup> *Ibid.*

<sup>661</sup> GCP (note 58 above) 2.3.1. See Chapter Five for a comparison of the different approaches taken in GCP and the NHREC ethical guidelines regarding the participation of children in research. It should be noted, as stated above, that the Principal Investigator in a clinical trial is required to sign a declaration that they will comply with the principles established in the GCP in their application for approval for the study by the MCC. This makes the guidance on children in the GCP indirectly enforceable.

<sup>662</sup> GCP *ibid* 17.

<sup>663</sup> 2.3.1 *ibid.*

<sup>664</sup> Stobie, Strode & Slack (note 59 above) 206–207.

<sup>665</sup> *Ibid.* See Chapter Five for further discussion on this issue as these norms have now been superseded by s 71 of the National Health Act (note 57 above).

Health is authorised by the NHA to appoint not more than 15 persons to the NHREC after consulting with the National Health Council.<sup>666</sup> Regulations relating to the NHREC provide more detail on the composition of the Council by stating in Regulation 2 that at least nine (of the 15 members) must be persons who have ‘extensive experience and knowledge in health research ethics’.<sup>667</sup> There should also be at least one representative from: the community, the Department of Health, the pharmaceutical industry, the MCC, the animal health research field and the legal profession.<sup>668</sup> There is a public process of appointing members to the NHREC. However, if an insufficient number of nominations is received through such process, the Minister of Health may appoint members to the Council.<sup>669</sup> The regulations provide that the NHREC must meet at least four times a year.<sup>670</sup>

The Council was first formally established in September 2006.<sup>671</sup> Its role is described in section 72(6) of the NHA as being to:

- (a) determine guidelines for the functioning of health research ethics committees;
- (b) register and audit health research ethics committees;
- (c) set norms and standards for conducting research on humans and animals including norms and standards for the conducting of clinical trials;
- (d) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by researchers who believe that they have been discriminated against by a health research ethics committee;

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<sup>666</sup> S 72(2) *ibid.* This section provides further that members of the NHREC will have a three-year term of office. However they may be re-appointed by the Minister of Health for one or more terms after this initial term: s 72(3) *ibid.*

<sup>667</sup> Regulations relating to the National Health Research Ethics Council, *Government Gazette*, No. 33574 23 September 2010.

<sup>668</sup> *Ibid.*

<sup>669</sup> Regulation 3 *ibid.*

<sup>670</sup> Regulation 5 *ibid.*

<sup>671</sup> Report for the National Health Research Ethics Council, 2010/2011, available from <http://www.nhrec.org.za/wp-content/uploads/2011/report2011.pdf> [Accessed: 12 March 2012].

- (e) refer to the relevant statutory health professions council, matters involving the violation or potential violation of an ethical or professional rule by a health care provider;
- (f) institute such disciplinary action as may be prescribed, against any person found in violation of any norms and standards, or guidelines set for the conduct of research in terms of the Act; and
- (g) advise the national department and provincial departments on any ethical issues concerning research.

It is submitted that the NHA creates four distinct roles for the NREC. Firstly, norm setting in that the Council is required to issue guidelines on both the functioning of ethics committees and on ethical norms and standards for health research.<sup>672</sup> Secondly, oversight over RECs, ensuring they perform their statutory mandate and are competent to undertake ethical review.<sup>673</sup> Thirdly, enforcing ethical norms and standards by adjudicating complaints, referring ethical violations to relevant professional councils and instituting disciplinary action against persons violating ethical norms.<sup>674</sup> Fourthly, advising the national and provincial departments of health on ethical issues.<sup>675</sup>

With regard to its first role, that of norm setting, previously, there were no national ethical guidelines.<sup>676</sup> The NHA changed this scenario by providing that one of the functions of the

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<sup>672</sup> S 72(6)(a) and (c) National Health Act (note 57 above).

<sup>673</sup> S 72(6)(b) *ibid.*

<sup>674</sup> S 72(6)(d)–(f) *ibid.*

<sup>675</sup> S 72(6)(g) *ibid.*

<sup>676</sup> However it has been argued that the GCP Guidelines could be considered national ethical guidelines in the sense that they applied to all institutions but were only binding on clinical trials. See Chapter Three for more discussion on the role played by the GCP prior to the establishment of the NHREC. Furthermore, it was argued by Van Oosten that the MRC ethical guidelines which applied to both clinical trials and social science research ought to be used by institutions without their own institutional ethical guidelines. Even though strictly speaking they only governed the work of MRC staff or research undertaken on its behalf s 17(1) Medical Research Council Act (note 448 above). Van Oosten (note 104 above) 8–9 argued that as the MRC ethical guidelines were issued by the only statutory body required to issue ethical guidelines they should have been followed as national ethical guidelines in the absence of other guidance. Similar views have been expressed by Andanda (note 166 above) 78–79. See Chapter Three for further discussion on this point.

NHREC is to set norms and standards for health research on humans and animals.<sup>677</sup> Acting in terms of this section the NHREC has issued national ethical guidelines, namely, Ethics in Health Research: Principles, Structures and Processes which apply to all health-related research involving animals or humans, including research undertaken by the military and national research institutions.<sup>678</sup> Accordingly, it is submitted that these guidelines apply to clinical trials, social science research and studies undertaken by the MRC.<sup>679</sup> The NHREC Guidelines have been given further legal force through section 73 of the NHA which states that RECs must approve health research that meets the ethical standards of the Committee. Given the obligation on the NHREC to produce national ethical norms and standards the 'ethical standards of that committee' would in fact be the standards established by the NHREC.<sup>680</sup>

The NHREC Guidelines deal specifically with child research by providing that children should participate in health research only when they are indispensable to the study and when it is not contrary to their individual best interests. Such research may not be approved unless it:

- (i) Places the child at no more than minimal risk;<sup>681</sup> or
- (ii) Poses more than minimal risk but provides the child with direct benefit; or
- (iii) Poses greater than minimal risk and does not hold out the prospect of direct benefit, but has a high probability of generating generalised knowledge. In such a case the risk must be justified by the knowledge ratio.<sup>682</sup>

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<sup>677</sup> S 72(6)(c) National Health Act (note 57 above).

<sup>678</sup> NHREC Guidelines (note 56 above).

<sup>679</sup> Andanda (note 166 above) 79–80. Andanda argues that in the light of this change in the law the MRC guidelines are now subservient to the NHREC ones.

<sup>680</sup> Smit (note 34 above).

<sup>681</sup> The NHREC's ethical guidelines define minimal risk as 'the risk commensurate with daily life or routine medical or psychological examinations' NHREC Guidelines (note 56 above) 21.

<sup>682</sup> *Ibid* 20–21.

These provisions require RECs to pay special attention to protecting the welfare of children by ensuring amongst others that they are not subjected to unacceptable levels of risk in the study. In doing so an REC may require researchers to take additional measures to protect children during the research process, such as ensuring that they report any abuse which may be disclosed to researchers.<sup>683</sup> Furthermore, the NHREC Guidelines provide that an REC may, if it deems necessary, conduct post-research investigations to ascertain whether there was compliance with the measures imposed.<sup>684</sup>

The provisions on children in the NHREC Guidelines are substantially similar to those in the GCP Guidelines<sup>685</sup> and those in the HSRC's ethical guidelines dealing with the participation of children in social science research.<sup>686</sup> All three sets of guidelines provide that children must be indispensable to the study, the consent of the parents, guardian or a custodian must be obtained where possible, and the child must be free to withdraw at any time.<sup>687</sup> Nevertheless, the obligations in these national ethical guidelines must be read with institution-specific guidelines, where they exist.

In terms of its second core function, that of oversight over RECs, again the NHREC has taken steps to fulfil this function, The NHA requires all RECs to be registered with and accredited by the NHREC.<sup>688</sup> Furthermore, the NHREC may audit RECs to ensure compliance with national

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<sup>683</sup> See Chapter Five for further discussion on this point.

<sup>684</sup> *Ibid.*

<sup>685</sup> Stobie, Strode & Slack (note 59 above) 206–207 for a detailed comparison of the way in which these guidelines approach risk standards and consent for research involving child participants.

<sup>686</sup> HSRC ethical guidelines and its Guidelines on the participation of children in research (note 541 above). The HSRC's Guidelines are premised on very similar principles as they provide that the 'proposed research must hold out no more than minimal risk of harm (defined as "the probability and magnitude of harm or discomfort anticipated in the research will not be greater than those ordinarily encountered or to be expected in daily life, including in routine medical, dental or psychological examinations and in social or education settings"). It must not be possible to do the research with adult participants and the research must propose to investigate a problem of relevance to minors'.

<sup>687</sup> S 1.4 *ibid.*

<sup>688</sup> S 72(6)(b) National Health Act (note 57 above).

norms and standards.<sup>689</sup> This provides the NHREC with the opportunity to ensure that RECs are administratively effective and acting in accordance with the national ethical guidelines.

To date the NHREC has issued a database of 34 RECs which have completed the registration process with it.<sup>690</sup> In 2009 it undertook an assessment of the extent to which all registered RECs comply with (a) composition requirements set out in the national ethical guidelines and (b) procedural obligations in such guidelines.<sup>691</sup> Currently, this process is being repeated.<sup>692</sup> The auditing of RECs addresses a significant gap in our ethical-legal framework. Moodley and Landon argue that prior to 2007, no research had been conducted on whether RECs were constituted in accordance with ethical guidelines.<sup>693</sup> This meant that there was no information on whether RECs, for example, included representatives of the community on their committees as required by the national ethical guidelines.<sup>694</sup> However, it does not appear that the NHREC has undertaken an evaluation of the more complex issue of the extent to which RECs comply with the substantive elements of its ethical guidelines.

The NHREC's third core function is that of investigating and adjudicating on research misconduct. In this regard it established a Complaints and Discipline Committee in 2007 to co-ordinate its investigative and enforcement role.<sup>695</sup> This Committee receives, investigates

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<sup>689</sup> S 72(6)(b) *ibid.*

<sup>690</sup> The untitled database is available from [http://www.nhrec.org.za/?page\\_id=21](http://www.nhrec.org.za/?page_id=21) [Accessed: 12 March 2012]. Report for the National Health Research Ethics Council, 2010/2011, (note 661 above) seems to imply that the database was developed in August 2009. It is not clear whether this database is regularly updated.

<sup>691</sup> National Health Research Ethics Assessment/Evaluation Quantitative Report, available from <http://www.nhrec.org.za/wp-content/uploads/2012/recreport.pdf> [Accessed: 12 March 2012]. See the section below for more discussion on this assessment.

<sup>692</sup> Personal communication, Professor Wassenaar, regarding the audit of the HSRC REC in June 2012, 25 August 2012.

<sup>693</sup> Moodley & Landon (note 451 above) 2.

<sup>694</sup> NHREC Guidelines (note 562 above).

<sup>695</sup> Report for the National Health Research Ethics Council, 2010/2011 (note 671 above). Regulation 7 Regulations relating to the National Health Research Ethics Council (note 649 above) gives the NHREC the authority to set up working groups (sub-committees) to deal with special issues.

and deals with all complaints by participants or researchers relating to research misconduct.<sup>696</sup> The NHA provides that the NHREC is empowered to adjudicate complaints regarding the functioning of RECs<sup>697</sup> as well as to investigate potential research misconduct by 'any person'.<sup>698</sup> The Commission's 2010/2011 Report indicates that during that one-year reporting period, six complaints were received, four of which were resolved.<sup>699</sup> The Regulations provide that if a person is aggrieved by a decision of the NHREC they may appeal to the Minister of Health.<sup>700</sup> It is submitted that this would include a decision by the Complaints and Discipline Committee.

The fourth and final core function of the NHREC is to advise government on issues relating to research ethics. The latest report issued by the NHREC does not provide any detail on the advice provided to the Ministry of Health on research ethics.<sup>701</sup>

#### *4.2.4 Regulatory and review bodies: Research Ethics Committees*

In the past there was no general statutory obligation to submit all health research for ethical review<sup>702</sup> even though several RECs had been in operation since 1966 and had institutional ethical guidelines requiring ethical approval for health research.<sup>703</sup> There were two exceptions to this. Firstly, health research undertaken or sponsored by the MRC had to be

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<sup>696</sup> *Ibid.*

<sup>697</sup> S72(6)(d) National Health Act (note 57 above).

<sup>698</sup> S 72(6)(f) *ibid.*

<sup>699</sup> Report for the National Health Research Ethics Council, 2010/2011 (note 671 above).

<sup>700</sup> Regulation 7 Regulations relating to the National Health Research Ethics Council (note 640 above). The Minister of Health is required to set up an appeals committee made up of at least three persons, the chairperson must be a person with knowledge of the law and two others should have knowledge of research ethics. The Regulations are not clear on whether the members of the appeals committee must be members of the NHREC.

<sup>701</sup> Report for the National Health Research Ethics Council, 2010/2011 (note 671 above). See Chapter Six for a critique of this function by the NHREC.

<sup>702</sup> Strode, Slack & Mushariwa (note 94 above) 599.

<sup>703</sup> The first University to create an REC was the University of Witwatersrand. In 2007 there were approximately 34 RECs in South Africa: Moodley & Landen (note 451above) 1 and Van Oosten (note 104 above) 7.

reviewed by an REC that the MRC recognised.<sup>704</sup> Secondly, all clinical trials had to obtain ethical approval before being submitted to the MCC for authorisation.<sup>705</sup> Nevertheless, beyond these instances, there was no legally binding obligation to submit health research to an REC for approval.<sup>706</sup> There was also no obligation on institutions conducting health research to establish an REC. The NHA changed this position by creating a clear obligation for all institutions, agencies or health establishments conducting health research to establish or have access to a registered REC. Section 73 of the NHA provides:

- (1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.
- (2) A health research ethics committee must –
  - (a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and
  - (b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocols meet the ethical standards of that health research ethics committee.

Section 73(1) of the NHA creates an institutional obligation to establish an REC. Thus, responsibility for failing to establish such an REC, to ensure that it is registered with the NHREC or that staff/contractors have access to an accredited REC, must be borne by the head or the governing structure of such an institution. It is not a direct obligation to submit health research for ethical review as such, as that is merely an ethical obligation.<sup>707</sup> However, the draft Regulations make it clear that researchers are under an obligation to submit their

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<sup>704</sup> S 17(1) Medical Research Council Act (note 448 above).

<sup>705</sup> Regulation 34(1)(e) General Regulations, Medicines and Related Substances Act (note 164 above).

<sup>706</sup> See Chapter Three for further discussion on this point.

<sup>707</sup> Point 2.5 NHREC Guidelines (note 56 above).

protocols for 'independent review by an accredited registered health research ethics committee'.<sup>708</sup>

Section 73(1) of the NHA defines two roles for RECs: (a) to review research and ensure that it is relevant; and (b) grant approval when it is ethical.<sup>709</sup> With regard to the first role, it is assumed that RECs should assess relevance by referring to the principles established in the South African Health Research Policy issued by the National Health Research Committee. However, this policy applies only to research conducted within the public sector or which utilises public funds.<sup>710</sup> Nevertheless, it is argued that the obligation in section 73(1)(a) means that even research conducted by private agencies must be relevant as it ought to 'promote health'. It follows therefore that RECs must establish that the protocol promotes the health of local communities.<sup>711</sup>

Regarding the second role, RECs must grant ethical approval if a protocol is found to be ethical. Accordingly, RECs must make their own independent determination of whether a protocol meets their ethical standards by drawing on internationally and nationally accepted ethical guidelines.<sup>712</sup>

The roles for RECs as described in the NHA are very similar to those set out in the national ethical guidelines. The NHREC Guidelines describe the roles of RECs as being: the review of

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<sup>708</sup> Regulation 2(h) draft Regulations on Human Subjects (note 13 above).

<sup>709</sup> The determination on when health research is ethical must be made in the light of the ethical standards of that REC: s 73(2)(b) National Health Act (note 57 above).

<sup>710</sup> National Health Policy (note 7 above).

<sup>711</sup> This approach reflects the well-established ethical principle of justice: R Gillon 'Medical ethics: Four principles plus attention to scope' (1994) Vol 309 *British Medical Journal* 1, 2–3, Tangwa (note 605 above) 56 and PL Knudsen 'Ethical principles in human subjects study' (2001) Vol 32 *Archives of Medical Research* 473, 474.

<sup>712</sup> Smit argues that this includes ensuring that the protocol is consistent with the ethical norms in the NHREC Guidelines (note 34 above) 15. This indirectly makes the national ethical guidelines legally enforceable, an approach which has been established by the courts in the past. For example, in *Jansen van Vuuren and Another NNO v Kruger* (note 157 above).

research protocols; ensuring that human subjects are treated with dignity and their well-being is promoted; ensuring that the informed consent procedures are adequate; and granting approval to protocols that meet the ethical standards of the committee.<sup>713</sup> There is a corresponding duty on the principal investigator of a study to submit the research for ethical approval.<sup>714</sup>

Detailed guidance is also provided to RECs in ethical guidelines regarding, amongst others: their functions; composition; appointment of members; procedures; the recording of decisions; monitoring; dealing with complaints; suspending or discontinuing research; and submitting compliance reports to the NHREC.<sup>715</sup>

Section 73 appears to be applicable to all forms of health research, and all institutions (public and private), agencies and establishments conducting health research must either establish or have access to an REC. This means that any research that falls within the ambit of 'health research' as defined in section 1 of the NHA must be submitted to an REC for review, and may proceed only if it is approved by the REC. Given the broad definition of health research it is argued that even research which does not involve human participants, such as record reviews, must be submitted for ethical approval.

#### 4.2.5 *Community liaison bodies: Community Advisory Groups (CAGs)*

Currently, in some instances, Community Advisory Boards (CABs) or CAGS exist to act as a liaison between researchers and communities even though there is no explicit legal obligation to establish such a structure.<sup>716</sup> The NHREC has recently released Guidelines on

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<sup>713</sup> *Ibid.*

<sup>714</sup> Point 2.5 NHREC Guidelines (note 56 above).

<sup>715</sup> *Ibid* 15–19.

<sup>716</sup> Reddy, Buchanan, Sifunda, James & Naidoo (note 345 above) 3. It appears that the terms CAG and CAB are inter-changeable as the National Health Research Ethics Council (2012) Guidelines for Community Advisory Groups available from [http://www.nhrec.org.za/wp-content/uploads/2012/guideline\\_cag.pdf](http://www.nhrec.org.za/wp-content/uploads/2012/guideline_cag.pdf) [Accessed: 28

CAGs which set out the roles, structure and functions that such bodies could undertake within community-based research.<sup>717</sup> It is argued that the development of these Guidelines is significant as, in particular, 'poor communities, can only benefit from national policies being established to specify types of representation, resourcing and legitimising authority, as the clinical trial milieu develops within the fledgling South African democracy'.<sup>718</sup> It is possible to argue that these Guidelines are enforceable as they are norms and standards regulating the conduct of research with human subjects issued by the NHREC in terms of section 72(6)(c) of the NHA.<sup>719</sup> Accordingly, researchers who fail to comply with them could be disciplined by the NHREC.<sup>720</sup>

The NHREC Guidelines on CAGs provide that 'community engagement may serve to increase the relevance and quality of proposed research, and its acceptance by affected communities'.<sup>721</sup> Furthermore, the NHREC recommends that:

investigators attempt to engage the participating community and other stakeholders in a relationship of mutual respect and collaboration because such engagement may add to the quality and acceptability of research projects, particularly those that involve vulnerable communities in complex research endeavours.<sup>722</sup>

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August 2012] do not draw a clear distinction between the terms and refer to both as acceptable. These Guidelines list the following CAGs as currently being in existence: Africa Centre CAB, Aurum Health KOSH CAB, CAPRISA CAB, Chris Hani-Baragwanath Peri-Natal Health Research Unit Soweto CAB, Desmond Tutu HIV Research Centre, Masiphulele and Nyanga CABs and the MEDUNSA CAB.

<sup>717</sup> National Health Research Ethics Council Guidelines for Community Advisory Groups *ibid.*

<sup>718</sup> Reddy, Buchanan, Sifunda, James & Naidoo (note 345 above) 3.

<sup>719</sup> National Health Act (note 57 above).

<sup>720</sup> S 72(6)(f) *ibid.*

<sup>721</sup> Point 1 National Health Research Ethics Council Guidelines for Community Advisory Groups (note 716 above).

<sup>722</sup> Point 9 *ibid.*

The Guidelines suggest that determining when a CAG should be established rests with the principal investigator in a study.<sup>723</sup> Nevertheless, RECs ought to exercise oversight over such decisions by raising the issue if they believe that a CAG is required in the circumstances.<sup>724</sup>

The NHREC Guidelines on CAGs state that the following should act as a guide as to when they should be established:

- (a) That the proposed research may hold distinct potential risks for participants and participating communities, such as stigma and discrimination;
- (b) That the populations to be recruited for the proposed research may have pre-existing vulnerabilities that increase their susceptibility to research-related risks;
- (c) That the proposed research may have a substantial impact on areas where it will be conducted;
- (d) The proposed research is particularly complex or lengthy;
- (e) That similar studies elsewhere have historically included CABs as an additional safeguard;
- (f) That investigators may need to harness the expertise of community representatives in order to design and conduct the research more effectively; and
- (g) That inequalities may exist between participating communities and investigators in terms of power, education and resources.<sup>725</sup>

The NHREC Guidelines on CAGs identify six roles for such bodies. These are: one, to educate researchers on community norms; two, to educate the community on the proposed research; three, to advise the researchers on any matter relating to the study, such as potential risks that may be faced by participants; four, providing inputs into the research process; five, ensuring the community has a voice in the research process; six, assisting in ensuring that the study meets ethical and human rights standards.<sup>726</sup>

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<sup>723</sup> *Ibid.*

<sup>724</sup> Point 8.1 *ibid.*

<sup>725</sup> Point 2.2 *ibid.*

<sup>726</sup> Point 3 *ibid.*

The HSRC Act does not require the establishment of CAGs in social science research. However, it provides that when research is being conducted in areas under the jurisdiction of traditional leaders, notice of intention to conduct research must be sent, in writing, to the House of Traditional Leaders.<sup>727</sup>

### **4.3 Institutions and mechanisms to monitor or enforce health research rights**

#### *4.3.1 Monitoring health research*

In the past, there were two key obligations regarding the monitoring of research. Firstly, the Regulations issued under the Medicines Act provided that researchers must submit progress reports to the MCC every six months.<sup>728</sup> Secondly, ethical guidelines generally required that RECs should monitor protocol compliance, study records, and progress with the research.<sup>729</sup>

The NHA has not significantly changed the monitoring framework. It has, however, firstly, given RECs a legally defined role and indirectly requires all health research to be reviewed by RECs.<sup>730</sup> This new role for RECs means that research may not continue if ethical approval is either not granted, or withdrawn, for a study due to non-compliance with ethical norms and standards. Secondly, RECs themselves must be registered with and accredited by the NHREC. This has created a new mechanism for ensuring that RECs act within the framework of both ethical guidelines and the law.<sup>731</sup> Thirdly, researchers are now obliged to comply with the ethical standards issued by the NHREC and failure to do so may result in their being disciplined.<sup>732</sup>

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<sup>727</sup> S 14(6) HSRC Act (note 62 above).

<sup>728</sup> General Regulations, Medicines and Related Substances Act Regulation 34(5)–(6) (note 164 above).

<sup>729</sup> NHREC Guidelines (note 56 above) and GCP (note 56 above).

<sup>730</sup> S 73 National Health Act (note 57 above).

<sup>731</sup> *Ibid* s 72(6)(b).

<sup>732</sup> *Ibid* s 72(6)(f). The extent to which this new authority will enhance the ability of RECs to undertake their monitoring function is discussed in Chapter Six.

Currently the following monitoring obligations are placed on the various ethical-legal role-players in terms of national ethical guidelines:

- (a) *Obligations on individuals*: Principal investigators (PIs). The responsibilities of a PI include: informing RECs of any amendments to the trial protocol which require REC approval, reporting any serious or unexpected adverse events and reporting on the progress of the trial at least annually, but more frequently if requested by the REC.<sup>733</sup>
- (b) *Obligations on the sponsors of research*: Sponsors are required to appoint a trial monitor in a clinical trial, who is responsible for overseeing and reporting on the progress of the study.<sup>734</sup> For example, during the course of the study, the designated person monitors progress through maintaining personal contact with the PI, visiting the site and meeting with staff, reviewing procedures, documents/source data, and discussing any problems that have arisen or are foreseen. The monitor is obliged to evaluate and report to the sponsor, ethics committee and MCC, on various aspects of the research, including: the progress of the study; adherence to the protocol; conformity of the data presented in reports with source data; whether there is accurate maintenance of essential documentation; monitoring of the informed consent process and regular reporting to the sponsor, ethics committee and regulatory authority.<sup>735</sup> Sponsors are not obliged, but they may elect, to appoint an independent auditor in a clinical trial to evaluate the conduct of a trial and compliance with the trial protocol and applicable regulatory requirements.<sup>736</sup> In the event of the audit finding non-compliance, the sponsor is obliged to: enforce compliance with the protocol or regulatory requirements; possibly terminate the PI's participation in the trial; or suspend or terminate the trial, where non-compliance continues. The sponsor is also required to inform the investigators,

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<sup>733</sup> GCP (note 58 above) Points 30 and 34.

<sup>734</sup> *Ibid* 47.

<sup>735</sup> *Ibid*.

<sup>736</sup> *Ibid* 60–61.

regulatory authority and the REC of the termination or suspension of the study, and the reasons for this action.<sup>737</sup>

(c) *Obligations on institutions*: Ethics committees are required to undertake ongoing monitoring of trials through reviewing reports provided by researchers, as well as by establishing procedures for the continuing review and re-approval of each study, at least once a year.<sup>738</sup> The MCC is given statutory powers to ensure that researchers comply with their ethical and legal obligations in clinical trials, as the Regulations provide that they may:

request additional information, inspect a clinical trial or withdraw authorization to conduct a clinical trial if the Council is of the opinion that the safety of the subjects of the trial is compromised, or that the scientific reasons for conducting the trial have changed.<sup>739</sup>

There are no special procedural or other measures for monitoring research involving child research participants.

#### 4.3.2 *Enforcing the rights of research participants*

Currently, there are six ways in which research participants can enforce their legal rights and ethical obligations.

Firstly, professional councils regulate the conduct of their members, and have powers of discipline over their members. Section 2 of the Health Professions Act establishes a Health Professions Council (HPC), with control over the training and registration of medical practitioners, dentists, practitioners of supplementary health service professions, and psychologists.<sup>740</sup> The Council has to determine strategic policy on matters such as ethics and the professional conduct of registered professionals. It also exercises control over the

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<sup>737</sup> *Ibid.*

<sup>738</sup> NHREC Guidelines (note 56 above) 18.

<sup>739</sup> Regulation 34(7) General Regulations, Medicines and Related Substances Act (note 164 above).

<sup>740</sup> Act 56 of 1974.

manner in which registered professionals carry out their duties.<sup>741</sup> The Council's powers include the authority to discipline practitioners for unprofessional conduct, that is, improper or disgraceful conduct.<sup>742</sup> Carstens and Pearmain argue that this includes the power to discipline members who act improperly or disgracefully towards patients by failing to follow ethical standards.<sup>743</sup> Although the authors do not refer to whether similar powers exist in order to discipline researchers, Van Oosten submits that unprofessional conduct by a medical practitioner during health research may be reported to the HPC.<sup>744</sup>

Secondly, institutions employing researchers may discipline their employees who bring the institution into disrepute for failing to comply with ethical, legal or regulatory standards.<sup>745</sup> It is argued that they could do this by bringing charges of misconduct against the researcher (employee) for failing to comply with the ethical norms and standards of the institution or, more generally, for failing to comply with legal and regulatory obligations. This could be regarded as a form of misconduct in that they will have breached a workplace rule by failing to comply with these obligations.

Thirdly, the NHREC has a wide range of functions, including powers to enforce good conduct by health researchers or RECs reviewing research. It can:

- (i) Adjudicate complaints regarding the functioning of an REC;<sup>746</sup>
- (ii) Refer to the relevant statutory professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider;<sup>747</sup> and

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<sup>741</sup> S 10 *Ibid.*

<sup>742</sup> Carstens & Pearmain (note 529 above) 262.

<sup>743</sup> 263 *Ibid.*

<sup>744</sup> Van Oosten (note 104 above) 8.

<sup>745</sup> GCP Guidelines (note 58 above) 8. For example, the University of the Witwatersrand took disciplinary action against a staff member for 'scientific misconduct' following allegations of research irregularities: Cleaton-Jones (note 152 above) 1011.

<sup>746</sup> S 72(6)(d) National Health Act (note 57 above).

- (iii) Institute disciplinary action against any person found to be in violation of any research-related norms and standards, or guidelines.<sup>748</sup>

Fourthly, it is submitted that researchers may be held criminally liable for their actions.<sup>749</sup> For example, if a researcher failed to obtain informed consent from a research participant, they could be charged with the crime of assault. However, the criminal law can only be utilised if it could be proved that the researcher intended to cause harm to the research participant.<sup>750</sup>

Fifthly, it is argued that if a researcher acted culpably or negligently towards a research participant, delictual principles could be used to hold them accountable. The civil law provides that a person who wrongfully and culpably harms another can be held responsible for the harm and, accordingly, is obligated to pay compensation.<sup>751</sup> For example, if researchers acted negligently in failing to warn participants of the potential side effects of an experimental drug used during pregnancy, participants could resort to the civil law to claim compensation for loss suffered such as pain and suffering, or medical expenses. Carstens and Pearmain submit that the failure to obtain informed consent is a figurative ‘assault’ on the patient’s body in the sense that it wrongfully violates their right to bodily integrity and is therefore actionable:

the lack of informed consent amounts to an assault (in the context of wrongfulness/unlawfulness) and not negligence (in context of the element of fault). The

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<sup>747</sup> S 72(6)(e) *ibid.*

<sup>748</sup> S 72(6)(f) *ibid.*

<sup>749</sup> McQuoid-Mason (note 363 above) 28.

<sup>750</sup> *Ibid.* See Chapter Two where reference is made to the Nuremburg doctor’s trial which is the most high profile use of the criminal law against researchers to date.

<sup>751</sup> J Neethling, JM Potgieter & PJ Visser *The law of delict* (2006) 110–112. Also see generally JA Singh ‘Using the courts to challenge irrational health research policies and administrative decisions’ (2009) 1125 *Acta Tropica* s 76–s 79.

concept of assault should not be assessed in its strict literal sense, but as a violation of a patient's right to bodily or physical integrity.<sup>752</sup>

It is argued that it is also possible to enforce a research participant's rights through contract law. The informed consent document is in essence a contract between the researcher and participant setting out the rights and obligations of both parties. Any breach of the terms of a validly concluded informed consent agreement would be enforceable.<sup>753</sup>

Finally, the Constitution establishes various statutory bodies to support our constitutional democracy.<sup>754</sup> These include the South African Human Rights Commission (SAHRC), which is tasked with promoting respect for human rights and developing a culture of human rights, promoting the protection, development and attainment of human rights, and monitoring and assessing the observance of human rights in the country.<sup>755</sup> The SAHRC is also given the power to investigate and report on the observance of human rights, to take steps to obtain redress where human rights have been violated, to carry out research and to provide human rights education.<sup>756</sup> Given this broad mandate, it is argued that the SAHRC could act on a complaint regarding human rights abuses during research. This argument is supported by recommendations issued by the Convention on the Rights of the Child Committee's General Comment Number Two, which highlights the important role that national human rights institutions can play in protecting children's rights.<sup>757</sup>

There are no child specific enforcement mechanisms.

#### **4.4 Conclusions**

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<sup>752</sup> Carstens & Permain (note 529 above) 687.

<sup>753</sup> Singh (note 13 above) s 71.

<sup>754</sup> Chapter Nine, Constitution of the Republic of South Africa (note 2 above).

<sup>755</sup> *Ibid* s 184(1).

<sup>756</sup> *Ibid* s 184(2).

<sup>757</sup> Sloth-Nielsen & Mezmur (note 235 above) 350.

South Africa has a well-established institutional framework for regulating health research established primarily by the NHA and the Medicines Act. Within the framework there are three statutory institutions and two non-statutory bodies, RECs and CAGs. Collectively, these institutions ensure that relevant research priorities are set, research is regulated (scientifically and ethically), norms for the conduct of research are established, there is community engagement and ethical norms and legal rights are enforced. The framework places a number of procedural obligations on key stakeholders. These obligations vary according to the nature and place of the health research being conducted.

Firstly, the conduct of health research places an obligation on all researchers who must:

- (i) If the study is state-funded or carried out by the public sector, ensure that its aims and objectives fit within the research priorities identified by the NHRC; and
- (ii) Comply with all obligations set by the NHREC.

Furthermore all institutions undertaking health research must establish an REC or have access to an REC.

Secondly, if the health research involves a living human participant then the following additional procedural obligations exist:

- (i) Compliance with the norms in sections 11 and 71 of the NHA;<sup>758</sup>
- (ii) If the health research is undertaken by the HSRC and is in an area under the control of the House of Traditional Leaders, they<sup>759</sup> must be notified of the intention to undertake the study; and
- (iii) If the research is classified as a clinical trial, the study must be registered with the MCC and the South African Clinical Trials Register (SANCTR).

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<sup>758</sup> See Chapter Five for a full description of these norms.

<sup>759</sup> The House of Traditional Leaders, not the individual leaders in that area.

Thirdly, if the health research enrolls human participants and is by its nature a health service which is experimental, then there are additional obligations to obtain consent from persons within the health institution and not just the patient or research participant.

A key strength of the current institutional framework is that it creates a platform for both procedural and substantive protections for research participants. This shifts the focus from individuals having to protect themselves through the doctrine of informed consent, and places the obligation on the institutions to ensure that health research is regulated in an objective manner in line with the prevailing ethical and legal norms. The institutional framework does not have a dedicated focus on child research participation. However, it is contended that this is not a key institutional weakness. Nevertheless, the lack of a coherent approach to the involvement of the community in research regulation, and the limited co-ordination between the ethical-legal institutions remain key problems.<sup>760</sup>

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<sup>760</sup> This is addressed in detail in Chapter Six.

## **Chapter Five:**

### **The normative framework for regulating health research with children**

The preceding Chapter described the institutions that make up the current ethical-legal framework. It examined the institutions which (a) create a policy framework, (b) establish a national system for regulating research ethics, (c) undertake ethical review at an institutional level, (d) engage with the community, and (e) implement monitoring and enforcement mechanisms.

The Chapter began with a description of the parameters of the current ethical-legal framework for regulating health research. This was followed by a description of the role and functions of each institution, namely, the NHRC, the MCC, the NHREC, RECs and CAGs. Monitoring and enforcement mechanisms were also individually described and discussed.

The Chapter concluded with a description of procedural obligations which institutions have placed on key research stakeholders, such as the obligation to obtain ethical approval for health research. It also made some comments on the strengths and weaknesses of the current institutional framework for regulating health research in South Africa.

This Chapter describes the key legal norms that regulate health research with children in South Africa. It sets out the rights of research participants to participate in research only with informed consent, to be treated equally and to have their privacy and dignity protected. It also describes the obligations on researchers to ensure that children are indispensable to the study, that the research has an acceptable level of risk and that it fits within broad public policy standards set for both so-called therapeutic and non-therapeutic research. Finally, the

Chapter discusses mandatory reporting requirements which, in certain instances, impact on the research relationship.

## 5.1 Introduction

Prior to the full implementation of the NHA legal provisions dealing with the protection of research participants were contained in various enactments of our law, and no single piece of legislation described the circumstances in which individuals could participate in health research. Even the Children's Act which describes in detail a child's health rights did not address the participation of children in health research.<sup>761</sup> Furthermore, where protections did exist, these were not research specific, resultantly, academic writers and RECs had in many instances to apply general principles relating to medical treatment or the norms established in ethical guidelines, to a research context.<sup>762</sup>

The position changed dramatically from 1 March 2012 with the implementation of sections 11 and 71 of the NHA.<sup>763</sup> These sections contain norms which set out the rights of research participants and how health research ought to be conducted. Draft Regulations on Research with Human Subjects were also published for public comment on 23 February 2007 and again in May 2013.<sup>764</sup> However, to date they have not been finalised. It is uncertain when a final version of these draft regulations will be promulgated. There are also some non-research specific laws which contain norms that are relevant to the conduct of health research with children. These are primarily laws which deal with other health rights of children and those that place specific obligations on certain adults, such as the mandatory reporting requirements.<sup>765</sup>

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<sup>761</sup> Strode, Slack & Essack (note 143 above) 247.

<sup>762</sup> Strode, Slack & Mushariwa (note 94 above) 600.

<sup>763</sup> *Government Gazette* No. 35081 (note 95 above).

<sup>764</sup> Regulations relating to research on human subjects 2007 and 2013 (note 13 above). This thesis only refers to the content of the 2013 draft regulations in the Addendum.

<sup>765</sup> For example, s 134 of the Children's Act which provides that a child may consent independently to contraceptives and contraceptive advice from the age of 12 (note 4 above). This provision may be relevant in an

Section 71 is the over-arching section setting norms for all health research involving human participants. It comprises of three parts; firstly, section 71(1) which sets out general provisions for health research on human participants. This part of the section also establishes a platform for the development of a wide range of legal norms for research involving human participants as it empowers the Minister of Health to issue regulations on this issue.<sup>766</sup> Secondly, sections 71(2) and (3) which deal with the circumstances in which health research with minors may be conducted. These sections read:

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.

(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

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HIV prevention study as it would mean that even if parental consent was required for enrolment in the study, if participants were provided with access to contraceptives during the trial they could consent to this intervention independently and without the knowledge of their parents provided they were over the age of 12. Likewise the mandatory obligation to report under-age sex, s 54 Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 could mean that if an efficacy study into a vaginal microbicide enrolled girls between the ages of 12–15 researchers would be obliged to report any sexual activity to the police where the girl's partners were over the age of 18 as their partners would be committing a sexual offence. See s 5.2.2 (vi) below for more detail on this point.

<sup>766</sup> Van Wyk (note 13 above) 47.

- (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 well-being of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

Sections 11 and 16 of the NHA deal with instances when a health service is provided by a health establishment for experimental or research purposes.<sup>767</sup> In other words these two provisions in the NHA deal with health research which is provided by or at a health establishment.

These three sections in the NHA are significant for a number of reasons, but particularly as they are the first legislative provisions to deal directly with the rights of all human participants involved in health research.<sup>768</sup> They also create a number of new norms in relation to health research with minors. These are:

- (i) Such research can only be conducted if the consent of a parent or guardian is obtained. The NHA does not allow consent by care-givers even if they are acting as de facto parents or guardians;
- (ii) Minors who demonstrate 'understanding' will consent alongside the person providing proxy consent and not merely assent to the study;

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<sup>767</sup> National Health Act (note 57 above).

<sup>768</sup> Pope (note 93 above) 167.

- (iii) Therapeutic research must be in the best interests of the minor; and
- (iv) Ministerial consent must be obtained for non-therapeutic research with minors.

The legislature has elected to provide additional protection to all 'minors' rather than just children. The reason for this approach is unclear. Minority is based on the notion that only persons with reasonable understanding and judgment should have the capacity to act.<sup>769</sup> Accordingly, the law provides that individuals between birth and 18 have limited legal capacity.<sup>770</sup> Nevertheless, in certain defined circumstances minority may end before the age of 18.<sup>771</sup> Thus by using the word 'minor' as opposed to 'child' it is possible that the legislature envisaged that certain children would have the legal capacity to consent to research before the age of 18 because they are married or have been emancipated.<sup>772</sup>

It is submitted that these research-specific provisions read with the obligations or norms in non-research laws create nine standards for research with children. These include both rights for child research participants and obligations on researchers.<sup>773</sup> These are described individually below.

## 5.2 The rights of child research participants

### 5.2.1 *Informed consent*

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<sup>769</sup> J Heaton *The South African Law of Persons* 3 ed (2008) 85.

<sup>770</sup> *Ibid.*

<sup>771</sup> 115 *ibid.*

<sup>772</sup> A child who marries before the age of 18 becomes a legal major for all purposes. In this instance the child remains a major even if the marriage ends due to death or divorce before the age of 18 *ibid* 114. A child may also become a legal major before the age of 18 if they are emancipated by their parent or guardian. Emancipation can occur when the minor acts without the assistance of their parent or guardian in juristic acts *ibid* 115.

<sup>773</sup> These are the rights to informed consent, privacy, dignity and equality. The obligations are to ensure that therapeutic research is in the best interests of the child, ministerial consent is obtained for non-therapeutic research with minors, mandatory reporting requirements are complied with, appropriate risk standards adhered to and scientific justifications exist for the inclusion of children in health research.

Informed consent to research participation is an accepted international law principle which has its roots in the Nuremburg Code and the Helsinki Declaration.<sup>774</sup> Prior to the full implementation of the NHA in March 2012 only the Constitution referred to a participant's right to participate in research with their informed consent with section 12(2)(c) stating:

Everyone has the right to bodily and psychological integrity, which includes the right . . . not to be subjected to medical or scientific experiments without their informed consent.<sup>775</sup>

This right includes protection against intrusions into a person's physical body and a right to autonomy in decision-making.<sup>776</sup> This implies that there is a constitutional obligation on researchers to obtain informed consent from research volunteers and research participants have the right to make autonomous research-related decisions.<sup>777</sup>

In the past there were no express legal provisions dealing with when and how consent should be obtained from children or their proxies for health research. Accordingly, it was argued that given the lack of legal guidance the key legislative and common law principles relating to informed consent to medical treatment and the principles established in ethical guidelines should be used as a framework for describing when consent to health research with children would be lawful.<sup>778</sup>

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<sup>774</sup> London et al (note 156 above) 288. See Chapter Two for a full description of the right to informed consent in international law and ethical codes.

<sup>775</sup> Constitution of the Republic of South Africa (note 2 above). This provision was inserted into the final Constitution after the narrow wording in s 11 of the interim Constitution was criticised: Constitution of the Republic of South Africa, Act 200 of 1993. The interim Constitution provided only that everyone 'shall have the right to freedom and security of the person, which shall include the right not to be detained without trial'. Furthermore no one 'shall be subject to torture of any kind, whether physical, mental or emotional, nor shall any person be subject to cruel, inhuman or degrading treatment or punishment' *ibid*.

<sup>776</sup> I Currie & J de Waal *The Bill of Rights Handbook* 5 ed (2005) 308 and F Veriava 'Ought the notion of informed consent be cast in stone'? *BRM v The Health Professions Council of South Africa* (2004) Vol 20 *South African Journal of Human Rights* 309, 313.

<sup>777</sup> *Ibid*.

<sup>778</sup> Smit (note 34 above) 15.

Sections 11, 16 and 71 of the NHA clarify this situation by providing detail on the nature of consent to health research and who may provide it when a child is to be enrolled in a study. The draft Regulations also deal with consent by providing that research participants have the right to bodily integrity.<sup>779</sup> The draft Regulations provide further those participants must be well-informed in order to facilitate appropriate decision-making and they outline the minimum information that should be provided to research participants.<sup>780</sup> The approach taken towards consent from children/minors for health research in the NHA and the draft Regulations is highly restrictive. It does not allow independent consent by children in any circumstances and it limits the persons who may provide proxy consent. In this regard it is at odds with the norms established in ethical guidelines.<sup>781</sup> Both the NHA and the draft Regulations on Human Subjects are silent on the issue of assent by child research participants.

Consent is a defence to what would otherwise be an unlawful act.<sup>782</sup> It is reflected in the common law principle of *volenti non fit injuria* (to one consenting no wrong is done).<sup>783</sup> In essence a person who willingly consents to a harmful act or an activity cannot claim that a delict has been committed against them.<sup>784</sup> It is argued that if the principle is to operate as a defence the following must exist; the research participant should:

- (i) Know the nature and extent of the harm or risk involved;<sup>785</sup>
- (ii) Appreciate and understand the nature of the harm or risk;<sup>786</sup> and
- (iii) Voluntarily consent to the harm or assume the risk.<sup>787</sup>

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<sup>779</sup> Regulation 2(f) Draft Regulations (note 13 above).

<sup>780</sup> Regulation 2(d) *ibid.*

<sup>781</sup> See Chapter Six for further discussion on this point.

<sup>782</sup> Carstens & Permain (note 529 above) 875.

<sup>783</sup> *Ibid.*

<sup>784</sup> McQuoid-Mason (note 363 above) 8.

<sup>785</sup> *Ibid.*

<sup>786</sup> *C v Minister of Correctional Services* (note 533 above) 301B.

<sup>787</sup> *Esterhuizen v Administrator, Transvaal* (note 516 above) 722.

Furthermore the act consented to must not be *contra bonos mores*<sup>788</sup> and the person consenting must have legal capacity.<sup>789</sup>

*(i) Provide research participants with knowledge of the health research*

Carstens and Permain argue that the standard of information that research participants are entitled to is ‘full disclosure’ of all relevant facts.<sup>790</sup> However, section 71 of the NHA simply requires researchers to inform research participants of any possible negative or positive consequences to their health.<sup>791</sup> Section 11 of the NHA provides further that where research is being conducted as part of a ‘health service’ or at a ‘health establishment’ the user must be ‘informed’ that the health service is experimental.<sup>792</sup> Regulation 2(d) of the draft Regulations provides that research participants should be well informed and ‘able to make appropriate choices’.<sup>793</sup> Regulation 6 details the content of the information that ought to be provided to participants:

(a) the purpose of the research; (b) treatments and possibility of random assignment of each treatment (if the research involves treatment); (c) methods and procedures to be followed or used during the research; (d) alternatives apart from participating in the research; (e) potential harms and risks involved in participation; (f) expected benefits to the participant and other persons in the research; (g) extent to which confidentiality and privacy will be maintained; (h) available insurance in the event of research-related injury, for more than minimal risk research; (i) details of the contact person in the event of a query or research-related injury; (j) reimbursement and/or incentives given for participation; (k) in cases of clinical trials, the availability of treatment beyond the duration of the trial; (l) details of the sponsor and any potential conflict of interests; (m) their freedom to decline or withdraw from

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<sup>788</sup> Van Oosten (note 104 above) 29–30.

<sup>789</sup> McQuoid-Mason (note 363 above) 8.

<sup>790</sup> Carstens & Permain (note 529 above) 894.

<sup>791</sup> S 71(1)(b) National Health Act (note 57 above).

<sup>792</sup> Draft Regulations on Human Subjects (note 13 above).

<sup>793</sup> *Ibid.*

the research without prejudice; and (n) proof of ethics committee approval or MCC approval, where relevant.<sup>794</sup>

These principles must be read with those established in the NHREC Guidelines which require researchers to disclose additional information on the investigator's qualifications, the contact details of the REC and the procedures that will be followed if a participant is harmed and is eligible for compensation related to a research-related injury.<sup>795</sup>

*(ii) Appreciating and understanding the risks of the research*

It is a well-established common law principle that a person providing consent must appreciate the information on which they base their decision.<sup>796</sup> In *Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as Amicus Curiae)* it was held that the 'requirement of "appreciation" implies more than mere knowledge . . . (the patient) must also comprehend and understand the nature and extent of the harm or risk'.<sup>797</sup>

The NHA does not expressly require research participants to understand the information presented in order to provide lawful consent except where the person is a minor and they are giving consent alongside their parent or guardian.<sup>798</sup> Nevertheless, the research participant must understand the nature and extent of the research risks given the central role understanding plays in the defence of *volenti non fit injuria*.

*(iii) Consents to or assumes the risk of research*

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<sup>794</sup> Regulation 6 *ibid*.

<sup>795</sup> NHREC Guidelines (note 56 above) 4–5.

<sup>796</sup> *McQuoid-Mason* (note 363 above) 8.

<sup>797</sup> *Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as Amicus Curiae)* 2005 (note 542 above) 515I–J.

<sup>798</sup> Ss 71(2)–(3) National Health Act (note 57 above) states that '(i)f the minor is capable of understanding, with the consent of the minor.'

In essence this principle requires research participants to give express consent to the research thus clearly indicating their intention to participate.<sup>799</sup> The NHA provides that participants must give written consent to research participation.<sup>800</sup> Furthermore, section 11 of the NHA provides that if the study occurs at a health establishment, consent must be obtained from the user, their health care provider, the head of the health care establishment, the REC and any other person to whom this authority has been delegated.<sup>801</sup> This section therefore requires both individual and institutional consent for research participation. The only exception to written consent is set out in section 16(2) of the NHA which provides that when record reviews are being done by health care providers for research purposes and no personal identifiers are being obtained, consent is not required from the patient, the health establishment or the REC.

The draft Regulations also provide that if a child elects not to participate in research they cannot be compelled to enrol simply because their parents or guardians have provided consent for their participation.<sup>802</sup>

#### *(iv) Voluntariness*

The NHA does not specifically require that consent to health research be voluntary. However, it is argued that the common law principles would nevertheless apply, and researchers would be obliged to take steps to both ensure that consent is always voluntarily given and that they take steps to minimise factors that may limit voluntariness. The draft Regulations on Human Subjects deal briefly with persons whose voluntariness may be compromised under the category of persons in dependent relationships, stating that RECs should give special attention to the vulnerability of persons who are in dependent

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<sup>799</sup> Van Oosten (note 104 above) 30.

<sup>800</sup> S 71(1)(b) National Health Act (note 57 above).

<sup>801</sup> National Health Act *ibid.*

<sup>802</sup> Regulation 4(c) Draft Regulations on Human Subjects (note 13 above).

relationships or comparable situations.<sup>803</sup> The draft Regulations on Human Subjects also deal with voluntariness in relation to prisoners.<sup>804</sup>

*(v) The act must be lawful*

It is a general principle of our common law that if consent is to be valid the act or conduct consented to must be in accordance with public policy and not contra bonos mores.<sup>805</sup> In other words, the consent must be permitted or ought to be permitted by the legal order.<sup>806</sup> This principle acts as a limit on individual autonomy.<sup>807</sup> Generally, courts use an objective test to establish whether consent to a particular act is considered contra bonos mores.<sup>808</sup> This involves an assessment of the prevailing legal convictions of the community.<sup>809</sup>

It is argued that in the context of health research, the prevailing legal norms are set out in the NHA. Accordingly, consent to health research would be valid if it was consistent with what is considered lawful research in the NHA, the draft Regulations on Human Subjects and the national ethical guidelines. For example, given that the NHA requires therapeutic research with minors to be in their best interests, health research which was found to be contrary to this standard could be considered contra bonos mores<sup>810</sup>

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<sup>803</sup> Regulation 4(3) *ibid.* The types of dependent relationships referred to in the draft Regulations include: (a) older persons and their care-givers; (b) patients and health-care professionals; (c) students and teachers; (d) persons with life-threatening diseases and their care-givers; (e) wards of the state and guardians or care-givers; (f) employees and employers; (g) prisoners and the relevant prison authorities; and (h) members of the South African National Defence Force.

<sup>804</sup> Regulation 5(4) *ibid.* This provides that 'Research studies involving prisoners must: (a) be undertaken in accordance with guidelines issued by the Department of Correctional Services; (b) present risks commensurate with risks that would be accepted by non-prison volunteers; (c) ensure protection of the rights of prisoners, including the right to dignity and humanity of the prisoners; and (d) facilitate the ability of prisoners, both sentenced and awaiting trial, to make voluntary decisions about research participation'.

<sup>805</sup> McQuoid-Mason (note 363 above) 14.

<sup>806</sup> Neethling, Potgieter & Visser (note 751 above) 36.

<sup>807</sup> See for example, *S v Collett* 1978 (3) SA 206 (RA) at 211D.

<sup>808</sup> Neethling (note 751 above) 36.

<sup>809</sup> *Ibid.*

<sup>810</sup> S 71(2)(a) National Health Act (note 56 above).

*(vi) Capacity*

Research participants must have legal capacity to consent to research.<sup>811</sup> The NHA stipulates that consent must be obtained from parents or legal guardians and where minors have the requisite understanding their consent must also be obtained. In other words, the NHA does not give children the capacity to consent independently to research below the age of 18 but it provides they may in certain circumstances provide dual consent alongside their parents.

This means that there are no circumstances in which persons who are legal minors can provide independent consent.<sup>812</sup> However, children who are no longer minors because they are married or have been emancipated may have the capacity to consent to health research before the age of 18.<sup>813</sup> Children who are parents would also not have the legal capacity to consent to health research on their own children even though they are ‘parents’ in terms of the NHA.<sup>814</sup> This is because as parents who are still under the age of 18 they would remain legal minors and therefore unable to meet the legal capacity requirements set by the NHA.

*5.2.2 Consent to certain therapeutic interventions that may be offered during a study*

Within some forms of health research, such as clinical trials, children may be offered a range of therapeutic services either as part of the study or as a benefit to participants. These are all relevant to the setting of research-related norms.<sup>815</sup> The age of consent to sex may also be relevant in studies relating to a child’s sexual and reproductive rights.<sup>816</sup>

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<sup>811</sup> Strode, Slack & Essack (note 143 above) 248.

<sup>812</sup> The only exception being children who have changed their legal status through marriage or emancipation.

<sup>813</sup> Heaton (note 760 above) 115.

<sup>814</sup> Strode & Slack (note 139 above) 56.

<sup>815</sup> See Table 2 in Chapter One for a comparison of these ages of consent.

<sup>816</sup> For example, Strode and Slack submit that the implications of the Sexual Offences Act for health research are that ‘in many instances researchers may become aware through bio-medical or social science research that an adolescent is involved in a sexual offences as they will have knowledge of a child’s sexual activity, this may be because they ask adolescents questions about their sexual activity, identify sexually transmitted diseases, provide HIV testing services or access to contraceptives. Many of these adolescents will be between the ages of 12–16. Through these interactions researchers may well gain knowledge of a sexual offence that has been committed against or by a child’: Strode & Slack (note 143 above) 9.



(i) *Consent to medical treatment*

The NHA provides that as a general principle a health service may not be ‘provided to a user without the user’s informed consent’.<sup>817</sup> The Children’s Act provides further that a child of 12 may consent independently to such a health service if it is considered to be a form of medical treatment provided that they have ‘sufficient maturity’ and the ‘mental capacity to understand the benefits, risks, social and other implications of the treatment’.<sup>818</sup> If the child is below the age of 12 or lacks capacity to consent, consent may be provided by amongst others, the parent, guardian or care-giver.<sup>819</sup> In certain circumstances when the parents, guardian or care-giver are not able to consent, the superintendent of the hospital or the Minister of Social Development may consent to the child’s medical treatment.<sup>820</sup>

(ii) *Consent to HIV testing*

The Children’s Act distinguishes HIV testing from medical treatment and creates four new norms relating to such testing, including that the testing must be in the best interests of the child, undertaken with informed consent, accompanied by pre- and post-test counselling and results should be kept confidential.<sup>821</sup> The Children’s Act also specifies when children will have the capacity to consent to HIV testing. Children above the age of 12 may consent independently to an HIV test. Unlike medical treatment parliament did not include a capacity requirement for HIV testing where the child is over the age of 12. This means there will be a general presumption that a child of 12 has sufficient capacity to consent to HIV testing,

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<sup>817</sup> S 7(1) National Health Act (note 57 above).

<sup>818</sup> S 129(2)(b) Children’s Act (note 4 above).

<sup>819</sup> S 129(4) *ibid.* If a child is over the age of 12 and has ‘sufficient maturity’ and the ‘mental capacity to understand the benefits, risks, social and other implications of the treatment’ they will have the capacity to consent to medical treatment on their own child as they are considered a ‘parent’ in terms of this section. For example, a 17-year-old girl who meets the capacity requirements could consent to vaccinations on her newborn baby.

<sup>820</sup> Ss 129(6)–(7) *ibid.*

<sup>821</sup> Ss 130–133 *ibid.*

children under 12 may also consent independently to HIV testing if they have 'sufficient maturity'.<sup>822</sup>

(iii) *Consent to a termination of pregnancy*

Girl children can consent to terminations of pregnancy at any age.<sup>823</sup> However, in order to ensure that they have support, section 5(3) of the Choice of Termination of Pregnancy Act (hereafter referred to as the 'Choice Act') provides that 'in the case of a pregnant minor, a medical practitioner or a registered midwife, as the case may be, shall advise such minor to consult with her parents, guardian, family members or friends before the pregnancy is terminated: provided that the termination of the pregnancy shall not be denied because such minor chooses not to consult them.'<sup>824</sup> Although the Choice Act does not specify an age at which a girl child may consent independently to a termination of pregnancy, in the *Christian Lawyers* case it was held that consent may be given only by someone with the intellectual and emotional capacity to understand the information provided, appreciate this and provide consent.<sup>825</sup> This means that young or immature girl children may not have the capacity and will not qualify to consent on their own and would need the assistance of a parent or guardian.<sup>826</sup>

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<sup>822</sup> Van Wyk (note 13 above ) 40. Nevertheless McQuoid-Mason submits that even though the Children's Act is silent on the issue of maturity with regard to HIV testing, children would have to have capacity in order to consent: D McQuoid-Mason 'The effect of the new Children's Act on consent to HIV testing and access to contraceptives by children' (2007) Vol 97(12) *SAMJ* 1252, 1253. This is in line with the outcome of the *Christian Lawyers* case (note 542 above).

<sup>823</sup> The Choice Act defines 'woman' in s 1 as 'a female person of any age'. In s 5 it provides that a termination of pregnancy may only be undertaken with 'the informed consent of the pregnant woman'. S 5(2) provides further that 'notwithstanding any other law or the common law, but subject to the provisions of subsections (4) and (5), no consent other than that of the pregnant woman shall be required for the termination of a pregnancy': Choice of Termination of Pregnancy Act 92 of 1996.

<sup>824</sup> *Ibid.*

<sup>825</sup> *Christian Lawyers Association case* (note 542 above) 516B–C.

<sup>826</sup> 516C–E *ibid.*

(iv) *Access to contraceptives and contraceptive advice.*

Children aged 12 and above may consent to contraceptives and the obtaining of contraceptive advice independently.<sup>827</sup> This means that children may access information and contraceptives within health research without the knowledge or consent of their parents if they are over the age of 12.

(v) *Consent to male circumcision*

The Children's Act limits the circumstances in which boys may be circumcised by prohibiting circumcisions on boys below the age of 16 unless they are performed for cultural, religious or medical reasons.<sup>828</sup> Boys below this age require the assistance of an appropriate adult as they cannot consent independently until they are 16.<sup>829</sup> The Children's Act does not describe the adults who would have the capacity to consent to a circumcision on boys below the age of 16. It is assumed that it would only be persons with full parental rights and responsibilities.<sup>830</sup> With boys above the age of 16, the Children's Act provides that they must (a) provide their own consent to the circumcision,<sup>831</sup> (b) receive counselling prior to the circumcision, and (c) the procedure must be carried out in the prescribed manner.<sup>832</sup> Taking into account a boy child's 'age, maturity and stage of development' every boy has the right to refuse to be circumcised.<sup>833</sup>

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<sup>827</sup> S 134 Children's Act (note 4 above).

<sup>828</sup> S 12(8) *ibid*. See DJ McQuoid-Mason 'Is the mass circumcision drive in KwaZulu Natal involving neonates and boys under 16 years of age legal? What should doctors do?' (2013) Vol 103(5) *South African Medical Journal* 283–284 for further discussion on when male circumcision on boys is lawful.

<sup>829</sup> S 12(9) *ibid*. The Children's Act is silent on which adults have the capacity to provide consent to a circumcision on a boy under the age of 16.

<sup>830</sup> S 18(2) *ibid* provides that parental rights and responsibilities include: firstly, a duty to care for the child; secondly, an obligation to maintain contact with the child; thirdly, to act as guardian of the child; and fourthly to contribute to the maintenance of the child. Persons with partial parental rights and responsibilities are required to safeguard the child's health, well-being and development and protect the child from harm: s 32(1) Children's Act *ibid*. It is argued that given these duties decision-making regarding male circumcision clearly falls within the obligations of persons with either full or partial parental rights and responsibilities.

<sup>831</sup> This must be provided in writing on a form identical to Form 2 from the Regulations: Regulation 5(1)(a), Consolidated Regulations Pertaining to the Children's Act, 2005, *Government Gazette* No. 33076, 1 April 2010.

<sup>832</sup> S 12(9) Children's Act (note 4 above).

<sup>833</sup> S 12(10) *ibid*.

(vi) *Capacity to consent to sex*

The Criminal Law (Sexual Offences and Related Matters) Amendment Act (hereafter referred to as the Sexual Offences Act)<sup>834</sup> describes a number of crimes against and involving children that may impact on health research. The Sexual Offences Act provides that a male or female under the age of 12 is incapable of consenting to a sexual act.<sup>835</sup> The age of consent to sexual penetration and other related sexual activities is 16. Until very recently, the Sexual Offences Act provided that if a child between the ages of 12 and 15 engaged in consensual sexual activity which included penetration, they would have been committing the crime of consensual sexual penetration with a child, or statutory rape.<sup>836</sup> If a child between the ages of 12 and 15 engaged in consensual sexual activity which included non-penetrative direct or indirect contact with the genital organs or mouth, they would have committed the crime of consensual sexual violation with a child or statutory sexual assault.<sup>837</sup>

The situation changed with a decision by the Gauteng High Court in January 2013 in the *Teddy Bear Clinic for Abused Children and Prevention of Child Abuse and Neglect (RAPCAN) v Minister of Justice and Constitutional Development* case.<sup>838</sup> In this matter the court found that where sections 15 and 16 of the Sexual Offences Act criminalised consensual sex and sexual activity between children of 12–15 or those of 12–15 with partners of 16 and 17 provided there was no more than a two-year age gap between them (if their partner was

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<sup>834</sup> Sexual Offences Act (note 765 above).

<sup>835</sup> S 57(1) *ibid.*

<sup>836</sup> S 15 *ibid.*

<sup>837</sup> S 16 *ibid.* A further complexity was that there was a mandatory reporting obligation on all persons aware of a sexual offence against a child, this obligation included the reporting of consensual sexual activity to the police: see D McQuoid-Mason 'Mandatory Reporting of sexual abuse under the Sexual Offences Act and the best interests of the child' (2011) Vol 4(2) *South African Journal of Bioethics and Law* 74–78 for further discussion on this issue. Also see Strode & Slack (note 143 above) where the authors look at the mandatory reporting of consensual sex within the context of health research.

<sup>838</sup> Case number 73300/10.

over 15), these were inconsistent with the Constitution.<sup>839</sup> This means that researchers enrolling children engaged in consensual under-age sex will no longer have to report these activities unless there is (a) a large age gap between the participants, or (b) one of the partners is under 12 or over the age of 18.

**Table 15: Consensual sexual offences by adolescents**

<b>Any person having consensual sex with a child below the age of 12</b>	<b>Children between 12–15 have consensual peer sex</b>	<b>Children between 12–15 having sex with partners of 16 or 17</b>	<b>Children between 12–15 having sex with partners of 18 or older</b>
All consensual sex is illegal – child has no capacity to consent to sex	Consensual sex between children who are both between 12–15 is not illegal	Consensual sex between children who are 12–15 is not illegal if their partner is 16 or 17 and there is no more than a two-year age gap between them	Consensual sex between children who are 12–15 is illegal if their partner is 18 or older
Older person commits a crime, the child under 12 is the ‘victim’	Neither party commits a crime	Neither party is committing a crime	Person over 18 commits a crime

### 5.2.3 Privacy<sup>840</sup>

Everyone has a right to privacy.<sup>841</sup> The right extends to those aspects of a person’s life that both the individual and society consider private.<sup>842</sup> Private facts are information which if disclosed ‘will cause mental distress and injury to anyone possessed of ordinary feelings and intelligence in the same circumstances and in respect of which there is a will to keep them private.’<sup>843</sup> In terms of this approach the right to privacy will be infringed if an expectation of

<sup>839</sup> Para 113 *ibid*. Also see DJ Mc Quoid Mason ‘Decriminalisation of consensual sexual conduct between children: What should doctors do regarding the reporting of sexual offences under the Sexual Offences Act until the Constitutional Court confirms the judgement of the Teddy Bear Clinic case? (2013) Vol 6(1) *SAJBL* 11 – 12 for a more in-depth discussion of the case.

<sup>840</sup> This section is based substantially on an article provisionally accepted for publication to the *Southern African Journal of HIV Medicine* in April 2013 namely, A Strode & C Slack ‘Adolescent privacy rights: A “Cinderella” issue in health research?’ Strode was the first author in this publication. She prepared the initial draft setting out the law on privacy. The application of these legal principles to research was developed collectively.

<sup>841</sup> A Govindjee ‘The right to privacy’ in A Govindjee & P Vrancken (eds) *Introduction to Human Rights* (2009) 101, 101–102.

<sup>842</sup> Currie & De Waal (note 776 above) 318.

<sup>843</sup> *National Media Ltd and Another v Jooste* 1996 (3) SA 262 (A) quoted in *NM and Others v Smith and Others (Freedom of Expression Institute as Amicus Curiae)* (note 357 above) para 34.

privacy existed and that expectation was considered reasonable.<sup>844</sup> Currie and De Waal argue that the subjective expectation of privacy means anything considered private by the individual themselves.<sup>845</sup> The objective element requires that this expectation must be reasonable.<sup>846</sup> An assessment of whether the right to privacy has been infringed should be based on an understanding of the value underpinning the right namely, the protection of an individual's autonomous identity and dignity.<sup>847</sup> Invasions of privacy which infringe a person's dignity ought to be regarded as unreasonable.<sup>848</sup>

Constitutional and other rights apply in most instances to adults and children equally.<sup>849</sup> Thus by implication children are entitled to the right to privacy. In the recent *Teddy Bear Clinic* case the court held that the Constitution recognises that children are the bearers of rights and that they 'are entitled to a realm of personal space and freedom in which to live their own lives'.<sup>850</sup> Nevertheless, applying these privacy principles to children is complex as they do not always have the capacity to form a subjective expectation of privacy. Or they may have less of an expectation of privacy in certain circumstances. Furthermore, the reasonableness of such an expectation, if it exists, will depend on a range of factors including whether a statutory limitation, such as a mandatory reporting obligation, limits the right.

It is argued that within the context of health research the right to privacy means that research participants can expect that their participation in a study will remain confidential unless they have agreed otherwise. Furthermore, any information disclosed or obtained

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<sup>844</sup> *Ibid.* This is also referred to as the 'legitimate expectation' test.

<sup>845</sup> *Ibid.* This element of the test enables individuals to waive their right to privacy by expressly consenting to an invasion of privacy. In such a case an individual cannot have a subjective expectation of privacy as they have consented to the disclosure or to allow others access to the information.

<sup>846</sup> *Bernstein and Others v Bester NO 1996 (2) SA 751 (CC) para 67.*

<sup>847</sup> Currie & De Waal (note 776 above) 319–320.

<sup>848</sup> *Ibid.*

<sup>849</sup> *Ibid.*

<sup>850</sup> *Teddy Bear Clinic and RAPCAN case (note 838 above) para 80.*

from participants during research will not be linked to their identity in any way unless agreement is given for such a disclosure.<sup>851</sup>

There have not been any legislative provisions dealing with a research participant's right to privacy, and the NHA is silent on this issue.<sup>852</sup> The NHREC Guidelines however describe the ethical norm on privacy as being that the:

researcher must ensure that 'where personal information about research participants or a community is collected, stored, used or destroyed, this is done in ways that respect the privacy or confidentiality of the participants or the community and any agreements made with the participants or community.'<sup>853</sup>

The draft Regulations change this position by stating in Regulation 2(f) that research involving human subjects must 'ensure that participants' rights are respected, including their rights to dignity, privacy, bodily integrity and equality.'<sup>854</sup> No further explanation is given of how the right to privacy will apply to health research or of the nature of the duty that this imposes on researchers. Although the NHA does not address privacy within research, the Children's and the Choice Acts specify how privacy rights apply in relation to certain other health care services by stating:

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<sup>851</sup> The NHREC Guidelines define privacy as a 'zone of exclusivity where individuals and collectivities are free from scrutiny of others. It may also include control over the extent, timing and circumstances of sharing oneself with others, whether physically, intellectually or in terms of behaviour': Point 1.4 NHREC Guidelines (note 56 above). These Guidelines distinguish between privacy and confidentiality. They state that the right to privacy deals with access to personal records whilst the right to confidentiality refers to the use of personal information once it has been disclosed: 2.7 *ibid*.

<sup>852</sup> The National Health Act (note 57 above) does however describe the right to privacy within the context of a therapeutic relationship. S 14(1) provides that a user has the right to confidentiality of all health information. Nevertheless s 14(2)(a)–(c) limits this right by stating that disclosures may be made if the user consents in writing to these, if a court order or law requires the disclosure, or if non-disclosure presents a serious public health threat. Furthermore, s 15(1) provides that a health care worker may disclose personal information about a user provided it is within the ordinary scope of their duties, necessary for a legitimate purpose and is in the interests of the user.

<sup>853</sup> 2.7 NHREC Guidelines (note 56 above).

<sup>854</sup> Draft Regulations on Human Subjects (note 13 above).

- (i) Children have the right to privacy regarding their ‘health status’ and access to condoms, contraceptives and contraceptive advice;<sup>855</sup>
- (ii) No person may disclose a child’s HIV status without the child or another responsible adult’s consent;<sup>856</sup>
- (iii) A child’s rights to privacy may be limited where this is in their best interests or where this is required by other provisions in the Children’s Act such as mandatory reporting obligations;<sup>857</sup> and
- (iv) The ‘identity of a woman who has requested or obtained a termination of pregnancy shall remain confidential at all times unless she herself chooses to disclose that information’.<sup>858</sup>

The Children’s Act also provides that a child has the capacity to consent independently to a number of therapeutic interventions.<sup>859</sup> Although it does not specify that children have a right to privacy regarding such services, it is argued that as they do not need parental assistance they would have an expectation of privacy which would be considered reasonable.<sup>860</sup>

It has been submitted that based on the general principles relating to privacy described above, the following norms can be extrapolated to guide health researchers. These are:

- (i) Children do not have a right to privacy regarding their participation in health research as parental or guardianship consent is always required in terms of section 71 of the NHA;

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<sup>855</sup> S 13(1)(d) and s 134(3) Children’s Act (note 4 above).

<sup>856</sup> Ss 133(1) and 110 *ibid.*

<sup>857</sup> S 13(d) *ibid.*

<sup>858</sup> S 7(5) Choice of Termination of Pregnancy Act (note 823 above). See the same note above regarding the meaning of ‘woman’ in terms of the Choice Act.

<sup>859</sup> These include for example, medical treatment and male circumcision. See Table 2 in Chapter One for a full list of these interventions.

<sup>860</sup> Strode & Slack (note 840 above).

- (ii) Children may have the right to privacy regarding certain therapeutic health interventions in a study to which they will be consenting independently, such as HIV testing or treatment for sexually transmitted infections (See Table 16 below); and
- (iii) A child’s right to privacy within research may be limited by both the concept of the best interests of the child or specific statutory provisions such as those relating to mandatory reporting.

**Table 16: Therapeutic interventions in respect of which children have the right to privacy within health research**

Health intervention to which children can expect privacy	Age at which children can expect that their privacy will be respected	Authority
Condoms, contraceptives and contraceptive advice	12	Children’s Act
HIV testing	12 or below the age of 12 if the child has ‘sufficient maturity’	Children’s Act
Termination of pregnancy	No age of specified	Choice of Termination of Pregnancy Act
Medical treatment	12, provided the child has ‘sufficient maturity’	Children’s Act
Male circumcision	16	Children’s Act
Operations	12 and the child is of ‘sufficient maturity and has the mental capacity to understand the benefits, risks, social and other implications of the surgical operation’. Child must be assisted by his or her parent or guardian	Children’s Act

#### 5.2.4 Dignity

The right to dignity is well established in international<sup>861</sup> and domestic law, and is increasingly being applied in the context of health research.<sup>862</sup>

<sup>861</sup> Article 10, International Convention on Civil and Political Rights (note 9 above).

<sup>862</sup> Kirchhoffer & Dierick (note 403 above) 75.

The Constitution provides in section 10 that everyone has inherent dignity and the right to have their dignity respected and protected.<sup>863</sup> This right requires a recognition of the intrinsic worth of human beings. This is done through ensuring that everyone is regarded as being worthy of equal respect and concern.<sup>864</sup> The Constitutional Court has also recognised that children have the right to have their dignity respected.<sup>865</sup>

Stone and Vrancken argue that as dignity is a highly personal right which is linked to one's own sense of inner value, to establish whether an infringement has occurred one must assess the impact of the offending conduct or law on the person.<sup>866</sup> The Constitutional Court has on a number of occasions articulated the importance of this right:

[T]he Constitution asserts dignity to contradict our past in which human dignity for black South Africans was routinely and cruelly denied. It asserts it too to inform the future, to invest in our democracy respect for the intrinsic worth of all human beings. Human dignity therefore informs constitutional adjudication and interpretation at a range of levels. It is a value that informs the interpretation of many, possibly all, other rights. This Court has already acknowledged the importance of the constitutional value of dignity in interpreting rights such as the right to equality, the right not to be punished in a cruel, inhuman or degrading way, and the right to life . . . In many cases, however, where the value of human dignity is offended, the primary constitutional breach occasioned may be of a more specific right such as the right to bodily integrity, the right to equality or the right not to be subjected to slavery, servitude or forced labour.<sup>867</sup>

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<sup>863</sup> S 10 Constitution of the Republic of South Africa (note 2 above).

<sup>864</sup> *S v Makwanyane* 1995 (3) SA 391 (CC) para 328. In *S v Jordan* the Constitutional Court held that this right inheres in its various aspects of what it means to be a human being: 2002 (6) SA 642 (CC) para 74.

<sup>865</sup> *S v M (Centre for Child Law as Amicus Curiae)* 2008 (3) SA 232 (CC) para 18.

<sup>866</sup> L Stone & P Vrancken 'Human dignity' in Govindjee & Vrancken (note 823 above) 68.

<sup>867</sup> *Dawood v Minister of Home Affairs* 2000 (3) SA 936 (CC) para 35.

The NHA is silent on the rights of research participants to dignity. However the NHREC Guidelines provide that all research participants have the right to have their dignity respected:

Respect for the dignity, safety and well-being of participants should be the primary concern in health research involving human participants. Culture, language, beliefs, perceptions, and customs must all be considered.<sup>868</sup>

The draft Regulations change the current lack of legal reference to the right to dignity by stating that research participants have the right to respect for their dignity.<sup>869</sup> They do not however set out the implications this has for the way in which research with human participants is undertaken. Nevertheless, it is submitted that this requires research to be conducted in a way which respects the inherent dignity of participants. In other words, researchers would be required to ensure that participants are treated with respect and not simply as a means to an end.

#### 5.2.5 Equality

The right to equality is well established in international law.<sup>870</sup> It is also recognised as being an element of the ethical principle of justice.<sup>871</sup>

Everyone has the right to equality.<sup>872</sup> This is the right to equal protection from the law, equal access to all rights and freedoms and the right to not be unfairly discriminated against.<sup>873</sup>

Given our history equality has a central place in our constitutional framework.<sup>874</sup>

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<sup>868</sup> Point 2.1 NHREC Guidelines (note 56 above).

<sup>869</sup> Regulation 2(f) draft Regulations on Human Subjects (note 13 above).

<sup>870</sup> Article 3 International Convention on Civil and Political Rights (note 175 above).

<sup>871</sup> Tangwa (note 597 above) 56.

<sup>872</sup> S 9 Constitution of the Republic of South Africa (note 2 above) and s 6 Promotion of Equality Prevention of Unfair Discrimination Act 4 of 2000.

<sup>873</sup> *Ibid* and S Jagwanth 'Expanding equality' (2005) *Acta Juridica* 131, 131.

The policy of apartheid, in law and in fact, systematically discriminated against black people in all aspects of social life. Black people were prevented from becoming owners of property or even residing in areas classified as 'white', which constituted nearly 90% of the land mass of South Africa; senior jobs and access to established schools and universities were denied to them; civic amenities, including transport systems, public parks, libraries and many shops were also closed to black people. Instead, separate and inferior facilities were provided. The deep scars of this appalling programme are still visible in our society. It is in the light of that history and the enduring legacy that it bequeathed that the equality clause needs to be interpreted.<sup>875</sup>

Nevertheless equality is a difficult and idealistic notion.<sup>876</sup> It can be violated not only when people are treated differently (formal equality)<sup>877</sup> but also when there is a failure to treat persons whose situations are different in a different manner, that is, the need for non-identical treatment to redress imbalances (substantive equality).<sup>878</sup> Establishing when a law,

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<sup>874</sup> *Ibid.*

<sup>875</sup> *Brink v Kitshoff NO 1996 (4) SA 197 (CC) para 40.*

<sup>876</sup> *Currie & De Waal (note 776 above) 230.*

<sup>877</sup> *Minister of Home Affairs and Another v Fourie and Another* is an example of formal equality 2006 (3) BCLR 355 (CC). In this matter gay couples were being treated differently to heterosexual couples as they were excluded from getting married by s 30(1) of the Marriage Act 25 of 1961 which provided that a marriage was the union of a wife and husband. The Constitutional Court held that this was a discriminatory form of unequal treatment on the grounds of 'sexual orientation': para 114.

<sup>878</sup> *Jagwanth (note 873 above) 132–133.* The Constitutional Court has held that 'equality should not be confused with uniformity . . . Substantive equality means treating persons with equal concern and respect across difference. It does not presuppose the elimination or suppression of difference': *National Coalition of Gay and Lesbian Equality v Minister of Justice 1999 (1) SA 6 (CC) para 132.* *President of the RSA v Hugo 1997 (4) SA 1 (CC)* is an example of the Constitutional Court's approach to substantive equality. In this matter President Mandela, using powers granted to him in the Interim Constitution of the Republic of South Africa, granted a remission of sentence to all mothers who were in prison on 10 May 1004 (provided they fell in certain categories) and had minor children under the age of 12. Hugo, an incarcerated male, who met all the requirements except that he was a father as opposed to a mother, argued that President Mandela had acted unconstitutionally in unfairly discriminating against fathers on the grounds of 'sex' when granting a presidential pardon to prisoners. The Constitutional Court held that the President's actions did not infringe the equality clause as to discriminate against fathers in this context was not unfair. Mothers had been a group facing enormous burdens and this had disadvantaged them. Thus relative to mothers, fathers were not a disadvantaged group and it was not unfair to discriminate against them. In other words the Constitutional Court

policy or conduct is discriminatory is achieved through the test for unfair discrimination.<sup>879</sup> The Promotion of Equality and Prevention of Unfair Discrimination Act provides that discrimination will exist if there is an 'act or omission, including a policy, law, practice, condition or situation which directly or indirectly imposes burdens, obligations or disadvantage on; or withholds benefits, opportunities or advantages from any person on one or more grounds'.<sup>880</sup> The test for whether such discrimination is unfair is set out in section 14 of the Equality Act. It requires a consideration of whether the alleged discrimination was fair by reviewing the context of the complaint, a range of factors relating to the impact and justifications for the discrimination and whether the discrimination was based on objectively determinable criteria, intrinsic to the activity.<sup>881</sup>

The only laws which refer to the rights of research participants to be treated equally are (a) the draft Regulations on Human Subjects which state that their rights to equality must be respected.<sup>882</sup> They do not give any further detail on how this principle would apply to health research. (b) The Schedule of an Illustrative List of Unfair Practices in certain Sectors which is attached to the Equality Act. This Schedule lists subjecting persons to research without their consent as an example of a discriminatory practice.<sup>883</sup>

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held that treating men differently to women was not unfair as giving women preferential treatment resulted in an equal outcome, a society based on egalitarian principles.

<sup>879</sup> Jagwanth (note 873 above) 133.

<sup>880</sup> S 1 Promotion of Equality and Prevention of Unfair Discrimination Act (note 872 above). The listed grounds include race, gender, sex, pregnancy, marital status, ethnic or social origin, colour, sexual orientation, age, disability, religion, conscience, belief, culture, language and birth.

<sup>881</sup> Factors include, amongst others, whether the discrimination impairs or is likely to impair human dignity, the impact or likely impact of the discrimination on the complainant, whether the discrimination has a legitimate purpose, the nature of the discrimination and any steps that have been taken to address diversity. See also C Albertyn, B Goldblatt & C Roederer (eds) *Introduction to the Promotion of Equality and Prevention of Unfair Discrimination Act, Act 4 of 2000* (2001) where the application of the test for unfair discrimination is discussed in more detail, 32–48.

<sup>882</sup> Regulation 2(f) Draft Regulations on Human Subjects (note 13 above).

<sup>883</sup> Promotion of Equality and Prevention of Unfair Discrimination Act (note 872 above) illustrative list of unfair practices in certain sectors.

It is submitted that the right to equality in this context means that research participants may not be unfairly excluded from research participation on arbitrary grounds such as race or gender as it has a disparate impact on their benefiting from the outcomes of health research. This is a particularly important issue for children as traditionally they have been excluded from research and this has resulted, for example, in the undesirable off-label use of medication with them.<sup>884</sup> The populations being targeted for the recruitment of research participants should also not unfairly focus on certain groups which have to then disproportionately bear the burdens and risks of research.

### **5.3 Obligations on researchers to promote the welfare of child research participants**

#### *5.3.1 Therapeutic research is in the best interests of the child*<sup>885</sup>

Section 71(2) of the NHA provides that therapeutic health research with minors may only be conducted if 'it is the best interests of the minor'.<sup>886</sup> This new norm requires researchers to demonstrate that the nature of the therapeutic health research is such that it is in the best interests of the potential child participants.<sup>887</sup> This provision adds to the norms in section 11 of the NHA which deal with research which takes place at a health establishment or forms part of a health service.<sup>888</sup> However, there is no further guidance provided in the draft Regulations on Human Subjects regarding how this principle is to be applied within the context of health research with minors.

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<sup>884</sup> See Chapter One for more detailed discussion on this point.

<sup>885</sup> This section is based largely on the ideas articulated in earlier work done in Stobie, Strode & Slack (note 59 above). In this Chapter, Strode was the second author. She wrote the sections describing the legal framework, including the description of the best interests principle. The analysis of these principles was developed collectively.

<sup>886</sup> National Health Act (note 57 above). Therapeutic research is not defined in the NHA or the draft Regulations but it has been suggested that this is research that holds out the prospect of direct benefit to the participant.

<sup>887</sup> Stobie, Strode & Slack (note 59 above) 198.

<sup>888</sup> National Health Act (note 57 above).

The concept of the best interests of the child has been recognised within our common law for almost 100 years.<sup>889</sup> Our courts have generally held that in applying this principle a wide range of factors should be considered to establish if a decision is to promote a child's physical, moral, emotional and spiritual welfare.<sup>890</sup> Essentially courts must evaluate, weigh and balance these competing factors including a consideration of the child's wishes.<sup>891</sup>

In the post-Apartheid era considering the best interests of the child has become a constitutional imperative as section 28(2) of the Constitution states that a child's best interests are of paramount importance in every matter concerning the child.<sup>892</sup> The Constitutional Court has stated that the standard should be flexible, as individual circumstances will determine which factors secure the best interests of a particular child.<sup>893</sup>

Section 7 of the Children's Act codifies the factors that ought to be used when applying this principle:<sup>894</sup>

(1) Whenever a provision of this Act requires the best interests of the child standard to be applied, the following factors must be taken into consideration where relevant, namely

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<sup>889</sup> Stobie, Strode & Slack (note 59 above).

<sup>890</sup> *McCall v McCall* (note 68 above).

<sup>891</sup> *F v F* [2006] 1 All SA 571 (SCA) 10.

<sup>892</sup> Constitution of the Republic of South Africa (note 2 above). The Constitutional Court has emphasised the importance of the use of this principle in interpretation in *S v M (Centre for Child Law as Amicus Curiae)* (note 865 above) para 15 where it stated that the 'comprehensive and emphatic language of s 28 indicates that just as law enforcement must always be gender-sensitive, so must it always be child-sensitive; that statutes must be interpreted and the common law developed in a manner which favours protecting and advancing the interests of children; and that courts must function in a manner which at all times shows due respect for children's rights.' The best interests of the child is therefore both a right and a guiding principle: *Minister of Welfare and Population Development v Fitzpatrick and Others* 2000 (7) BCLR 713 (CC) para 17.

<sup>893</sup> *Ibid* para 18. The best interests inquiry has subjective and objective elements. In the Australian case of *In the Marriage of Homan* the court held that the 'test of the welfare of the child has to be determined having regard to contemporary social standards, that is, it cannot be a totally subjective test based upon the views or standards of the individual parent [or child or other interested party] but objective at least in the sense of falling within the wider range of existing social standards' (1976) FLC 90-024 quoted in J Heaton 'Some general comments on the concept of the best interests of the child' (1990) Vol 53 *THRHR* 97, 101.

<sup>894</sup> Children's Act (note 4 above).

- (a) the nature of the personal relationship between
  - (i) the child and the parents, or any specific parent; and
  - (ii) the child and any other care-giver or person relevant in those circumstances;
- (b) the attitude of the parents, or any specific parent, towards
  - (i) the child; and
  - (ii) the exercise of parental responsibilities and rights in respect of the child;
- (c) the capacity of the parents, or any specific parent, or of any other care-giver or person, to provide for the needs of the child, including emotional and intellectual needs;
- (d) the likely effect on the child of any change in the child's circumstances, including the likely effect on the child of any separation from
  - (i) both or either of the parents; or
  - (ii) any brother or sister or other child, or any other care-giver or person, with whom the child has been living;
- (e) the practical difficulty and expense of a child having contact with the parents, or any specific parent, and whether that difficulty or expense will substantially affect the child's right to maintain personal relations and direct contact with the parents, or any specific parent, on a regular basis;
- (f) the need for the child
  - (i) to remain in the care of his or her parent, family and extended family; and
  - (ii) to maintain a connection with his or her family, extended family, culture or tradition;
- (g) the child's:
  - (i) age, maturity and stage of development;
  - (ii) gender;
  - (iii) background; and
  - (iv) any other relevant characteristics of the child;
- (h) the child's physical and emotional security and his or her intellectual, emotional, social and cultural development;

- (i) any disability that a child may have;
  - (j) any chronic illness from which a child may suffer;
  - (k) the need for a child to be brought up within a stable family environment and, where this is not possible, in an environment resembling as closely as possible a caring family environment;
  - (l) the need to protect the child from any physical or psychological harm that may be caused by:
    - (i) subjecting the child to maltreatment, abuse, neglect, exploitation or degradation or exposing the child to violence or exploitation or other harmful behaviour; or
    - (ii) exposing the child to maltreatment, abuse, degradation, ill-treatment, violence or harmful behaviour towards another person;
  - (m) any family violence involving the child or a family member of the child; and
  - (n) which action or decision would avoid or minimise further legal or administrative proceedings in relation to the child.
- (2) In this section parent includes any person who has parental responsibilities and rights in respect of a child.

Nevertheless, applying this principle to health research is complex.<sup>895</sup> It has been argued that achieving a balance between promoting the best interests of children as a class and as individual research participants is difficult, as allowing the involvement of children in research so as to develop new health interventions which are in the best interests of all children, is not always in the best interests of those who bear the individual burdens and risks of research participation.<sup>896</sup> This task is made even more difficult by (a) the limited legal literature on what this obligation means in the context of health research, and the absence

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<sup>895</sup> Stobie, Strode & Slack (note 59 above) 201.

<sup>896</sup> 200–201 *ibid*. Given this complexity it has been argued by some that it is not possible for some forms of health research to be in the best interests of the child, instead it can at most not be contrary to their best interests: see Roscam Abbing (note 47 above) for a more detailed explanation of this argument.

of research-specific case law,<sup>897</sup> (b) the wording in the NHA which requires therapeutic study to be in the best interests of individual child participants rather than children as a class, and (c) the limited examples of how the principle has been used in other jurisdictions except in English law, where it has been argued that subjecting a child to an unacceptable risk level is contrary to their best interests.<sup>898</sup>

Stobie et al submit that the principle should be applied in the following way:

Firstly, the need to protect children must be balanced with an equal need to facilitate their participation in research. Secondly, the need to protect the child from research-related risks must be balanced against the potential health benefits of enrolment to child trial participants, as well as children in broader society who will benefit from receiving an efficacious vaccine. The criteria used in the best interests analysis are able to accommodate these diverse considerations when carefully balanced. It is not dissimilar to a risk-benefit analysis, as it requires a consideration of both what may be harmful to the child and what may benefit a child.<sup>899</sup>

### 5.3.2 Ministerial approval is obtained for non-therapeutic research with minors<sup>900</sup>

Section 71(3) of the NHA creates an obligation to obtain consent from the Minister of Health for all forms of non-therapeutic research with minors.<sup>901</sup> This is a new layer of research regulation which requires the Minister of Health to determine whether non-therapeutic

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<sup>897</sup> *Ibid.*

<sup>898</sup> Kennedy & Grubb (note 51 above) 1729–1730.

<sup>899</sup> Stobie, Strode & Slack (note 59 above) 202.

<sup>900</sup> This section is based substantially on earlier work published as Strode, Slack, Wassenaar & Singh (note 119 above). Strode was the first author of this piece. Strode and Slack conceptualised the article. Strode prepared the first draft. Wassenaar and Singh provided specific insights to sections of the article.

<sup>901</sup> National Health Act (note 57 above). The term non-therapeutic research is not defined in the National Health Act but the draft Regulations on Human Subjects define it as ‘any research not directed towards the benefit of individual but rather towards improving scientific knowledge or technical application and developing generalisable knowledge’: Regulation 1 Draft Regulations on Human Subjects (note 13 above).

research with minors meets scientific, ethical and public policy justifications. Any research which does not receive ministerial consent may not be undertaken.<sup>902</sup> The NHA requires the existence of four pre-conditions before ministerial consent may be granted for non-therapeutic research with minors.

*i. Children must be indispensable to the research*

Section 71(3)(b) of the NHA provides that research may only be approved by the Minister of Health if it can be shown that participation of minors is indispensable to the research. This condition appears to refer to the ethical principle of 'scientific necessity'. Currently, the NHREC Guidelines require researchers to justify the inclusion of children in a study. In other words, there is an ethical obligation to expressly set out why the study could not be done on a less vulnerable population such as adults.<sup>903</sup> Researchers will have to show that the study relates to, for example, the health of children living in child-headed households and therefore cannot be undertaken on any other population.

*ii. The research will result in significant improvement in the understanding of the minor's condition or disorder*

Section 71(3)(b) of the NHA requires researchers to demonstrate that the study will result in a significant improvement in the understanding of the minor's condition or disorder. It is argued that this consideration also requires the scientific merits and its relevance to be demonstrated. In other words, it appears that the Minister of Health may only grant consent for the study to be undertaken if it can be shown that it will result in 'significant' improvements to our understanding of the condition or disorder.

The wording used in this instance is problematic as so-called non-therapeutic research involves the enrolment of healthy individuals and not those with a condition or disorder.

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<sup>902</sup> Strode, Slack, Wassenaar & Singh (note 119 above) 202.

<sup>903</sup> S 5.3.1 NHREC Guidelines (note 56 above) and Pope (note 93 above) 179.

Accordingly, it has been argued that the use of the words ‘condition, disease or disorder; should be interpreted broadly to include something a minor may be at risk of acquiring at some point in the future. or a set of physical, psychological, neuro-developmental, or social characteristics that has been shown to affect the health, well-being or risk of future health problems for children’.<sup>904</sup> This appears to be the only way in which so-called non-therapeutic research which involves healthy children can be approved. This would mean, for example, that an HIV vaccine study could be undertaken with children. In such a case, HIV negative children would be enrolled and it would have to be argued that although they do not have the ‘condition’ (HIV) they are at risk of acquiring it.

*iii. Consent to the research will not be contrary to public policy*

The third consideration that must be taken into account by the Minister of Health in terms of s 71(3)(b) is whether consent to the research by the parents, legal guardian or the minor will be contrary to public policy.<sup>905</sup> It is a well-established common law principle that consent to medical treatment must not be *contra bonos mores*.<sup>906</sup> It has been argued that this requires any consent to harm or the risk of harm to be in line with public policy and prevailing legal norms.<sup>907</sup> In determining the acceptability of the consent it is submitted that courts examine prevailing legal norms within that particular area of the law, including those established by the Constitution.<sup>908</sup> For child research, the Minister of Health would have to examine the legal norms underlying children’s law and research-related legislation. Key considerations could be the emphasis in the Children’s Act on promoting child well-being and protecting children from discrimination, exploitation and any other physical, emotional or moral harm.<sup>909</sup> It has also been argued that research would be in accordance with public policy if it

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<sup>904</sup> Smit (note 34).

<sup>905</sup> National Health Act (note 57 above).

<sup>906</sup> McQuoid-Mason (note 363 above) 8.

<sup>907</sup> Strode & Slack (note 143 above)

<sup>908</sup> *Ibid* and *S v Collett* (note 807 above).

<sup>909</sup> Children’s Act (note 4 above).

presents acceptable standards of risk.<sup>910</sup> The NHA sets a standard of acceptable risk by stating that the non-therapeutic research with minor's research must not pose a significant risk to their health.<sup>911</sup>

*iv. The research does not pose a significant risk to the minor, or if there is some risk this is outweighed by the benefits to the minor*

The final consideration for the Minister of Health when approving non-therapeutic research with minors is that the health research must not be a significant risk and if there is some risk it must be outweighed by the benefits to the minor.<sup>912</sup> 'Significant risk' is a new term within our ethical-legal framework. Currently, the highest acceptable level of risk for non-therapeutic research set in most ethical guidelines is that of a minor increase over minimal risk.<sup>913</sup> It appears that a significant risk may represent a new upper level of risk as it appears to be more than a minor increase over minimal risk.

Finally, the draft Regulations do not deal with how or when ministerial consent must be obtained. Thus, although this provision became operational on 1 March 2012 it appears that no applications for ministerial consent have been made as yet. How the provision will operate in the future is unclear. It is possible that any regulations which are published in the future will detail how researchers apply for ministerial consent after receiving ethical approval (See Figure 3 below).

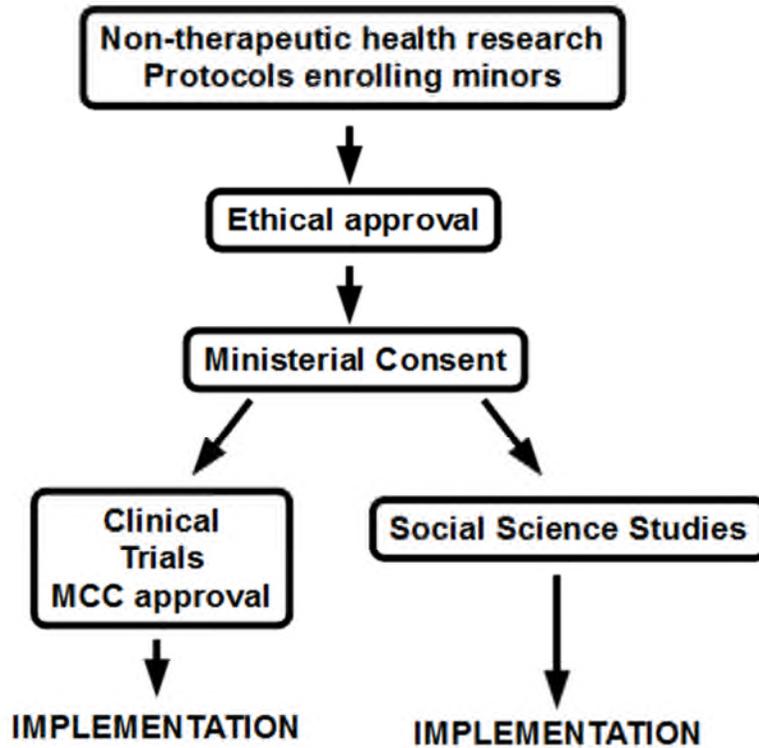
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<sup>910</sup> Van Oosten (note 104 above) 6 and Van Wyk (note 13 above) 12.

<sup>911</sup> S 71(3)(b)(iv) National Health Act (note 57 above).

<sup>912</sup> *Ibid.*

<sup>913</sup> Strode & Slack (note 143 above).



**Figure 3: The possible procedure that will have to be followed when undertaking non-therapeutic health research with minors**

### 5.3.3 Mandatory reporting of children in need of care and protection

There are a number of legal provisions which ensure that children in need of care or protection are identified and steps taken to protect them from further harm. These provisions place obligations on various people to report children who are being abused, neglected or who are in need of care and protection.<sup>914</sup> Children participating in research are

<sup>914</sup> S 110 Children’s Act (note 4 above). The Children’s Act defines all three terms. Abuse is defined as ‘any form of harm or ill-treatment deliberately inflicted on a child, and includes— (a) assaulting a child or inflicting any other form of deliberate injury to a child; (b) sexually abusing a child or allowing a child to be sexually abused; (c) bullying by another child; (d) a labour practice that exploits a child; or (e) exposing or subjecting a child to behaviour that may harm the child psychologically or emotionally’. Neglect is described in the same section as ‘a failure in the exercise of parental responsibilities to provide for the child’s basic physical, intellectual, emotional or social needs’: s 1 *ibid*. In contrast children in need of care and protection are defined according to the vulnerable circumstances they may find themselves in. S 150(1) provides that a child will be in need of care and protection if (a) they have been abandoned or orphaned and are without any visible means of support; (b)

in a special relationship with researchers and in certain circumstances as a result of information disclosed or discovered, mandatory reporting obligations may be triggered. Furthermore, the draft Regulations on Human Subjects require researchers to comply with mandatory reporting obligations by at a minimum providing that they must 'refer participants for professional assistance where necessary'.<sup>915</sup>

The Children's Act requires reportable information to be submitted to the provincial Department of Social Development, a designated child protection organisation or the police for further investigation.<sup>916</sup> Section 110(1) of the Children's Act identifies the following persons who are mandatorily required to report a child in need of care and protection, they include:

Any correctional official, dentist, homeopath, immigration official, labour inspector, legal practitioner, medical practitioner, midwife, minister of religion, nurse, occupational therapist, physiotherapist, psychologists, religious leader, social service professional, social worker, speech therapist, teacher, traditional health practitioner, traditional leader or member of staff or volunteer worker at a partial care facility, drop-in centre or child and youth care centre.

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are displaying behaviour which cannot be controlled by the parent or care-giver; (c) lives or works on the streets or begs for a living; (d) is addicted to a dependence-producing substance and is without any support to obtain treatment for such dependency; (e) has been exploited or lives in circumstances that expose the child to exploitation; (f) lives in or is exposed to circumstances which may seriously harm that child's physical, mental or social well-being; (g) may be at risk if returned to the custody of the parent, guardian or care-giver of the child as there is reason to believe that he or she will live in or be exposed to circumstances which may seriously harm the physical, mental or social well-being of the child; (h) is in a state of physical or mental neglect; or (i) is being maltreated, abused, deliberately neglected or degraded by a parent, a care-giver, a person who has parental responsibilities and rights or a family member of the child or by a person under whose control the child is living.

<sup>915</sup> Regulation 3(f) draft Regulations on Human Subjects (note 13 above).

<sup>916</sup> S 150(2) Children's Act (note 4 above). The Children's Act also refers specifically to children performing child labour and those living in child-headed households as being in need of care and protection: s 150(2). The report must be made in a standard way on Form 22, Regulation 33(1) *Government Gazette* Regulation Number 497/35476/3 29 June 2007.

Although researchers are not specifically listed as a group of persons who must report, some members of a research team may be obligated because they are medical practitioners, nurses, psychologists or social workers. Furthermore, the Children's Act also provides that 'any person who on reasonable grounds believes that a child is in need of care and protection' may report such a belief to the provincial Department of Social Welfare, a designated child protection agency or the police.<sup>917</sup> The use of the word 'may' in this section implies that such persons are not compelled by law to report a belief that a child is in need of care or protection. Nevertheless, it could be argued that given the research relationship, they may be ethically bound to protect the child by reporting their circumstances to the authorities.

There are also provisions in other laws which place obligations on certain persons to take steps to protect children, which may or may not be linked to reporting obligations. In some forms of child research they may place obligations on researchers. Such provisions include obligations to ensure that children are:

- (i) Not required to work before the age of 15, and that those that are older than 15 do not undertake work that places their well-being, education, physical or mental health, or spiritual, moral or social development at risk.<sup>918</sup> Although there is no legal obligation to report children in this situation in employment legislation, any person may contact a labour inspector at the Department of Labour to inform them of a child performing child labour or inappropriate work. Furthermore the definition of abuse in the Children's Act includes 'a labour practice that exploits a child' and therefore it is argued that child labour would be reportable in terms of this Act.<sup>919</sup>

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<sup>917</sup> S 110(2) *ibid.*

<sup>918</sup> S 43(1) and (2). Basic Conditions of Employment Act 75 of 1997.

<sup>919</sup> S 1 Children's Act (note 4 above).

- (ii) Protected from sexual offences in terms of the Criminal Law, Sexual Offences and Related Matters Amendment Act, such as rape, sexual assault, sex work, under-age sex/sexual activity or sexual exploitation.<sup>920</sup> Any person who is aware of a sexual offence having been committed against a child must report this to the police.<sup>921</sup> These provisions place obligations on researchers to report any knowledge of sexual offences against children. Researchers involved in research on child sexuality, reproductive health or even broader issues may well become aware of sexual offences, such as incest or abuse.<sup>922</sup> They may also be faced with the complexities of reporting consensual sex in for example, in HIV prevention trial where participants under the age of 16 may be engaging in inter-generational but consensual sex.<sup>923</sup> Bhana et al suggest that in such situations researchers should work with Childline who can act as an intermediary in the reporting process:

. . . report the matter to Childline South Africa at toll-free number 0800 055 555. Childline will then contact a registered social worker in the area who will investigate and inform the South African Police Service (SAPS) accordingly. The interviewer will record details of the child's name, physical address and the school attended. As proof of meeting the statutory reporting obligation, the interviewer must obtain a Childline reference number as proof of reporting.<sup>924</sup>

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<sup>920</sup> Sexual Offences Act (note 765 above). The Act prohibits a wide range of sexual offences including amongst others rape, s 3; sexual assault, s 5; and incest, s 12. The Act also contains a number of child specific sexual offences such as consensual sexual penetration with certain children, s 15; consensual sexual violation of certain children, s 16; sexual exploitation of a child, s 17; and using children for or benefiting from child pornography, s 20.

<sup>921</sup> S 54 *ibid*.

<sup>922</sup> A Bhana, S Swartz & A Davids 'Standards for reporting of sex/sexual activity of minors in a research context' 2010) Vol 100(10) *SAMJ* 642, 642.

<sup>923</sup> See Strode & Slack (note 143 above) for a more detailed discussion of this issue. Also see s 5.2.2(vi) above for more detail on this point.

<sup>924</sup> Bhana, Swartz & Davids (note 922 above) 643.

- (iii) Able to attend school between the ages of seven and 15. All children between seven and 15 must attend school in terms of the South African Schools Act.<sup>925</sup> Although there is no reporting obligation, parents are required to ensure that their children of school-going age attend school.<sup>926</sup> This has implications for researchers working with children between the ages of seven and 15 as they must consider whether to inform parents if they are aware that children are not attending school.

#### 5.3.4 *An appropriate risk standard*

It is a well-accepted ethical principle that children may only participate in research if there is an acceptable level of risk.<sup>927</sup>

Currently the law does not set a clear legal standard for acceptable levels of research-related risk with children.<sup>928</sup> Accordingly, some authors refer to ethical guidelines to fill this void<sup>929</sup> as they provide that research interventions should pose acceptable levels of risk for child participants.<sup>930</sup> The draft Regulations on Human Subjects change the current position by setting express risk standards that cannot be exceeded when undertaking research with children:

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<sup>925</sup> S 3(1) South African Schools Act 84 of 1996.

<sup>926</sup> Parents who fail to comply with the South African Schools Act are guilty of an offence: s 3(5) *ibid*.

<sup>927</sup> Wendler & Grady (note 397) above) 203.

<sup>928</sup> Strode, Slack, Grant & Mushariwa (note 114 above) 224.

<sup>929</sup> Van Wyk (note 13 above) 48.

<sup>930</sup> Points 2.9 and 5.2 NHREC Guidelines (note 56 above). These provide that where the research or research interventions do not hold out the likelihood of direct health-related benefit for the child participants, the allowable level of risk is a 'slight' increase over the risks children would normally face in their everyday lives, and this is justified by a risk-knowledge ratio. In other words, there should be only a minor addition to life's risk as a result of the research intervention: s 5.2. Only MRC Book One (note 12 above) does not allow any increase over everyday risk for non-therapeutic research. Where the research or interventions in the research do hold out the prospect of direct benefit, then the allowable level of research risk is not specified but is justified by the benefits to individual child participants, that is, a risk-benefit ratio *ibid*.

- 4.(1) Children can only participate in research in instances where:
- (a) the research poses a minimal risk to the child;
  - (a) the research poses a greater risk, but possibly be for the benefit of the child;
  - (b) the research can only be done on children; and
  - (c) the parent or legal guardian of the child gives consent for such a child to participate.
- Always, refusal to participate by a child should precede the consent of the guardian..<sup>931</sup>

The draft Regulations conflict with the position in national ethical guidelines as they do not allow a minor increase over minimal risk which prohibits most clinical trials from taking place.

#### 5.3.5 *Children must be indispensable to the research*

It is a well-established ethical principle that children should be indispensable to the research.<sup>932</sup>

There is no current law which requires researchers to demonstrate that children are indispensable to the study. It is however a criterion that the Minister of Health must consider when giving consent for non-therapeutic research with minors.<sup>933</sup> It is also a well-established ethical guideline, with the NHREC Guidelines providing that ‘minors should participate in research only where their participation is indispensable to the research’.<sup>934</sup> A similar point is made with regard to social science research in the ethical guidelines on research with children issued by the HSRC.<sup>935</sup> This means that RECs must find research with children to be ethical only if researchers are able to demonstrate that it is not possible to do the research with a less vulnerable group. For example, if researchers propose a study of low birth weight

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<sup>931</sup> Regulation 4(1) draft Regulations on Research with Human Subjects (note 133 above).

<sup>932</sup> Andanda (note 166 above) 63 and Guidance Point 14 CIOMS (note 182 above).

<sup>933</sup> S 71(3)(b) National Health Act (note 57 above).

<sup>934</sup> S 5.1 of the NHREC Guidelines (note 56 above).

<sup>935</sup> HSRC Guidelines (note 541 above).

babies, although these are frequently born to young mothers, they must justify why they could not get the same data from mothers who are 18 and older.<sup>936</sup>

The draft Regulations change this position by providing that children must be indispensable to the research.<sup>937</sup> This transforms the ethical norm into a legal obligation and it becomes an important protection ensuring that children are not used in health research unless scientific indispensability can be demonstrated.

#### **5.4 Conclusions**

There is currently a normative framework which sets out the rights of research participants and the circumstances in which health research may take place. This focuses primarily on informed consent as the key mechanism for protecting research participants. However, the rights to privacy, dignity and equality are also described in the draft Regulations. Many of the norms created by the NHA are child-specific and there is a strong focus on ensuring that only appropriate research with children is undertaken. This is done through the provisions in the NHA which require therapeutic research to be in the best interests of the child and non-therapeutic research to have ministerial consent. These are supplemented by provisions in the draft Regulations which set appropriate risks standards and require researchers to demonstrate that they are indispensable to the study. As a result of these norms, research with children can only be undertaken if:

- (i) Written consent is obtained from the child's parent or legal guardian;
- (ii) Written consent is obtained from the child if they have understanding;
- (iii) Consent is obtained from the participant's health care provider, the head of the institution and its REC if the research takes place at a health facility or is an experimental health service;

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<sup>936</sup> Personal communication, Professor Wassenaar, chair Bio-medical Research Ethics Committee, University of KwaZulu-Natal, 18 November 2012.

<sup>937</sup> Regulation 4(1)(e) Regulations on research with Human Subjects (note 13 above).

- (iv) It has been demonstrated that therapeutic research is in the best interests of the child;
- (v) Ministerial consent has been obtained for non-therapeutic research; and
- (vi) Mandatory reporting requirements are complied with.

When the draft Regulations are finalised, researchers will have to ensure:

- (i) Research participants' rights to privacy, dignity and equality are protected;
- (ii) The study does not exceed the set risk standards; and
- (iii) It has been demonstrated that children are indispensable to the study.

The current framework has dealt with a number of problems that existed before the NHA was fully implemented. Firstly, it has clarified the issue of when and how children can participate in non-therapeutic health research. The NHA recognises that children (minors) can participate in all forms of so-called non-therapeutic research, including studies that involve invasive procedures. In the past there were divergent approaches in ethical guidelines regarding the types of non-beneficial research children could participate in. Secondly, there was a lack of uniformity regarding the age at which children could consent independently to health research. This has been settled by section 71 of the NHA which does not allow independent consent to health research.

While this new framework strengthens the protections for child research participants, cumulatively these new protections will reduce the pool of children eligible to participate in health research, place additional administrative burdens on researchers and may result in time delays.

Using Nielsen's models for classifying ethical-legal frameworks the normative framework can be considered to fall within the prohibitive approach as the norms are highly restrictive.<sup>938</sup> Even though children or minors are not excluded per se from participating in health research, the over-emphasis on protection severely limits the circumstances in which they may participate in health research. The emphasis in the normative framework is on substantive protections for child research participants and accordingly there is less flexibility in the standards and very little focus on child or parental autonomy.

In conclusion, the normative framework is now overly protective and does not facilitate research; there is also a limited focus on child participation as there are no circumstances in which children can consent independently to research and only a cursory reference to children assenting to research participation.

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<sup>938</sup> Nielsen (note 42 above) 42. See Chapter Two for a more detailed discussion of this model.

## Chapter Six:

### **A critique of the ethical-legal framework for regulating health research with children**

In the preceding Chapter the normative framework for health research was set out. It described the rights of research participants to participate in health research only with informed consent, to be treated equally, to have their privacy respected and their dignity protected. It also detailed the five obligations on researchers to promote the welfare of child research participants including, firstly, to ensure that children are indispensable to the study. Secondly, to demonstrate that the research has an acceptable risk standard. Thirdly, to show that therapeutic research is in the best interests of minors. Fourthly, to obtain ministerial approval for non-therapeutic research. And fifthly, when necessary, to comply with mandatory reporting requirements.

Chapter Five concluded by stating that a well-developed normative framework exists in South Africa, which describes the rights of research participants and the circumstances in which health research may take place. Furthermore, it deals directly with when and how children should participate in health research and, as a result, researchers must comply with nine key norms. However, the framework is over-protective and in the future will hinder the amount and nature of research that can be undertaken with children. As a result it can be considered to fall within the prohibitive approach of the ethical-legal models described by Nielsen.<sup>939</sup>

This Chapter uses the norms described in Chapter Two of this dissertation as benchmarks against which the current South African ethical-legal framework is measured. It concludes

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<sup>939</sup> Nielsen (note 42 above) 42. See Chapter Two for a more detailed discussion of this model.

with an assessment of the extent to which the framework protects child research participants, facilitates their involvement in research-related decisions and facilitates research.

## 6.1 Introduction

Chapters One and Two of this thesis argue that the regulation of research is important to safeguard participants from harm<sup>940</sup> and ensure that the interests of society or science do not outweigh the individual interests of research participants.<sup>941</sup> At a micro-level, research regulation creates a framework for the procedural and substantive regulation of individual studies.<sup>942</sup> Following the approach of Nielsen it is submitted that the regulation of research ought to ensure that norms which declare certain interests as worthy of protection are established.<sup>943</sup> Furthermore, these norms ought to be carefully balanced so that the interests of various stakeholders do not outweigh the rights of research participants. Finally, the norms ought to be enforced through an institutional framework which can make declarations on certain issues, thus clarifying the manner in which norms are applied in individual situations.<sup>944</sup> Accordingly, it is submitted that the key elements of an effective ethical-legal framework are: it must require research to demonstrate scientific indispensability, ie that it cannot be done without human participants; it carries an appropriate risk standard; it will undergo scientific and ethical review; and there is the protection of research participants' rights.<sup>945</sup> Using these principles this thesis argues that to meet these standards, ethical-legal frameworks require firstly, institutions which are able to (a) create policy guidance on the most appropriate forms of research that ought to be undertaken, (b) review and regulate research (scientifically and ethically), issue ethical norms and standards dealing with both

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<sup>940</sup> Hope, Savulesen & Hendrick (note 163 above) 193.

<sup>941</sup> *Ibid.*

<sup>942</sup> Chima (note 166 above) 848.

<sup>943</sup> Nielsen (note 42 above) 42.

<sup>944</sup> *Ibid.*

<sup>945</sup> Article 16 Convention on Human Rights and Biomedicine (note 179 above).

procedural and substantive issues, (c) liaise with and involve the community, and (d) implement effective enforcement mechanisms. Secondly, it requires legally established norms which set minimum standards for the conduct of research.

## **6.2 Review of the extent to which South Africa's current institutional framework meets key international norms**

It has been argued that an ethical-legal framework protects research participants by setting procedural obligations enforced by institutions.<sup>946</sup> Accordingly, these institutions play a critical role in ensuring that children are protected, that they participate in research decision-making, and that research with them is facilitated.

Currently South Africa has a good institutional framework which is created by, amongst others, the NHA<sup>947</sup> and the Medicines Act.<sup>948</sup> This framework has established as statutory bodies, the NHRC,<sup>949</sup> the MCC,<sup>950</sup> the NHREC,<sup>951</sup> and institutionally based RECs.<sup>952</sup> In some circumstances Community Advisory Boards (CABs) exist even though currently there is no direct legal obligation to establish such structures.<sup>953</sup>

### *6.2.1 Research policy body: NHRC*

There is no international ethical-legal norm regarding the need for a policy-making body to establish the priority research areas for a country. However, the well-established ethical principle of justice requires 'fairness in the treatment of individuals and communities and the

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<sup>946</sup> Glantz (note 90 above) 128.

<sup>947</sup> National Health Act (note 57 above).

<sup>948</sup> Medicines Act (note 164 above).

<sup>949</sup> S 69 *ibid* and Regulations Relating to the Establishment of the National Health Research Committee (note 616 above).

<sup>950</sup> *Ibid*.

<sup>951</sup> S 72 *ibid*.

<sup>952</sup> S 73 *ibid*.

<sup>953</sup> Reddy, Buchanan, Sifunda, James & Naidoo (note 345 above) 3.

equitable distribution of the burdens and benefits of research'.<sup>954</sup> Accordingly, participants should be invited to participate in research 'for reasons directly related to the problem being studied' not because of their 'easy availability, their compromised position, or their manipulability'.<sup>955</sup> This principle places an obligation on RECs to consider whether the research will be relevant to the participants and their communities. It is submitted that the establishment of institutions to establish such priorities facilitates the implementation of this ethical principle. There are many examples in other jurisdictions of institutions which have been established to set research priorities.<sup>956</sup> More recently, some of the international discussion on this issue has focused expressly on the mechanisms (institutional and other) for public participation in setting the research agenda.<sup>957</sup>

Within the current framework, the NHA and its accompanying regulations create a statutory body, the NHRC, to set research priorities for health research undertaken by or on behalf of the public sector.<sup>958</sup> This is a significant departure from the past in which (a) national research priorities were established in two separate silos (social science and medical research),<sup>959</sup> and (b) there were allegations of the research agenda being driven by political ideology.<sup>960</sup>

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<sup>954</sup> Tangwa (note 597 above) 56.

<sup>955</sup> K Moodley 'HIV vaccine trial participation in South Africa' (2002) Vol 27(2) *Journal of Medicine and Philosophy* 197, 209.

<sup>956</sup> See Chapter Two for more discussion on this point.

<sup>957</sup> See for example, Bhan, Singh, Upshur, Singer & Daar (note 343 above) 0040272.

<sup>958</sup> See Chapter Four for a detailed discussion on the policy framework for setting research priorities.

<sup>959</sup> See Chapters Three and Four for a discussion on how the HSRC and the MRC advised their respective ministers on research priorities.

<sup>960</sup> It has been submitted that during the Apartheid era health research aimed at achieving 'two primary considerations: (a) the desire to improve the health of white citizens; and (b) the desire to improve the health of non-white citizens, but primarily only in so far as their health posed a threat to white citizens, or threatened to undermine the national economy. As such, health research in the country was motivated by economic considerations and not humanitarian ones': Singh & Strode (note 45 above). See Chapter One for further discussion on this issue.

The strength of the approach taken by the NHA is that as a statutory body the NHRC has defined roles and responsibilities and can be held accountable to the Ministry of Health. Furthermore, the NHA has expressly identified children as a vulnerable group requiring prioritisation in the research plans of the NHRC.<sup>961</sup> This places a statutory obligation on the NHRC to ensure that research benefiting children is prioritised. Although not required by the NHA to act consultatively, the NHRC has held four national conferences with key research stakeholders in developing and updating the research agenda.<sup>962</sup> It is argued that this consultative approach minimises the possibility of political interference in the development of the research agenda.

It is submitted that there are two key weaknesses with the structure and functions of the NHRC. Structurally, the NHA does not assert the independence of the NHRC. Given our apartheid history in which the research agenda was motivated by political ideology, ensuring that the NHRC is able to act independently is important. It was argued in Chapter Two that finding the balance between oversight and interference in the research agenda is complex. Furthermore, this must be done within the framework of the constitutional right to freedom of expression which includes a right to 'academic freedom and freedom of scientific research'.<sup>963</sup> Research priorities should be rational and not promote a particular political ideology. If the statutory body mandated to set such priorities is independent it facilitates such an approach. However, the NHA fails to state that the NHRC is an independent body. Furthermore, the Regulations only refer to possible conflicts of interest in one instance, requiring that members voluntarily recuse themselves if a potential conflict arises.<sup>964</sup> Of even greater concern is that in two instances the Regulations potentially undermine the independence of the NHRC through:

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<sup>961</sup> S 70(d) National Health Act (note 57 above).

<sup>962</sup> 2<sup>nd</sup> *National Conference on Priority Setting for Health Research* (note 606 above). See Chapter Four for further discussion on this issue.

<sup>963</sup> S 16(1)(d) Constitution of the Republic of South Africa (note 2 above).

<sup>964</sup> Regulation 7(7) Regulations on the Establishment of the NHRC (note 671 above).

- (i) Providing that the Minister of Health may make appointments to the NHRC if there are no or 'insufficient' nominations for positions on the Committee.<sup>965</sup> There is no process of calling for further nominations or for the soliciting of nominations from experts in the field of health research. The circumstance in which the Minister may declare that there are 'insufficient' nominations is not specified. It is submitted that this gives the Minister the power to potentially subvert the process of nominations to the NHRC and to appoint persons sympathetic to a particular research agenda; and
- (ii) The Minister of Health has the power to appoint the Chairperson and Deputy Chairperson of the NHRC.<sup>966</sup> It is submitted that this gives the Minister undue control over the workings of the Committee, instead of allowing the members to appoint their own chairperson and deputy.

Furthermore, the NHA and the Regulations are silent on who the Committee reports to on an annual basis. However, given that the members of the Committee are appointed by the Minister of Health, it is assumed that they report to him or her rather than to parliament. It is argued that this further undermines the independence of the NHRC.

A further structural weakness of the NHRC is that neither the NHA nor its Regulations provide any mechanism for the Committee to enforce its research agenda.<sup>967</sup> Although researchers are required to submit research to the provincial health research committees it is not clear what such committees could do if institutions fail to comply. It is argued that the Regulations ought to have established a link between the NHRC, the NHREC and RECs in order to ensure that during the process of ethical review, such committees are made aware

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<sup>965</sup> Regulation 4 *ibid.*

<sup>966</sup> Regulation 5 *ibid.*

<sup>967</sup> Ironically the Regulations allow researchers or research institutions to appeal against decisions made by the NHRC but do not provide the Committee with any means to enforce its own decisions: Regulation 10(3) *ibid.*

of national and provincial research priorities. This could also assist the NHRC in fulfilling one of its core roles, that of co-ordinating health research.

A key gap in the statutory role created for the NHRC is the inadequate approach to public participation in setting the research agenda. As set out in Chapter Two, Holman and Dutton argue that the public ought to participate in the development of research policies as their democratic right, thereby ensuring that public interests are reflected in research policies.<sup>968</sup> The NHA does not create such a role for the NHRC. The Regulations accompanying the NHA simply provide that the NHRC must have as one of its members a community representative.<sup>969</sup> However, neither the NHA nor its Regulations describes or creates any other mechanism for engaging with the public on the development of research priorities. As a result the NHRC appears to view stakeholder engagement as consultation with researchers and research institutions. For example, at the most recent prioritisation conference, 271 delegates attended, none of these represented community groups, or even community advisory boards.<sup>970</sup> Most delegates came from either the Department of Health or RECs.<sup>971</sup>

### 6.2.2 *National drug regulatory authority: MCC*

The Helsinki Declaration provides that research must conform to scientific standards and clinical trials should be registered with an appropriate regulatory authority.<sup>972</sup>

The national drug regulatory authority in South Africa is the MCC which is established in terms of the Medicines Act.<sup>973</sup> The strength of the approach is that the MCC has been created as a statutory body with an obligation to ensure that drugs are safe, efficacious and

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<sup>968</sup> Holman & Dutton (note 320 above) 1508.

<sup>969</sup> Regulation 3(1) Regulations on the Establishment of the NHRC (note 616 above).

<sup>970</sup> 2<sup>nd</sup> National Conference on Priority Setting for Health Research (note 606 above).

<sup>971</sup> *Ibid.*

<sup>972</sup> *Ibid.*

<sup>973</sup> Medicines Act (note 164 above). See Chapter Four for a description of the role and functions of the MCC.

their use is in the interests of the public.<sup>974</sup> This includes a mandate to regulate clinical trials which may precede the registration of a new drug.<sup>975</sup> A further strength is that there is a direct link between the MCC and the NHREC as a member of the MCC is required to sit on the NHREC.<sup>976</sup> This means that the legal framework requires some co-ordination in the regulation of clinical trials between the national drug regulatory authority and the national ethics structure. This is significant as the overlapping of roles between these two bodies has been identified as a key complexity by the WHO.<sup>977</sup>

A key weakness in the way in which the Medicines Act has established the MCC is that it fails to provide that the MCC is an independent body. Furthermore, following a recent change to the Medicines Act the MCC is now no longer accountable to the legislature but directly to the executive through the Minister of Health.<sup>978</sup> Vawda submits that although the MCC has the appearance of an independent institution being a juristic person, it is in terms of its new structure simply one of the many line functions of the Department of Health.<sup>979</sup> This lack of clear statutory protection regarding the independence of the MCC as an institution compounds pre-existing concerns with the MCC. For example, there were allegations that the former Minister of Health, Dr Tshabala-Msimang interfered in its work and this new structure will not prevent such interference in the future.<sup>980</sup> Singh gives a further example of the failure of the MCC to register an HIV prevention trial during a period in which the then

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<sup>974</sup> S 15(3)(a) *ibid*. Also see Y Vawda 'Ensuring access through the Medicines and Related Substances Amendment Act No. 72 of 2008 – Another lost opportunity?' (2010) *The South African Law Journal* 668–669 for more detailed discussion on this issue.

<sup>975</sup> S 35(1)(xxxix) Medicines Act (note 164 above).

<sup>976</sup> See Chapters Four and Six for a more detailed discussion on this point.

<sup>977</sup> Ratanawijitrasin and Wondemagegnehu (note 328 above) 96 – 97.

<sup>978</sup> Ss 3–4 *ibid*. Vawda (note 974 above) 671. Vawda submits further that the independence of the MCC is also compromised by its CEO being appointed by and reporting to the Minister of Health. This could result in political manipulation of internal processes within the MCC: *ibid* 672.

<sup>979</sup> *Ibid*.

<sup>980</sup> *Mail and Guardian* (note 313 above) and N Natrass 'AIDS and the scientific governance of medicine in the post-apartheid South Africa' (2003) Vol 107(427) *African Journal Online* available at <http://afraf.oxfordjournals.org/content/107/427/157.full> [Accessed: 16 May 2011].

President Thabo Mbeki denied the existence of HIV.<sup>981</sup> In this instance researchers had to resort to a High Court action to compel the MCC to authorise the clinical trial.<sup>982</sup> It has been submitted that the lack of institutional separation from the Department of Health is thus a flaw which has enabled political interference in its work.<sup>983</sup> Furthermore, it impacts on the reputation of the MCC as it no longer appears to be able to act as an independent body.<sup>984</sup> A further concern with the the lack of structural independence of the MCC is the issue of 'regulatory capture'.<sup>985</sup> There are concerns in the literature that if drug regulatory authorities are not structured in a way that ensures efficiency, accountability and transparency they can inadvertently become 'captured' by the interests of drug companies and begin to serve their priorities over the interests of the general public.<sup>986</sup> In the current context, where the MCC reports directly to the Minister of Health, it poses a risk that it may be captured by political rather than private industry interests.

There are two key gaps in the structuring of the MCC. Firstly, the Medicines Act does not create a mechanism for the engagement of the public in decisions regarding when to register a new drug. Given that one of its roles is to ensure that the registration of a drug is in the interests of the public it appears to be an anomaly not to have strong community

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<sup>981</sup> Singh (note 10 above) s 77. In this instance researchers at the University of KwaZulu-Natal applied for permission to undertake a clinical trial investigating whether providing HIV positive mothers with the HIV drug Nevirapine for a period of six months after the birth of their child and whilst breast feeding would reduce mother-to-child transmission of HIV *ibid*.

<sup>982</sup> S 78 *ibid*.

<sup>983</sup> Natrass (note 960 above).

<sup>984</sup> Vawda (note 974 above) 672.

<sup>985</sup> The 'capture theory' of regulation is one which postulates that in certain circumstances organisations being regulated could control or 'capture' the very bodies that were regulating them WD Berry 'An alternative to the captive theory of regulation: The case of state public utility commissions' (1984) Vol 28(3) *American Journal of Political Science* 524, 524. The theory is based on the assumption that the public (the majority) has an interest in regulation whilst the organisations being regulated (the minority) have an interest in a de-regulated environment *ibid*. The state capitulates to the majority and establishes a regulatory framework however given that the public lose interest in the issue after the establishment of regulation space is created for those being regulated to influence the regulator in such a way that they start to serve the interests of the minority *ibid*. Ironically this can mean that the regulator starts to serve the interests of those they are supposed to regulate S Ratanawijitrasin and E Wondemagegnehu (note 328 above).

<sup>986</sup> *Ibid*.

representation on the MCC. Furthermore, while there is a structural link between the MCC and the NHREC, the MCC does not have any formal relationship with the NHRC.<sup>987</sup>

Secondly, the Medicines Act does not deal in detail with the regulation of clinical trials. It does however provide that the MCC may only register medicines if it is satisfied with the application and this implies the application must be based on research.<sup>988</sup> It is argued in Chapter Four that this implies that the MCC's role is to ensure that trials are scientifically valid and will provide information on whether the product could be registered for use in South Africa. However, this is not clearly specified. The concern with this approach is that it means in reality that the national drug regulatory authority has a much greater focus on the post-trial approval of drugs rather than the registration or supervision of clinical trials.<sup>989</sup>

### 6.2.3 National Research Ethics Structure: NHREC

Although there is no international norm on a national research ethics structure this thesis argues in Chapter Two that RECs should operate within a national framework. This should include affiliation to a national structure which monitors the composition, training, standards of ethical review and the reporting requirements of RECs.

In South Africa, a national research ethics body exists, namely the NHREC,<sup>990</sup> which is a statutory body established by the NHA.<sup>991</sup> This is significant as in the past there was no direct regulation of RECs and they were not required to follow national ethical guidelines unless the research was defined a clinical trial.<sup>992</sup>

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<sup>987</sup> Regulation 2(f) Regulations relating to the National Health Research Ethics Council (note 667 above).

<sup>988</sup> General Regulations, Medicines and Related Substances Act, Regulation 15(3)(a) (note 164 above).

<sup>989</sup> A Hedgecoe 'A deviation from standard design? Clinical trials, research ethics committees, and the regulatory co-construction of organizational deviance' (2014) Vol 44: 59 *Social Studies of Science* 59, 64.

<sup>990</sup> The NHREC is established in terms of s 72 of the National Health Act (note 57 above).

<sup>991</sup> *Ibid.*

<sup>992</sup> See Chapters Three and Four for more detailed discussion on these points.

The strengths of the NHREC are that: one, it is a statutory body with defined roles and responsibilities; and its structure as created by the NHA and the accompanying Regulations enable it to fulfil its roles regarding the issuing of norms and standards, exercising oversight over RECs and advising government. Two, its empowering legislation requires it to be made up primarily of experts in the field of research ethics.<sup>993</sup> This ensures that it has the capacity to carry out its mandate. Three, the NHREC has been able to ensure national uniformity in research ethics by issuing national ethical guidelines,<sup>994</sup> accrediting RECs and auditing RECs.<sup>995</sup> Four, the ethical guidelines issued by the NHREC are legally enforceable as section 73(2)(b) of the NHA provides that RECs must give ethical approval for health research which meets 'the ethical standards of that health research ethics committee'. It has been argued that the 'standards of that REC' is a reference to the NHREC Guidelines.<sup>996</sup> Five, the structure of the NHREC as described by the NHA does to some extent address the lack of a national body which co-ordinates all institutions within the ethical-legal framework<sup>997</sup> as the Regulations require that the NHREC be made up of, amongst others, a representative of the MCC.<sup>998</sup> Six, the NHREC is given the authority to discipline any person violating norms and guidelines established by the NHA.<sup>999</sup> This is significant as it has moved our framework away from the professional control model in which the primary regulation of the conduct of researchers was exercised by professional bodies such as the Health Professions Council of South Africa.<sup>1000</sup> The provisions in the NHA allow the NHREC to discipline 'any person' who has violated norms set by the NHREC or those found in the NHA.<sup>1001</sup> It is argued that this

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<sup>993</sup> Regulation 2 Regulations relating to the National Health Research Ethics Council (note 667 above).

<sup>994</sup> NHREC Guidelines (note 56 above).

<sup>995</sup> Report for the National Health Research Ethics Council, 2010/2011 (note 653 above).

<sup>996</sup> Smit (note 34 above).

<sup>997</sup> Strode, Slack & Mushariwa (note 94 above) 41.

<sup>998</sup> Regulation 2 Regulations relating to the National Health Research Ethics Council (note 667 above).

<sup>999</sup> S 72(6)(f) National Health Act (note 57 above).

<sup>1000</sup> See Chapter Two for a full discussion of the theoretical models of ethical-legal frameworks as described by Nielsen (note 42 above).

<sup>1001</sup> S 72(6)(f) National Health Act (note 57 above).

means that field workers, data capturers and other researchers who are not registered with a professional body may be disciplined for an ethical-legal violation.

The weaknesses of the framework creating the NHREC are that firstly, its independence is undermined to some extent by the powers given to the Minister of Health in the Regulations. Although the Minister must call for nominations to the Council through a public process, if none or 'insufficient' nominations are received, the Minister may simply appoint persons to the NHREC.<sup>1002</sup> Furthermore, just as in the case of the NHRC, the chair and vice-chair are appointed by the Minister of Health.<sup>1003</sup> Both these provisions undermine the independence of the NHREC and its ability to perform its key functions.<sup>1004</sup> Furthermore, the NHREC is required to report to the Minister of Health rather than parliament, which again does not facilitate the Council acting as an independent advisory and regulatory body on ethical issues.<sup>1005</sup>

Secondly, although empowering the NHREC to discipline any person who violates ethical-legal norms is an important innovation, the NHA has undermined this by only expressly including one sanction, that of referring violations by health care workers to relevant statutory bodies for disciplining.<sup>1006</sup> Accordingly, it is unclear what other type of sanctions

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<sup>1002</sup> Regulation 3(3) Regulations relating to the National Health Research Ethics Council (note 667 above).

<sup>1003</sup> Regulation 4(1) *ibid.*

<sup>1004</sup> Although the Minister of Health is democratically accountable to parliament and hence has to report to parliament on any decisions s/he may make in their official capacity, it is submitted that in an emerging democracy such as South Africa, this is not always an effective way of ensuring that power is not abused given that we have a single dominant political party.

<sup>1005</sup> Although neither the National Health Act (note 57 above) nor the Regulations relating to the National Health Research Ethics Council (note 667 above) refer to the reporting requirement it is argued that it can be inferred that reporting must be to the Minister of Health who has appointed the members of the Council.

<sup>1006</sup> S 72(6)(e) National Health Act (note 57 above). Nielsen (note 42 above) argues that codes of conduct describing key ethical standards for health professionals can be an important protection that promotes a high scientific standard in research. However, not all health researchers or members of a research team may be registered with a professional council, for example, field workers collecting data in communities are generally not health care workers. Accordingly, they cannot be disciplined by professional bodies.

could be applied to a member of a research team who cannot be defined as a health care worker.

Finally, it is a key gap that the NHA does not provide a structural way of linking the work of the NHREC and the NHRC.

#### 6.2.4 *Research Ethics Committees*

It is a well-established, international ethical-legal principle that health research should be submitted for ethical review.<sup>1007</sup> The important role of RECs within ethical-legal frameworks has been cemented by both the Helsinki Declaration and the WHO's GCP Guidelines which require researchers to develop a research protocol and submit this for ethical review.<sup>1008</sup> In essence this requires that an independent committee should provide third party assessment of research protocols in order to minimise possible conflicts of interests, protect research participants and avoid the exploitation of vulnerable individuals or communities.<sup>1009</sup>

South Africa has a well-established ethical-legal framework for RECs. Section 73 of the NHA requires every institution, agency or health establishment conducting health research to establish or have access to an REC.<sup>1010</sup> The draft Regulations on Human Subjects provide further that there is an obligation on health researchers to obtain ethical review of their protocol.<sup>1011</sup> This innovation in the NHA is significant as in the past there was no legal obligation on institutions to establish RECs or on researchers to submit their protocols for ethical review, unless they were undertaking research for the MRC or conducting a clinical trial.<sup>1012</sup>

The strengths of the framework are: firstly, that institutions, agencies and health establishments conducting health research are required by the NHA to establish RECs. This places a legal obligation on institutions to ensure that ethical review of health research takes place and a failure to create this infrastructure could result in the institution being

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<sup>1007</sup> See Chapter Two for a more detailed discussion of this point.

<sup>1008</sup> Guidance Points 14 and 15 Declaration of Helsinki (note 41 above); Point 3.2 WHO Good Clinical Practice Guidelines (note 163 above).

<sup>1009</sup> Kass, Hyde, Ajuwon, Appiah-Poku, Barsdorf et al (note 324 above) 0026 and Perley, Fluss, Bankowski & Simon (note 197 above) 195–196..

<sup>1010</sup> National Health Act (note 57 above).

<sup>1011</sup> Regulation 2(h) draft Regulations on Human Subjects (note 13 above).

<sup>1012</sup> See Chapters Three and Four for more detail on this point.

sanctioned by the NHREC.<sup>1013</sup> Secondly, RECs operate within a national framework in terms of which they are accountable not only to their institution but also the NHREC which registers and accredits them.<sup>1014</sup> This ensures that ethics review is of an acceptable standard and operates in accordance with national norms and standards. It also assists with ensuring that RECs are administratively competent as they may be audited by the NHREC.<sup>1015</sup> Thirdly, RECs are required to consider whether the proposed health research is relevant and will 'promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases'.<sup>1016</sup> It is argued that this places an obligation on RECs to consider the objectives of the proposed study and whether they are relevant to the local context. Fourthly, section 73 of the NHA applies to all health research<sup>1017</sup> which creates a very broad obligation for all forms of health research to be reviewed, even those that do not have human subjects, such as record reviews.<sup>1018</sup>

It is argued that there are no structural weaknesses in the way in which the NHA and its accompanying regulations deal with RECs except in relation to the role of community participation in REC decision-making. Currently, the NHREC Guidelines require each REC to appoint a community representative as a member of the committee. Nevertheless, who such an individual should be and how they can reflect the voice of the community in ethical decision-making is unclear. At an implementation level the NHREC also appears to have

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<sup>1013</sup> It is assumed that the head of the institution or its governing structure could be held accountable as opposed to the institution itself. See the section above on the limitations of the NHREC's role as defined by the NHA in terms of enforcing ethical-legal norms.

<sup>1014</sup> S 72(6)(b) National Health Act (note 57 above).

<sup>1015</sup> *Ibid.*

<sup>1016</sup> S 73(2)(a) *ibid.*

<sup>1017</sup> See the definition of health research in s 1 National Health Act *ibid.* This definition is discussed in detail in Chapter Four.

<sup>1018</sup> The only exception to this is record reviews undertaken at health establishments by health care workers which do not require ethical approval if the personal identifiers of users (research participants) have been removed: s 16 *ibid.* See below and Chapter Four for more detail on this point.

weaknesses. It has noted that 23 per cent of all RECs are less than three years old.<sup>1019</sup> It is possible that such committees may be inexperienced and lack expertise. It is also probable that this impacts on the quality of ethical review. Furthermore, there are no RECs registered with the NHREC in three provinces, Mpumalanga, the North West and the Northern Cape.<sup>1020</sup> This is of particular concern as there are a number of tertiary institutions in these provinces and it may indicate that research is either being reviewed by unregistered RECs or not being reviewed at all.

Finally, it is a shortcoming that the NHA does not expressly require ethical review of all health research, as there is an inappropriate exception to ethical review provided for in section 16(2) of the NHA. This allows record reviews to be done by health care providers without ethical approval, provided no personal identifiers are obtained during the study. This treats record reviews by health care providers differently to those being done by other researchers, such as social scientists, and is out of step with international norms.

#### 6.2.5 *Community Advisory Groups*

In Chapter Two it was argued that it is an emerging international ethical norm that in large community-based studies, some type of structure must be established to facilitate engagement between researchers and communities.<sup>1021</sup>

In South Africa, there is no statutory body within the ethical-legal framework to facilitate public participation in research. However, the NHREC has issued Guidelines on the establishment of CAGs (study or site-based committees which act as a liaison between

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<sup>1019</sup> Report for the National Health Research Ethics Council, 2010/2011 (note 652 above).

<sup>1020</sup> *Ibid.*

<sup>1021</sup> Chapter Two argues that this obligation flows from debates on public participation in science/research. The types of structures that are need to facilitate this participation continue to be debated: Swartz & Kagee (note 156 above) 1142.

researchers and the community).<sup>1022</sup> These guidelines are the first set of national guidelines dealing with when and how CAGs should be set up.

One of the strengths of the South African system is that national guidelines on CAGs exist. It is submitted in Chapter Four that these Guidelines are indirectly enforceable as they are norms and standards regulating the conduct of research issued by the NHREC in terms of section 72(6)(c) of the NHA.<sup>1023</sup> The Guidelines are very broad and provide direction on when a CAG ought to be established, its role and how it ought to function.<sup>1024</sup> Although Principal Investigators must determine whether a CAG should be established RECs are given the responsibility of providing oversight on this decision. This is a flexible approach which enables decisions as to when a CAG is required, to be made at local site level.

A weakness of the system is that oversight is to be provided by RECs, but they can only intervene once an application for ethical approval for the study has been submitted. At this stage, the study design, methodology and procedures have already been developed and therefore, if ordered to establish a CAG at this point, communities may have missed the opportunity for consultation on the conceptualisation of the study. It has been argued by authors such as Mc Neil that ethical review is a political process in which various community interests ought to be balanced.<sup>1025</sup> Given the political nature of the decision-making he submits that the majority of the members of the regulatory structures ought to represent the community.<sup>1026</sup>

#### 6.2.6 *Monitoring and enforcement measures within the ethical-legal framework*

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<sup>1022</sup> National Health Research Ethics Council Guidelines for Community Advisory Groups (note 716 above).

<sup>1023</sup> National Health Act (note 57 above).

<sup>1024</sup> See Chapter Four for more detailed discussion on these issues.

<sup>1025</sup> PM McNeil *The ethics and politics of human experimentation* (1993) Cambridge University Press, 72 – 73.

<sup>1026</sup> *Ibid.*

In Chapter Two it is argued that a range of monitoring and enforcement mechanisms need to exist, including structures which are able to enforce ethical codes and a national regulatory body to regulate research on new medical products.<sup>1027</sup> Furthermore, the Helsinki Declaration requires RECs to monitor ongoing studies.<sup>1028</sup> It also places a corresponding obligation on the researchers to provide monitoring information to their REC.<sup>1029</sup>

In South Africa, there are obligations to monitor research which have been included in ethical guidelines.<sup>1030</sup> There are also some legal obligations on researchers undertaking clinical trials as they are required to report on their progress to the MCC.<sup>1031</sup> The MCC can request additional information from researchers, inspect a clinical trial site and withdraw authorisation for a trial if it believes that the safety of trial participants is compromised or the scientific reasons for conducting the trial have changed.<sup>1032</sup> There are also a wide range of enforcement mechanisms established by institutions within the ethical-legal framework, the civil and criminal courts and institutions established by the Constitution.

The strengths of the monitoring measures are that they are indirectly legally enforceable as these obligations are set out in ethical guidelines in terms of which RECs must act.<sup>1033</sup>

However Strode, Slack and Mushariwa argue that the weakness of these mechanisms is that they tend to focus on formalistic compliance with the protocol rather than 'on site processes or dynamic interaction with trial participants'.<sup>1034</sup> Furthermore, they submit that most RECs

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<sup>1027</sup> See Chapter Two for more detailed discussion on this topic.

<sup>1028</sup> Declaration of Helsinki (note 41 above).

<sup>1029</sup> *Ibid.*

<sup>1030</sup> NHREC Guidelines (note 56 above) and GCP Guidelines (note 58 above). See Chapter Four for a more detailed discussion on this point.

<sup>1031</sup> Regulation 34(6) General Regulations, Medicines and Related Substances Act (note 164 above).

<sup>1032</sup> Regulation 34(7) *ibid.*

<sup>1033</sup> Smit (note 34 above).

<sup>1034</sup> Strode, Slack & Mushariwa (note 94 above) 600.

do not always have the capacity to undertake a more active monitoring role in health research.<sup>1035</sup>

There are six different ways in which research participants could enforce their rights in our system.<sup>1036</sup> They include a novel mechanism introduced by the NHA which provides the NHREC with the power to adjudicate research-related complaints.<sup>1037</sup>

The strengths of the system are: firstly, there is a range of enforcement mechanisms which can be used. Secondly, some of the mechanisms do not require the participants to have financial resources, for example, complaints to the NHREC or the HPCSA do not require the assistance of a lawyer or any other administrative cost. Thirdly, researchers are not the only ones who can be held accountable; regulatory institutions within the ethical-legal framework are also called to account. For example, the NHREC has the power to adjudicate complaints regarding the functioning of an REC.<sup>1038</sup> Fourthly, administrative law remedies can be used to hold institutions accountable.<sup>1039</sup> In other words, the courts can be used to hold institutions accountable if they fail to fulfil their mandate.<sup>1040</sup> Fifthly, it has been argued that our enforcement mechanisms can also be a 'useful mechanism to reverse irrational ideology-driven science policy and decision-making'.<sup>1041</sup>

Admittedly, the courts are certainly not a panacea to all the challenges that bedevil researchers and research participants. Moreover, they should not become battlegrounds for

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<sup>1035</sup> *Ibid.*

<sup>1036</sup> See Chapter Four for a detailed outline of these mechanisms.

<sup>1037</sup> S 72(6)(f) National Health Act (note 57 above).

<sup>1038</sup> S 72(6)(d) *ibid.* This means for example, that if a health establishment conducting health research fails to establish an REC or ensure that its researchers have access to one, they would have violated s 73 of the NHA and the NHREC could hold them liable for this omission.

<sup>1039</sup> Singh (note 10 above) 77.

<sup>1040</sup> *Ibid.* See Chapter Two for where there is more discussion of the examples used by Singh of decisions made by administrative bodies that have been reviewed by the courts.

<sup>1041</sup> 76 *ibid.*

scientific matters in all instances or be approached as a first recourse. However, as the South African experience demonstrates, the judiciary can play a crucial role when authorities abuse their power in the research arena.<sup>1042</sup>

Overall, the enforcement systems within the ethical-legal framework are weak and research participants' wishing to enforce their rights would face the following constraints:

- (i) The general mechanisms are 'constrained by cost, low levels of knowledge of legal rights and limited access to legal services';<sup>1043</sup>
- (ii) Even enforcement mechanisms which should be cheap, speedy and easy to use are fundamentally flawed. For example, Slack, Singh, Strode and Essack identify a number of shortcomings with the GCP's approach to compensation for research-related harm in clinical trials, including that the GCP Guidelines limit claims for harm to those of an 'enduring' nature. The authors argue that this is a narrow approach as harms may be serious but not enduring. Furthermore, the GCP only allows claims for bodily injury, thus excluding damages for psychological harm. Finally, Slack et al argue that the procedural requirement that participants must make their claim for compensation via the researchers is problematic as it requires a party (the researcher) who has a direct interest in defending the matter to assist in resolving the dispute.<sup>1044</sup> Likewise there have been criticisms of the effectiveness of reporting a health professional to the HPCSA. Some NGOs have submitted that the complainant's version is seldom accepted over that of the accused medical professional;<sup>1045</sup> and

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<sup>1042</sup> S 78 *ibid*.

<sup>1043</sup> Strode, Slack & Mushariwa (note 94 above) 600.

<sup>1044</sup> Slack, Singh, Strode & Essack (note 143 above) 93.

<sup>1045</sup> For example, in a submission to parliament the AIDS Law Project noted that it had 'assisted a number of clients in laying complaints with the Health Profession's Council and has attended (as observer) several hearings into alleged professional misconduct . . . We have also observed that committees are made up of registered professionals who are at times more responsive to the medical professional accused of misconduct. This conduct may or may not be indicative of bias on the part of the committee. However, even if it does not affect the outcome in any matter, it certainly undermines the complainant's confidence in the impartiality of the

- (iii) Using courts to settle such disputes has its limits, amongst others, the uncertainty of the outcome, the time it takes to resolve the matter, remedies may or may not be commensurate with the extent of the harm suffered and the outcome may not offer a comprehensive solution to the problems associated with bio-technology.<sup>1046</sup>

A gap in the framework is that the NHA has not created a clear set of sanctions that could be imposed by the NHREC. It must, in terms of section 72(6) of the NHA, 'refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider'. This is a very narrow remedy which can only be used against persons registered with a health professions council. As articulated in Chapter Two this approach is premised on the professional control model of an ethical-legal framework and has a number of limitations given that research teams are often multi-disciplinary. Neither the NHA nor the Regulations relating to the NHREC describes any other sanctions that it can impose.

### **6.3 Review of the extent to which South Africa's current normative framework meets key international norms**

#### *6.3.1 Overview*

The norms regulating health research with human subjects (including specific norms regarding children) are contained in sections 11, 16 and 71 of the NHA.<sup>1047</sup> The Children's Act does not refer to the rights of a child regarding research participation. However, it does refer to a child's rights regarding other health interventions. Child research participants have

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committee, and makes the proceedings more uncomfortable and stressful for complainants and their witnesses'. Submission on the Health Profession's Amendment Bill (B10–2005), AIDS Law Project available from <http://www.alp.org.za/pdf/Parliament/Health%20Professions%20Amendment%20Bill%20-%202006%20-%20ALP.pdf> [Accessed 1 July 2009].

<sup>1046</sup> Nielsen (note 42 above) 41.

<sup>1047</sup> National Health Act (note 57 above).

rights to informed consent, privacy, dignity and equality. There are also five legal obligations on researchers to promote the welfare of child research participants.

### 6.3.2 *The rights of research participants*

It has been argued that effective ethical legal frameworks are those that protect the dignity and rights of participants and promote their welfare.<sup>1048</sup>

#### (i) *Informed consent to research participation*

Informed consent is a well-established international ethical-legal norm which is based on the principle of respect for a person's autonomy and the right to bodily integrity.<sup>1049</sup> Both the Nuremburg Code and the Helsinki Declaration clearly articulate the fundamental nature of consent to health research.<sup>1050</sup>

There is a clear but highly restrictive framework for informed consent to health research. Sections 11, 16 and 71 of the NHA provide that written consent is required for all forms of health research except record reviews by health care providers and health studies without living human participants. The framework provides norms for obtaining consent in research involving minors. Independent consent by children is prohibited and only parents or legal guardians may provide proxy consent.<sup>1051</sup> Ministerial consent is also required if the research is classified as non-therapeutic.<sup>1052</sup> The draft Regulations on Human Subjects provide further that participants must be well informed accordingly, they outline the minimum information that should be provided to research participants.<sup>1053</sup> There is no express mention of the

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<sup>1048</sup> Annas & Grodin (note 190 above) 327.

<sup>1049</sup> Lee, Havens, Sato, Hoffman & Leuthner (note 382 above) 724, London et al (note 156 above) 288 and Wendler & Grady (note 397 above) 205.

<sup>1050</sup> *Ibid.* See Chapter Two for a full description of the right to informed consent in international law and ethical codes.

<sup>1051</sup> S 71(2)–(3) National Health Act (note 57 above).

<sup>1052</sup> S 71(3) *ibid.*

<sup>1053</sup> Regulations 2(d) and 6 draft Regulations on Human Subjects (note 13 above).

voluntary nature of informed consent in the legislation but it is a well-established common law principle.<sup>1054</sup>

The strengths of the system are that the NHA has established clear norms on informed consent, which deal with the former problem of RECs taking differing approaches due to inconsistencies in ethical guidelines.<sup>1055</sup> The framework protects children by ensuring that very stringent consent norms are in place. It also promotes child participation at one level as minors must consent to health research alongside their parents or guardians, if they have understanding.<sup>1056</sup>

The weakness of the approach in the NHA and its accompanying draft Regulations on Human Subjects is that despite being overly protective, they fail to create a comprehensive framework for informed consent to health research, as:

- (i) Ensuring that research participants have a right to a basic level of information on the study is not comprehensively established. It is a well-established international ethical-legal principle that research participants must be given information in order to make an informed choice to participate in research.<sup>1057</sup> Both the ICH Good Clinical Practice Guidelines and those issued by CIOMS stipulate that participants must be told that they are being invited to volunteer to participate in research.<sup>1058</sup> It has been argued that these principles place an obligation on researchers to inform participants or persons consenting, in layperson's language, of the nature, scope, consequences, risks, dangers, complications, benefits,

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<sup>1054</sup> See Chapter Five for a more detailed discussion of the obligation on researchers to ensure that consent is voluntarily obtained.

<sup>1055</sup> See Chapters Three and Four for more detail on this point.

<sup>1056</sup> S 71(2)–(3) National Health Act (note 57 above).

<sup>1057</sup> Lee, Havens, Sato, Hoffman & Leuthner (note 382 above) 724, London et al (note 156 above) 288 and Wendler & Grady (note 397 above) 205. See Chapter Two for a more detailed discussion of these principles.

<sup>1058</sup> Guidance Point 5 CIOMS Guidelines (note 182 above) and Guidance Point 4.8.10 ICH Guidelines (note 178 above).

disadvantages and prognosis as well as any alternatives.<sup>1059</sup> The NHA requires researchers to inform research participants of any possible negative or positive consequences to their health as well as (if applicable) being informed that the 'health service' they are receiving is experimental.<sup>1060</sup> The draft Regulations supplement this by listing the information that ought to be provided to research participants.<sup>1061</sup> However, neither the NHA nor the Draft Regulations on Human Subjects emphasises the importance of advising research participants that they are volunteering for research, except where that research is offered as part of a health service;

- (ii) Written consent is required for all forms of health research involving human subjects. Obtaining written consent for health research is not a requirement in the common law, and the new provisions in the NHA have serious implications for certain types of research such as telephonic interviews, postal or electronic studies in which the completion and voluntary return of the questionnaire is commonly regarded as implied consent. Furthermore, requiring written consent outlaws the obtaining of passive consent, a practice frequently used in social science research with children.<sup>1062</sup> This approach is out of step with the more flexible one set out in the NHREC Guidelines which provide that consent may be

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<sup>1059</sup> Van Oosten (note 104 above) 6 and C van Wyk 'Clinical trials, medical research and cloning in South Africa' (2004) Vol 67(1) *THRHR* 1, 7.

<sup>1060</sup> S 71(1)(b) and 11 National Health Act (note 57 above).

<sup>1061</sup> Regulation 6 Draft Regulations on Human Subjects (note 13 above).

<sup>1062</sup> Passive consent has been defined as a 'procedure typically involv(ing) distributing a letter to the children's parents or guardians explaining the nature of the study and providing a method to retract permission. In an active consent procedure, the introductory letter explains the nature of the study and provides a method to document permission. The important distinction between these two procedures is that the passive consent procedure assumes that the parent or guardian has consented unless some action is taken, whereas the active consent procedure requires the parent or guardian to signify in writing their permission for the minor to participate in the study' <http://www.4researchers.org/articles/146> [Accessed: 2 September 2009] and Zuch, Mason-Jones, Mathews & Henley (note 121 above) 4.

given verbally or in writing. It may also in certain circumstances be waived if prior approval of the REC is obtained;<sup>1063</sup>

- (iii) The authority to provide consent to health research involving minors has been limited to parents or guardians. The NHA does not allow for consent by care-givers even if they act as de facto parents or guardians and can consent to medical treatment on the child in terms of the Children's Act.<sup>1064</sup> Nevertheless, Pope argues that where children have no parents or guardian, for example, children living in a child-headed household, the High Court could be approached to provide consent as the upper guardian of all minors.<sup>1065</sup> There have been criticisms of this approach particularly as many children live away from their parents or guardians.<sup>1066</sup> Furthermore, there are a significant number of child-headed households.<sup>1067</sup> Strode and Slack argue that the approach should be less rigid and re-focused around a graded standard which is dependent on risk levels. Thus they submit that care-givers should be able to provide consent for research which 'would approximate decisions regarding children's day-to-day care'.<sup>1068</sup> Using this approach care-givers ought to be able to consent to minimal risk research as this would be in line with the approach taken in the Children's Act.<sup>1069</sup> They also submit that this would ensure that children not living with their parents

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<sup>1063</sup> NHREC Guidelines (note 56 above) 4.

<sup>1064</sup> S 129 Children's Act (note 4 above). The Children's Act defines a care-giver in s 1 as 'any person other than a parent or a guardian, who factually cares for a child and includes – (a) a foster parent; (b) a person who cares for a child with the implied or express consent of a parent or guardian; (c) a person who cares for a child whilst the child is temporarily in safe care; (d) the person at the head of a child and youth care centre where the child has been placed; (e) the person in charge of a shelter; (f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and (g) the child at the head of a child headed household'.

<sup>1065</sup> Pope (note 93 above) 170.

<sup>1066</sup> Zuch, Mason-Jones, Mathews & Henley (note 121 above) 3; Stobie, Strode & Slack (note 59 above) 195; and Slack, Strode, Grant & Milford (note 143 above) 683.

<sup>1067</sup> Singh, Abdool Karim, Abdool Karim, Mlisana et al (note 78 above) 181.

<sup>1068</sup> Strode & Slack (note 139 above) 71.

<sup>1069</sup> *Ibid.*

or guardians are not inappropriately excluded from potential benefits of being research participants; and

- (iv) There are no circumstances in which a child may consent independently to health research. It has been argued that not allowing children to consent independently to any form of health research is an overly restrictive approach which will prevent some important health research from taking place.<sup>1070</sup> Singh et al argue that some forms of research, for example, studies on teenage drug use may place children at risk if parental consent is required.<sup>1071</sup> Likewise, it is clear that a study on why teenagers are continuing to undergo backstreet abortions would struggle to recruit girls if parental consent was required.<sup>1072</sup> This is also out of step with the approach taken in the Children's Act where there is recognition of a child's evolving capacity to consent to a range of health interventions from the age of 12 onwards.<sup>1073</sup> Finally, this approach inappropriately treats all health research alike without recognising that research with some risk ought to be treated differently to low or no risk studies.<sup>1074</sup>

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<sup>1070</sup> Strode, Grant, Slack & Mushariwa (note 114 above) 266; Zuch, Mason-Jones, Mathews & Henley (note 121 above) 3.

<sup>1071</sup> Singh, Abdool Karim, Abdool Karim, Mlisana et al (note 78 above) 182.

<sup>1072</sup> For example, there is research which shows that less than 20 per cent of American adolescents wished to involve their parents when they were accessing sexual and reproductive health services: DM Reddy, R Flemming & C Swain 'Effect of mandatory parental notification on adolescent girls' use of sexual health care services' (2007) Vol 288 *JAMA* 711. Furthermore, several studies on access to abortions and contraceptives have shown that the potential negative reactions from parents deter adolescents from using such services: S Jackson, & TI Hafemeister 'Impact of parental consent and notification policies on the decisions of adolescents to be tested for HIV' (2001) Vol 29 *Journal of Adolescent Health* 85. With the most common reasons for non-disclosure to parents being a concern for their parent's feelings including a fear of disappointment or embarrassment and expected negative results such as physical punishments or other forms of retaliation *ibid* 86.

<sup>1073</sup> Strode, Slack & Essack (note 143 above) 247. Singh, Abdool Karim, Abdool Karim, Mlisana et al (note 78 above) argue for a recognition of some children as 'mature minors', in other words capable of making independent research-related decisions 182.

<sup>1074</sup> Zuch, Mason-Jones, Mathews & Henley (note 121 above) 4.

A key omission in the framework is that the law does not provide that participants must appreciate or understand the information that they have been provided on the study. The NHA and its draft Regulations are silent on the issue of appreciation. This is a gap as establishing whether a research participant understands the risks of research is clearly a complex issue which requires normative guidance.<sup>1075</sup> This is particularly important given that ‘understanding’ is now the benchmark for when a minor may consent rather than assent to health research.<sup>1076</sup>

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<sup>1075</sup> Lindegger & Richter describe some of the key issues as being ‘understanding is an elusive concept, and it is not a simple matter to gauge the nature and level of understanding that someone has of a concept, an event or process. While it may be relatively easy to evaluate the adequacy of information disclosed (eg, showing information on a videotape) it is far more difficult to assess how the information and its implications are truly understood’: Lindegger & Richter (note 511 above) 315.

<sup>1076</sup> S 71(2)–(3) National Health Act (note 57 above).

(ii) *Rights to privacy, dignity and equality in health research*

Everyone has a right to privacy, dignity and equality in international law.<sup>1077</sup> The right to privacy within the context of research is also a well-established ethical principle.<sup>1078</sup> The right to dignity is also recognised in the international ethical-legal framework although applying this right to research is not as well developed as the right to privacy.<sup>1079</sup> The right to equality is not recognised as a rights issue in the international ethical codes other than the Universal Declaration of Human Rights and the Human Genome however, many of the values underpinning the right to equality are recognised in the ethical concept of justice.<sup>1080</sup>

The NHA is silent on the issue of the rights to privacy, dignity and equality within research. However, the NHREC Guidelines clearly provide that participants are entitled to privacy regarding any personal information collected from them.<sup>1081</sup> They also state that respect for participants' dignity must be a primary concern for all researchers.<sup>1082</sup> They do not refer to participants' rights to equality. Nevertheless, there is a reference to inequalities in the consent processes of research in the Schedule of an Illustrative List of Unfair Practices in certain Sectors which is attached to the Equality Act.<sup>1083</sup>

The strength of the current system is that although the NHA is silent on these three rights within the context of health research, the draft Regulations on Human Subjects require studies to be respectful of participants' rights to privacy, dignity, bodily integrity and equality.

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<sup>1077</sup> Articles 17, 10, 2 and 3 International Convention on Civil and Political Rights (note 170 above).

<sup>1078</sup> Tolich (note 391 above) 101, Guidance Point 6 Declaration of Helsinki (note 41 above) and Guidance Points 4 and 5 CIOMS (note 176 above).

<sup>1079</sup> Guidance Point 2 Helsinki Declaration *ibid* and Guidance Point 4 CIOMS *ibid*.

<sup>1080</sup> Tangwa (note 597 above) 56.

<sup>1081</sup> Point 2.7 NHREC Guidelines (note 102 above).

<sup>1082</sup> Point 2.1 *ibid*.

<sup>1083</sup> Promotion of Equality and the Prevention of Unfair Discrimination Act (note 854 above).

The weakness is that the draft Regulations do not provide any further detail on how these rights apply within the context of research. This is particularly problematic in relation to the privacy rights of children, where there is a lack of clarity regarding what information will be disclosed to parents or guardians who are providing over-arching consent for research participation. The failure of the NHA to address these rights also reflects a superficial approach to the promotion of the well-being of research participants with the primary protection being on the right to informed consent.

### 6.3.3 *Obligations on researchers to protect child research participants*

There are a number of specific obligations on health researchers who are undertaking research with children to ensure that their rights and welfare are protected.

#### *(i) Therapeutic research with minors must be in the best interests of the child*

There is no international norm requiring therapeutic research to be in the best interests of the child. Nevertheless, section 71(2) of the NHA requires researchers to demonstrate that therapeutic research is in the best interests of minors.

The advantage of the approach taken in the NHA is that the concept of the best interests of the child is well developed in our law.<sup>1084</sup> It is a flexible standard which is well suited to being applied with due consideration of the needs of the particular situation.<sup>1085</sup> However, Stobie,

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<sup>1084</sup> Stobie, Strobe & Slack (note 58 above) 198.

<sup>1085</sup> *S v M (Centre for Child law as Amicus Curiae)* (note 847 above) para 24; *Minister of Welfare and Population Development v Fitzpatrick and Others* (note 874 above) para 18; and Strobe, Grant, Slack & Mushariwa (note 93 above) 266. Kopelman has defended the use of the concept of the best interests of the child as a standard for establishing when health research is appropriate., She suggests that it is a useful benchmark for establishing whether the study is reasonable, see L Kopelman 'The Best-Interests Standard as threshold, ideal, and standard of reasonableness' (1997) Vol 22 (3) *Journal of Medical Philosophy* 271-289.

snowboarding gold medallist Seth Wescott, the Sochi-bound Canadian biathlete Rosanna Crawford and the Australian four-man bobsled team. Megan Rapinoe, who won gold in the women's football in London, said she believed the IOC should have done more and made it clear that this was not a political issue but a basic question of human rights. 'I understand and respect that the Olympics are not the time nor place for political statements, but this is far beyond any kind of statement,' the report quotes her as saying.

[Full report in The Guardian](#)

**Criminal: Niquab row woman admits witness intimidation**

A Muslim woman who wore a full-face veil in court during her trial has admitted witness intimidation. A report in *The Guardian* states that the jury trying Rebekah Dawson (22), at Blackfriars Crown Court in London, was discharged after failing to reach a verdict after deliberating for more than 12 hours. But in a dramatic twist after a short delay, **Dawson came back into court and admitted the same charge of witness intimidation that she had denied at her trial.** The jury had also failed to reach a verdict in the case of her brother Matthias Dawson (32), who faced the same charge. Rebekah Dawson wore a niqab that showed just her eyes during the seven-day trial. But she had waived her right to give evidence in her defence during the trial after being told by Judge Peter Murphy that she would have to show her face to the jury during her testimony. She had argued it was against her religious views to show her face to men. Judge Murphy released Dawson, of Hackney, east London, on bail ahead of sentencing on a date to be fixed. She had intimidated Daudi Yusuf, a security guard at the Finsbury Park mosque in north London, last June, several weeks after he was involved in a row with her husband, Royal Barnes, the report states.

[Full report in The Guardian](#)

**TODAY'S BRIEFS**

\* Eduard Pretorius (33), **accused of murdering and mutilating Maria Mathe (25) last weekend**, has appeared in the Swartuggens Magistrate's Court, where the case was postponed to 7 February for a formal bail application.

[- loL](#)

\* Ambiga Naidu (53), **who pleaded guilty to defrauding former Springbok flanker and Sharks captain Wayne Fyvie of R1.4m**, has been sentenced by Magistrate K Chamberlain of the Pinetown Regional Court to eight years' imprisonment.

[- Daily News](#)

\* The case against a man (28), **arrested in connection with acts of terrorism against Sanral**, has been struck off the roll in the Pretoria Magistrate's Court. The man was the only one left in the holding cell when Magistrate Maryke de la Rey was informed the case was *nolle prosequi*.

[- loL](#)

\* The Tshwane University of Technology has **obtained a court order stopping protests at its campuses.** 'In view of the on-going student unrest, TUT ... obtained an interdict to prevent anyone from participating in protest action on any of TUT's campuses, to disrupt TUT activities or cause damage to TUT property,' a spokesperson said.

[- Mail & Guardian](#)

Strode and Slack identify some key problems in using this concept as the standard for assessing whether therapeutic research with children ought to be approved. Firstly, it is unclear how the principle will apply, and limited literature exists on applying it to health research with children.<sup>1086</sup> Secondly, the norms for a best interests analysis articulated in section 7 of the Children's Act cannot be easily applied to health research. Thirdly, within the context of research there will always be a tension between protecting individual child participants and promoting the health of all children.<sup>1087</sup>

This is compounded by section 71(2) which is unclear as to whether the 'best interests' analysis relates to children as a group or as individuals. In other words, whether RECs may only approve therapeutic research which is in the best interests of children as a class, or whether parents, guardians and minors (if they have understanding) may only consent to therapeutic research if it is in their individual best interests. It is submitted that using a purposive approach to interpretation, the obligations in section 71(2) of the NHA ought to be understood as imposing obligations on RECs to consider children as a class of research participants during ethical approval, as in many instances it could be argued that requiring therapeutic research to be in the best interests of individual children is not always possible given that, for example, the efficacy or dosage of the experimental drug has not been established with the age group under trial. Roscam-Abbing argues that it is only possible to establish that the research is not contrary to a child's best interests.<sup>1088</sup> On the other hand, the obligations on parents, guardians or minors consenting to the research are to consider the individual interests of the child participant.

(ii) *Ministerial consent must be obtained for non-therapeutic research with minors*

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<sup>1086</sup> Similar points are made in Slack, Strode, Grant & Milford (note 141 above) 683.

<sup>1087</sup> Stobie, Strode & Slack (note 58 above) 200–201.

<sup>1088</sup> Ros-cam-Abbing (note 50 above) 148.

There is no international norm requiring executive approval for non-therapeutic research with minors.<sup>1089</sup> It is however an accepted ethical principle that there should be greater scrutiny and protection in studies which do not offer a direct benefit to the child.<sup>1090</sup> The NHA provides that the Minister of Health must provide consent to all non-therapeutic health research with minors.<sup>1091</sup> The draft Regulations on Human Subjects do not provide any guidance on how or when researchers must apply for ministerial consent.

The strength of the approach taken in the NHA is that it settles the debate on whether children can participate only in certain limited forms of so-called non-therapeutic research.<sup>1092</sup> In the past ethical guidelines and academics took different approaches to the nature of the studies and the level of risk to which a child could be exposed in so-called non-therapeutic research.<sup>1093</sup> It also creates a novel procedural protection for minors participating altruistically in health research.<sup>1094</sup> Furthermore, the NHA clearly sets out the circumstances in which the Minister of Health may provide his or her consent to non-therapeutic research, thus creating certainty.<sup>1095</sup> This is in accordance with the Constitutional Court jurisprudence which has found unconstrained discretionary powers given to the executive are inconsistent with the Constitution.<sup>1096</sup>

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<sup>1089</sup> There is however an example in foreign law, the US Code of Federal Regulations provides research with children which poses a risk of more than a minor increase over minimal risk must be referred to the Secretary of the Department of Health and Human Services for approval: Strode, Slack, Wassenaar & Singh (note 119 above) 201.

<sup>1090</sup> Wendler & Grady (note 397) above) 203.

<sup>1091</sup> S 71(3) National Health Act (note 57 above).

<sup>1092</sup> Strode, Slack, Wassenaar & Singh (note 119 above) 201.

<sup>1093</sup> See for example, the MRC's Ethical Guidelines (Book One) (note 12 above), Van Wyk (note 13 above) 46, Smit (note 34 above) 155 and Burchell (note 13 above) 193.

<sup>1094</sup> Strode, Grant, Slack & Mushariwa (note 114 above) 266.

<sup>1095</sup> *Ibid.*

<sup>1096</sup> *Dawood v Minister of Home Affairs* (note 849 above) paras 43–48. This case dealt with the circumstances in which foreign spouses of South African residents were entitled to live in South Africa pending the outcome of their application for an immigration permit. The Court held that when the legislature confers discretionary powers on officials, in this case the discretionary power to issue temporary residence permits which allowed foreign spouses to remain in South Africa whilst they applied for an immigration permit, the parameters of this discretion should be clearly described in legislation, '(I)n a constitutional democracy such as ours the

However, Strobe, Slack, Wassenaar and Singh argue that the NHA has created new problems by requiring ministerial consent for all forms of so-called non-therapeutic research with minors.<sup>1097</sup> They submit that section 71(3) is problematic as:

- (a) The NHA inappropriately treats all forms of non-therapeutic research alike.<sup>1098</sup> In other words a low risk study into the amount of exercise teenagers undertake in a week is treated in exactly the same manner as a study into a microbicide gel which may pose a minor increase over minimal risk. This is a simplistic approach which over-protects participants in low risk research;
- (b) The need for the additional protection over and above ethical approval is unclear;<sup>1099</sup> and
- (c) This is an example of the over ‘bureaucratism’ of ethics’ which may have many unintended negative consequences such as; discouraging researchers from conducting non-therapeutic research with minors or encouraging them to misclassify their research as therapeutic in nature.<sup>1100</sup>

Slack et al argue further that (a) some of the factors that must be used by the Minister of Health in approving non-therapeutic research in terms of the NHA are unclear and it is uncertain as to how they will be applied in practice,<sup>1101</sup> and (b) this new procedural obligation may result in unnecessary delays.<sup>1102</sup> Finally, given there are no regulations in

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responsibility to protect constitutional rights in practice is imposed both on the legislature and on the executive and its officials. The legislature must take care when legislation is drafted to limit the risk of an unconstitutional exercise of the discretionary powers it confers’ para 48.

<sup>1097</sup> Strobe, Slack, Wassenaar & Singh (note 119 above) 201.

<sup>1098</sup> *Ibid.*

<sup>1099</sup> *Ibid.*

<sup>1100</sup> *Ibid.*

<sup>1101</sup> *Ibid.* Slack, Strobe, Grant & Milford (note 143 above) give the example of s 71(3)(b)(iii) of the National Health Act (note 57 above) where the Minister of Health may only approve non-therapeutic research with minors if the reasons they are consenting is contrary to public policy. The authors argue that there is a lack of clarity on what this factor would mean in practice.

<sup>1102</sup> *Ibid.*

place setting out the nature of the application process,<sup>1103</sup> it appears that since March 2012 when the provision became operational no applications have been made for ministerial consent. Thus this is essentially a lame duck provision.

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<sup>1103</sup> Slack, Strode, Grant & Milford (note 143 above) 683.

*(iii) The mandatory reporting of abuse, neglect or children in need of care and protection*

There is no international norm on the obligations on researchers to report abuse and neglect. Currently, in South Africa there are a number of legal provisions which ensure that children in need of care or protection are identified and steps taken to protect them from further harm. In some instances these are mandatory obligations.<sup>1104</sup> These obligations also apply in most instances to researchers.<sup>1105</sup>

The strength of the current approach is that the provisions in the Children's Act place duties to report on a broader category of persons than was required previously in terms of the Child Care Act.<sup>1106</sup> Consequently a number of persons in the research team would be under an obligation to report.<sup>1107</sup> These provisions are supported by both criminal and civil liability if the child suffers further harm as a result of the report not having being made.<sup>1108</sup>

There are however also a number of weaknesses in the legal approach to the reporting of abuse or neglect of child research participants. Firstly, the NHA and the Children's Act are silent on how these obligations apply within the context of research. Secondly, there are no ethical guidelines giving express guidance on this issue for researchers and RECs. This is particularly problematic given the extent of research into the sexual and reproductive health of adolescents. Thirdly, the mandatory reporting of consensual underage sex with an adult or a much older partner in terms of the Sexual Offences Act may pose complexities for sexual and reproductive health research with children. Although there has been a recent change in the law, described above, and resultantly certain instances of consensual underage

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<sup>1104</sup> S 110 Children's Act (note 4 above) and Sexual Offences Act (note 765 above).

<sup>1105</sup> See Chapter Five for further discussion on this point.

<sup>1106</sup> D McQuoid-Mason 'The Children's Amendment Act and the Criminal Law (Sexual Offences and Related Matters) Amendment Act: Duty to report child abuse and sexual offences against children and mentally disabled persons' (2008) Vol 98 (12) *SAMJ* 929, 930.

<sup>1107</sup> Slack, Strode & Mamashela (note 49 above) 13.

<sup>1108</sup> *Ibid.*

sex/activity are no longer illegal,<sup>1109</sup> consensual inter-generational sex remains a sexual offence. This means that where there is a large age gap between those in the sexual relationship or one is an adult, the older person is committing a sexual offence and an obligation to report the sexual activity continues to exist.<sup>1110</sup> Given, that inter-generational sex is often a norm in communities researchers will be faced with the dilemma of reporting sexual partners who are not part of the study and this may impact on recruitment strategies.<sup>1111</sup>

(iv) *Appropriate risk standards*

It is an internationally accepted ethical norm that the risks in health research ought to be appropriate. This is a public policy consideration which is particularly important given that in many instances participants altruistically accept research-related risks for the benefit not of themselves but others.<sup>1112</sup>

The NHA does not set risk levels for children participating in research. There is however an indirect risk standard in the NHA as the Minister of Health may not give consent for non-therapeutic research if the study will pose a 'significant risk' to the minor.<sup>1113</sup> Previously, this lack of guidance was compensated by the principles set out in ethical guidelines.<sup>1114</sup> The draft Regulations change the current position by setting express risk standards that cannot be exceeded when undertaking research with children.<sup>1115</sup>

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<sup>1109</sup> See Chapter Five where this issue is discussed in more detail.

<sup>1110</sup> A Strode, J Toohey & C Slack 'Brief memo on the *Teddy Bear Clinic for Abused Children and Prevention of Child Abuse and Neglect (RAPCAN) v Minister of Justice and Constitutional Development case (case number 73300/10)*' (2013) CHAMPS: Choices for Adolescent Methods of Prevention in South Africa.

<sup>1111</sup> *Ibid.*

<sup>1112</sup> Wendler & Grady (note 397 above) 203.

<sup>1113</sup> S 71(3)(b)(iv) National Health Act (note 57 above).

<sup>1114</sup> Stobie, Strode & Slack (note 59 above) 193–194.

<sup>1115</sup> Regulation 4(1) draft Regulations on Research with Human Subjects (note 13 above).

The strengths of the position in the draft Regulations on Human Subjects are that it is the first time that clear legal guidelines have been issued on acceptable standards of research-related risk. This is an important protection which ensures that children, who do not have the legal capacity to consent to research, are protected from participating in studies that may inappropriately place them at risk of harm. It has been argued that as the Minister of Health may approve non-therapeutic research with minors if it does not pose a significant risk to the participants, that this is recognition of a new upper level of risk.<sup>1116</sup> Accordingly, allowing the Minister of Health to approve such exceptional studies will facilitate research which is not currently approvable by RECs.<sup>1117</sup>

The weakness of the approach in the NHA is that the term significant risk is not defined. It is therefore not clear whether it is in fact a new upper level of risk. Furthermore, the risks standards in the draft Regulations on Human Subjects are not in line with the well-established principles in the ethical guidelines. The maximum level of risk to which a child may be subjected is minimal risk. There may only be an increase in this level of risk if the study is of direct benefit for the child.<sup>1118</sup> Many non-therapeutic studies do not offer direct benefits to the child participant and currently ethical guidelines allow children in such studies to be subjected to a maximum of a minor increase over minimal risk.<sup>1119</sup> This proposed new approach therefore will prevent many clinical trials from taking place.

(v) *Children must be scientifically indispensable to the research*

It is an internationally accepted ethical norm that children must be indispensable to the research.<sup>1120</sup> Currently, the NHA does not refer to this principle except narrowly with regard to when the Minister of Health may give consent for non-therapeutic research with

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<sup>1116</sup> Strode, Slack, Wassenaar & Singh (note 119 above) 201.

<sup>1117</sup> *Ibid.*

<sup>1118</sup> Regulation 4 draft Regulations on Human Subjects (note 13 above).

<sup>1119</sup> See Chapter Four for a more detailed discussion of this issue.

<sup>1120</sup> Guidance Point 14 CIOMS (note 182 above).

minors.<sup>1121</sup> It is however a well-established principle in the national ethical guidelines.<sup>1122</sup> The draft Regulations on Human Subjects change this position by stating expressly that children must be indispensable to the research.<sup>1123</sup>

The strength of the approach in the draft Regulations on Human Subjects is that it transforms an ethical norm into a legal obligation which ensures that children are protected from participating in studies which could be done with a less vulnerable population.

#### **6.4 Key themes emerging from the critique of the ethical-legal framework**

A review of the critique of the institutional and normative framework for regulating health research, particularly research with children, reveals seven key themes which cut across all elements of the ethical-legal framework.

##### *6.4.1 The ethical-legal framework is premised solely on the principle of protecting child research participants*

In Chapter Two of this thesis the key norms that have been established in international law and ethical codes were described. The key elements of effective ethical-legal frameworks were also set out. It is argued that an ethical-legal framework which protects research participants, promotes their active participation and facilitates research, should be based on these three principles which are balanced against each other. Within the normative framework for regulating health research with children in South Africa the only clear principle that the system appears to be based on is that of protecting research participants. This is done by restricting when and how children can participate in health research.<sup>1124</sup>

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<sup>1121</sup> S 71(3)(b) National Health Act (note 57 above).

<sup>1122</sup> S 5.1 of the NHREC Guidelines (note 56 above).

<sup>1123</sup> Regulation 4(1)(e) Regulations on research with Human Subjects (note 13 above).

<sup>1124</sup> See Chapter Three where it is argued that there are no policy documents which reflect the principles that underlie the ethical-legal framework. It is argued that the norms in s 71 National Health Act (note 57 above) are all protective in nature, for example, this section does not allow minors to consent independently to any form

A framework which is based solely on the principle of protecting child research participants is problematic as firstly, it is out of step with the modern approach towards promoting the involvement of children within research in order to improve their health and welfare.<sup>1125</sup> Secondly, it ignores the constitutional imperative<sup>1126</sup> to consider the best interests of the child which requires the consideration of a range of factors in decisions which affect children.<sup>1127</sup> Protecting the child from harm is just one of the considerations within a best interest analysis.<sup>1128</sup> Thirdly, focusing on protection is contrary to the approach taken in the national ethical guidelines which balance a range of factors in holistically promoting the welfare of child research participants.

#### 6.4.2 *There is on-going uncertainty regarding ethical-legal norms as the system continues to be in a state of flux*

Although the NHA ushered in a new era by creating a comprehensive ethical-legal framework, only parts of it were implemented in 2005.<sup>1129</sup> This meant that between 2005–2012 the institutional aspects of the new ethical-legal framework were in place but the norms described in sections 11 and 71 of the NHA were not legal obligations.<sup>1130</sup> As a result RECs and other research stakeholders have had to operate in an uncertain environment with

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of health research. This is clearly a protective measure as it requires proxy consent for all forms of health research even low or no risk studies. See Chapter Five for further discussion on this point.

<sup>1125</sup> See Chapter One for a more detailed discussion of the importance of involving children in health research and the international shift towards ethical-legal systems which both facilitate research and protect child research participants.

<sup>1126</sup> S 28(2) Constitution of the Republic of South Africa (note 2 above).

<sup>1127</sup> *McCall v McCall* (note 68 above).

<sup>1128</sup> See for example, s 7 Children's Act (note 4 above) which lists the factors that ought to be taken into account in establishing the best interests of the child. Although the Act appears to indicate that this is a closed list of factors the Constitutional Court in *S v M (Centre for Child law as Amicus Curiae)* (note 865 above) para 24 indicated that there should be an individual approach and not the use of a 'predetermined formula'. It could be argued that this implies that the list of factors in s 7 of the Children's Act is not exhaustive.

<sup>1129</sup> *Government Gazette* No. 27503 (note 94 above).

<sup>1130</sup> See Chapters Three and Four for more detail on these points.

disparate approaches to, amongst others, the age of consent to research.<sup>1131</sup> In March 2012 sections 11 and 71 of the NHA were operationalised with almost no advance warning in the *Government Gazette*<sup>1132</sup> and as a result the final elements of the ethical-legal framework were implemented. However, given that no regulations had been issued to accompany these sections, some of the norms in section 71 remain in limbo. For example, there is no guidance on the process and form an application for ministerial consent for non-therapeutic research ought to take. As a result it appears that RECs are not requiring researchers to apply for this form of authorisation.<sup>1133</sup> Even the NHREC on its website has issued a statement indicating that it is aware that clarity is needed on how RECs can meet the new norms in the NHA and that section 71 conflicts with the position taken in the national ethical guidelines.<sup>1134</sup> No explanation has been issued by the Ministry of Health for its failure to finalise the draft Regulations on Human Subjects.

This on-going uncertainty undermines the ethical-legal framework as it results in a lack of clarity and its accompanying disparate approaches.<sup>1135</sup> Furthermore, investigators, RECs and other stakeholders face an uncertain ethical-legal future with no clear instruction on when they will have to change current practices, such as allowing independent consent by children in certain circumstances in accordance with the national ethical guidelines.<sup>1136</sup> Ultimately, this on-going state of flux could affect recruitment and informed consent processes.<sup>1137</sup>

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<sup>1131</sup> Slack, Strode, Grant & Milford (note 143 above) 682. For example, the authors describe how some RECs during this period allowed children over the age of 14 to consent independently to therapeutic research on the basis that children could consent to medical treatment from this age in terms of the Child Care Act 74 of 1983. *Ibid.*

<sup>1132</sup> *Government Gazette* No. 35081 (note 96 above).

<sup>1133</sup> See for example, the approaches of UKZN and the HSRC (note 123 above).

<sup>1134</sup> Statement from the Council on the Proclamation of s 71 of the National Health Act, undated, available from <http://www.nhrec.org.za/wp-content/uploads/2012/letter.pdf> [Accessed: 28 December 2012].

<sup>1135</sup> Slack, Strode, Grant & Milford (note 143 above) 682.

<sup>1136</sup> See Chapters Three and Five for a discussion on when the ethical guidelines allow independent consent to health research by children.

<sup>1137</sup> Slack, Strode, Grant & Milford (note 143 above) 683.

#### 6.4.3 *The protection of children within the ethical-legal framework is undermined by the lack of institutional independence of some of the regulatory institutions*

In Chapter Two the importance of ethical-institutions being independent was described. The significance of this principle has been illustrated by the actions of both the apartheid and post-apartheid governments. Under apartheid, research aimed to promote the prevailing political ideology of white supremacy. Accordingly, funds were channelled towards research to improve health services for whites<sup>1138</sup> and in genomic research to ‘prove’ or provide a rationale for white domination.<sup>1139</sup> In the post-apartheid era, political interference in the research agenda has continued. As described above there have been allegations of political pressure being placed on the MCC<sup>1140</sup> and Singh has argued that this same political influence has resulted in for example, ‘ill-founded ideology-driven redundant and unreasonable operational research’ by the Department of Health in relation to the prevention of mother-to-child transmission of HIV.<sup>1141</sup> Given this context, it is of concern that the independence of three statutory bodies within the ethical-legal framework, the NHRC, the MCC and the NHREC, has not been assured through their empowering legislation. Furthermore, their independence has been actively undermined by (a) powers given to the Minister of Health to appoint their members and chairpersons/deputies, and (b) their reporting structures which require reporting directly to the Minister of Health rather than parliament. It is argued that this inappropriately places power in the hands of the executive to control such bodies.

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<sup>1138</sup> Singh & Strode (note 45 above).

<sup>1139</sup> *Ibid.*

<sup>1140</sup> *Mail and Guardian* (note 959 above).

<sup>1141</sup> Singh (note 10 above) s 77. Heywood refers to this as the ‘sometimes hidden, sometimes open, relationship . . . between the President and AIDS denialists’: M Heywood ‘Prevention of Mother to Child HIV Transmission in South Africa: Background, strategies and outcomes of the Treatment Action Campaign case against the Minister of Health’ (2003) Vol 19 *South African Journal of Human Rights* 278, 282.

#### 6.4.4 *The ethical-legal framework has a superficial approach to community participation in health research*

The value of community participation in health research is well established.<sup>1142</sup> In our ethical-legal framework the principle of community engagement in research is reflected in a number of different ways. Firstly, by ensuring that the ‘community’ as a key stakeholder in research is represented by members appointed in this capacity on certain statutory bodies (the NHRC and NHREC) as well as RECs.<sup>1143</sup> Secondly, in some instances researchers are required to establish a formal link with the community in which they are doing research through a Community Advisory Board or Group.<sup>1144</sup> This facilitates a broader community engagement process relating to the research. Thirdly, in one instance community representatives (the House of Traditional Leaders) must be informed of potential studies as the HSRC is required to notify them of research it is undertaking in areas under their jurisdiction.<sup>1145</sup>

It is argued that nevertheless this approach to community engagement in health research is superficial and haphazard as:

- (a) The community is not required to be represented on all statutory bodies within the ethical-legal framework, for example, the Medicines Act does not expressly require a community representative on the Council. This is an uneven approach as they are represented on the NHRC, NHREC and RECs;
- (b) Community representatives are given nominal positions on regulatory structures and would not be in a position to exert great influence over decisions;<sup>1146</sup>
- (c) The role of community representatives or how they ought to be nominated / elected onto statutory bodies and RECs is not described in any detail in policy documents.

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<sup>1142</sup> Point 1 National Health Research Ethics Council Guidelines for Community Advisory Groups (note 716 above). See Chapter Two for more detail on this point.

<sup>1143</sup> See Chapter Four for a more detailed discussion on this point.

<sup>1144</sup> National Health Research Ethics Council Guidelines for Community Advisory Groups (note 716 above).

<sup>1145</sup> S 14(6) HSRC Act (note 62 above).

<sup>1146</sup> See for example, the critique by Mc Neil (note 1025 above) in which he argues that ethics committees do not have sufficient representation from the community.

This makes it difficult to ensure that the broader community engagement in research policy and regulation is meaningful. Key questions include for example, should the community representative be someone from a democratically elected structure, a person living in the area or a member of a non-governmental organisation? and

(d) Only the HSRC is required to 'notify' traditional leaders when researching in rural areas. Although this is a form of community engagement it is very limited as it does not require such leaders to input into the research process or to facilitate access to community members living in those areas.

#### *6.4.5 Ensuring there is consistency across the ethical-legal framework is hampered by a lack of co-ordination across regulatory institutions*

The current framework lacks cohesion and as a result although it is made up of a number of institutions all playing a unique role in the broader spectrum of regulating research regulation, there is no co-ordination between them. Co-ordination between the various institutions within the ethical-legal framework is required ensure that research is regulated in a holistic way through policy controls and ethical/scientific review. Prior to the implementation of the NHA there was no mechanism for co-ordinating the work of the limited institutions within the ethical-legal framework. This resulted in disjunctive approaches and overlaps between the various institutions.<sup>1147</sup> For example, the MCC issued guidance on HIV vaccine trials which included a stipulation that participants must have a matric in order to be eligible to volunteer as a participant.<sup>1148</sup> This was criticised as it was argued that the norms for informed consent are based on ethical obligations and should be set by RECs and not the MCC.<sup>1149</sup>

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<sup>1147</sup> Strode, Slack & Mushariwa (note 94 above) 588.

<sup>1148</sup> *Ibid.*

<sup>1149</sup> *Ibid.*

This lack of co-ordination has continued after the full implementation of the NHA since there is still no express mechanism to ensure co-ordination between all the ethical-legal institutions. The Regulations establishing the NHREC require that a member of the MCC sit on the NHREC.<sup>1150</sup> However, there is no reciprocal obligation. Nevertheless, the direct link between the MCC and the NHREC does ensure a measure of co-ordination between these two institutions. However, there is no link between the MCC, the NHREC, RECs and the NHRC and this remains a gap. Furthermore, there is no direct link between the NHRC and any of the other institutions in the ethical-legal framework.

#### *6.4.6 The protections in the ethical-legal framework have been undermined by drafting errors and inconsistencies between the approaches to child autonomy in the NHA and the Children's Act*

The protections within the normative framework are undermined by a number of problems in the way they have been drafted. Firstly, some of the drafting reflects outdated approaches, for example, section 71 of the NHA distinguishes between so called therapeutic and non-therapeutic research with minors. This is a contested approach which has been criticised in the literature, with some academics arguing that studies cannot be neatly categorised into one or the other group.<sup>1151</sup> Furthermore, some international guidelines such as the CIOMS guidelines have moved away from using these terms.<sup>1152</sup> In our context, using this approach is made even more complex as the NHA does not define either term and the draft Regulations on Human Subjects only define non-therapeutic research.<sup>1153</sup> Secondly, the drafters of the NHA have failed to reconcile the sections on child research participants with the principles underpinning the Children's Act even though this is the most comprehensive

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<sup>1150</sup> Regulations relating to the National Health Research Ethics Council (note 667 above).

<sup>1151</sup> Slack & Kruger (note 53 above) 269–270, Stobie, Strode and Slack (note 59 above) 197 and RJ Levine *Ethics and Regulation of Clinical Research* (2nd ed) (1988) 122.

<sup>1152</sup> *Ibid* and CIOMS Guidelines (note 182 above)..

<sup>1153</sup> Slack, Strode, Grant & Milford (note 143 above) 683 and Regulation 1 draft Regulations on Human Subjects (note 13 above).

piece of legislation describing the rights of children. As a result, (a) different terminology is used in the two acts, for example, the NHA in section 71 refers to minors rather than following the Children's Act and referring to children, and (b) there are different principles underpinning each act which results in conflict. For example, the NHA does not recognise the ability of children to consent independently to any form of health research.<sup>1154</sup> This is in direct contrast to the Children's and Choice of Termination of Pregnancy Acts which specifically allow persons under the age of 18 to consent to certain health interventions without the assistance of their parent, guardian or care-giver.<sup>1155</sup> No reason has been advanced by the drafters of the NHA for restricting children from consenting independently to any form of research.<sup>1156</sup> Thirdly, poor drafting has resulted in inconsistencies and errors within the NHA. For example, section 16 of the NHA reflects a highly permissive approach to health research by not requiring any form of approval or consent for record reviews undertaken at health establishments by health care providers.<sup>1157</sup> This is inconsistent with the rest of the highly restrictive framework created by sections 11 and 71.

#### *6.4.7 The Minister of Health has an inappropriately large decision-making role in the ethical-legal framework*

The firm hand of the Minister of Health is felt throughout the ethical-legal framework in that firstly, the Minister is required to appoint the members to three of the key statutory regulatory institutions namely, the NHRC, the MCC and the NHREC.<sup>1158</sup> Secondly, the

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<sup>1154</sup> S 71 National Health Act (note 57 above).

<sup>1155</sup> Children's Act (note 4 above) and Choice of Termination of Pregnancy Act (note 823 above). Also see Table Two in Chapter One which sets out the ages of consent to various health interventions.

<sup>1156</sup> Slack, Strode, Grant & Milford (note 143 above) 683.

<sup>1157</sup> S 16(2) National Health Act (note 57 above). It should be noted that in many instances health care providers would be required to obtain ethical approval despite this gap in the law as institutional policies would require REC approval for all health research and journals will not accept papers for publication without proof of ethics review.

<sup>1158</sup> Regulation 4 Regulations relating to the establishment of the National Health Research Committee (note 598 above), s 3–4 Medicines Act (note 430 above) and Regulation 3 Regulations relating to the National Health Research Ethics Council (note 667 above).

Minister appoints the chairperson and deputy of each of these bodies.<sup>1159</sup> The Minister is thus directly involved in the composition and leadership of all the regulatory bodies within the ethical-legal framework except for RECs. Thirdly, the Minister is required to grant consent to all non-therapeutic research with minors.<sup>1160</sup> Thus the Minister is required to be directly involved in decisions regarding what is or is not appropriate research with children. It is submitted that the involvement of the executive in such research-related decisions undermines the institutional framework for regulating research and adds little or no value to the protection of human subjects.

## 6.5 Conclusions

In conclusion this critique has shown that although the ethical-legal framework has all of the elements of an effective system, it fails child research participants for a number of reasons. Firstly, the current normative framework is over-protective and as a result limits the number of potential child research participants, as well as the types of research that may be conducted with children. In essence the NHA has removed the flexibility that was in the hands of RECs which flowed from the principles in ethical guidelines.

It is argued that this will have the unintended consequence of excluding important research with children, thus retarding health gains for this sector of the population. Secondly, the framework does not promote active community participation in research-related decisions. There is even less focus on child participation given that unlike the approach in the Children's Act which recognises that children have evolving capacity the NHA does not allow independent consent to any forms of health research by children. It is also silent on children assenting to research participation. Thirdly, despite the well-established institutional framework which ought to promote research with children, such studies will be tethered by the restrictive normative framework. Thus the over-protective normative framework

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<sup>1159</sup> Regulation 5 *ibid*; s 2–3 *ibid*; and Regulation 4 *ibid*.

<sup>1160</sup> S 71 National Health Act (note 57 above).

dominates all aspects of the ethical-legal system resulting in more onerous procedures for approving research with children, and complex and restrictive consent procedures all of which act as barriers to the use of evidenced based approaches to promote children's health.

## **Chapter Seven:**

### **Using the principles of child protection, participation and research facilitation to develop law and policy reform proposals**

The previous Chapter was a critique of the current ethical-legal framework. It used the international norms described in Chapter Two as benchmarks against which the South African ethical-legal framework was measured. It concluded that it fails children as the research norms in the NHA are over-protective thereby limiting the number of potential child research participants as well as the types of research that may be conducted with children. Furthermore, the framework does not promote the participation by children in research-related decisions. For example, unlike the Children's Act the NHA does not recognise the evolving capacity of children, thus excluding them from active and independent participation in any forms of health research. The Chapter concluded that the current ethical-legal framework was strangling child research rather than facilitating it as the over-protective normative framework was dominating all other aspects of the system. This has the unintended consequence of excluding children from beneficial research and thus retarding health development for them.

This Chapter establishes a theoretical framework for the proposed law and policy reforms by setting out how the three principles underpinning this thesis ought to be used with children's rights and well-established ethical norms to establish when and how children should participate in health research. An explanation is provided of how the proposed normative reforms to the framework balance the three competing interests which underpin this thesis namely, protection, participation and research facilitation. Detailed law reform proposals are

included. The Chapter concludes with an explanation of how the proposed framework differs from the current one.

## 7.1 Introduction

It has been argued that the regulation of research is important for two reasons. Firstly, in order to safeguard participants from harm, ensure that their autonomy is protected, and secondly, to ensure that the interests of society and of science do not outweigh the individual interests of research participants.<sup>1161</sup> This dissertation argues that where ethical-legal frameworks regulate health research with children they should within this context ensure that they not only protect child research participants but also promote their active participation in research decision-making and facilitate appropriate health research. Balancing these competing interests is complex and many frameworks either over-protect or over-facilitate health research.<sup>1162</sup>

South Africa is no exception with the ethical-legal framework having moved from being under-protective and overly facilitative of research to over-protective and highly restrictive.<sup>1163</sup> It is submitted that the vacillation between access and protection does not serve the best interests of child health. Furthermore, in our current context the sudden implementation of the new restrictive provisions in sections 11 and 71 of the NHA appears to be undermining public confidence in research regulation with several universities and research institutions publicly declaring that they will not comply with these sections in the NHA until draft regulations are finalised.<sup>1164</sup> They justify this position by arguing that they have deep-rooted concerns about (a) the lack of clarity on how to implement the new norms

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<sup>1161</sup> Hope, Savulesen & Hendrick (note 165 above) 163.

<sup>1162</sup> Friedman Ross (note 91 above) 2–3.

<sup>1163</sup> A Strode 'Law reform dealing with blood, tissues, organ transplants and health research: A lagging legal framework that is strangling innovation' (2012) Vol 102(9) *South African Medical Journal* 741, 741.

<sup>1164</sup> *Ibid.* The universities include the University of KwaZulu-Natal, the University of the Witwatersrand and the University of Cape Town. The HSRC has also adopted a similar position (see note 123 above).

in the NHA without detailed regulations, and (b) the direct contradictions between the approach taken in section 71 of the NHA and that contained in the NHREC ethical guidelines.<sup>1165</sup> Although these institutions submit that their refusal to comply with section 71 of the NHA in particular is justified in the circumstances, this approach nevertheless undermines the principle of legality. Furthermore, it reflects deeper concerns regarding the principled basis on which the NHA has based its norms. Given that there appears to be limited stakeholder support for the new approach contained in section 71 of the NHA it is unclear how child research will be regulated in the future without significant law and policy reform.

## **7.2 Creating a theoretical framework for the protection and empowerment of child research participants whilst facilitating appropriate health research with children**

Based on the discussion in Chapter Three of this thesis which reflected on the way in which the evolution of the ethical-legal framework had failed to find equipoise between child protection, participation and research facilitation, and the critique in Chapter Six, this Chapter argues that a new legal and policy framework is required which is clearly premised on the three principles underpinning this thesis.

### *7.2.1 The principles underpinning children's rights*

It is submitted that children's rights bring together two concepts. Firstly, the idea that every person has human rights, and secondly, children are persons in their own right and are not the property of their parents.<sup>1166</sup> Within such a framework children are the bearers of rights including child-specific rights<sup>1167</sup> and any limitation on their rights must be justified.<sup>1168</sup> The

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<sup>1165</sup> *Ibid.*

<sup>1166</sup> Human (note 132 above) 165.

<sup>1167</sup> *Ibid.* This approach is also clearly reflected in South Africa's Constitution where the drafters elected to create a specific section in the Bill of Rights describing the rights of children: s 28 Constitution of the Republic of South Africa (note 2 above).

<sup>1168</sup> *Ibid.*

CRC is based on an acceptance of this approach.<sup>1169</sup> It describes the basic human rights of all children through 54 articles and two Optional Protocols.<sup>1170</sup> Its provisions include amongst others: the right to survival; to develop to the fullest; to protection from harmful influences, abuse and exploitation; and to participate fully in family, cultural and social aspects of life.<sup>1171</sup>

The CRC has made children's rights a core part of international law.<sup>1172</sup> The Constitutional Court in *S v M* held that 'since its introduction the CRC has become the international standard against which to measure legislation and policies, and has established a new structure, modelled on children's rights'.<sup>1173</sup> Given that so many countries have acceded to the CRC<sup>1174</sup> it is clear that at one level its norms are broadly accepted and that there is now a high level of consensus on the idea and content of children's rights.<sup>1175</sup> The Convention does not specifically mention the rights of child research participants. However, many of its provisions are broad enough to allow their application to health research with children.<sup>1176</sup>

Given the normative consensus on the content of children's rights, it is argued that the principles underpinning such rights are also almost universally accepted. Furthermore, as the discourse around children's rights has had to deal with the complexity of balancing the protection and empowerment of children, it creates an appropriate theoretical framework

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<sup>1169</sup> Wolfson (note 237 above) 7.

<sup>1170</sup> Convention on the Rights of the Child (note 48 above).

<sup>1171</sup> *Ibid.* The CRC was the first international instrument to incorporate civil, political, cultural, economic, political and social rights within a single convention.

<sup>1172</sup> Sloth-Nielsen & Mezmur (note 229 above) 331.

<sup>1173</sup> *S v M* (note 865 above) para 16.

<sup>1174</sup> *Ibid.*

<sup>1175</sup> *Ibid.* More countries have ratified the CRC than any other human rights treaty in history [http://www.unicef.org/crc/index\\_30229.html](http://www.unicef.org/crc/index_30229.html) [Accessed 29 April 2013]. To date the United Nations reports that it has been ratified by 193 countries [http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IV-11&chapter=4&lang=en](http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-11&chapter=4&lang=en) [Accessed: 29 April 2013].

<sup>1176</sup> The Committee on the Rights of the Child in General Comment No. 3 has issued guidance on HIV prevention research (note 174 above). This guidance only applies narrowly to children participating in HIV-related studies not health research generally. See Chapter Two for further discussion on this point.

for developing principles that can form the foundation of health research norms for this group.

### *7.2.2 Balancing key principles to inform the development of an ethical-legal framework for health research with children*

Throughout this thesis it has been argued that the three principles of child protection, child participation and research facilitation ought to guide the development of ethical-legal norms regulating research with children. Although these principles are inter-dependent and are all equally important, they must be weighed and balanced against each other when developing individual research norms.

At an over-arching level this thesis recognises that there is a right to ‘enjoy the benefits of scientific progress and its applications’ in the ICESCRs.<sup>1177</sup> However, there is no similar provision in our Bill of Rights.<sup>1178</sup> Nevertheless, this study submits that given that scientific progress in this field requires research with human participants, the facilitation of health research falls within the broad ambit of Article 15 of the ICESCRs. It is submitted that this right to improved child health through evidence-based approaches must nevertheless be balanced with two child-specific rights, ie child protection and child participation (See Table 17 below).

**Table 17: Balancing research facilitation with child protection and participation**

<b>Right to benefit from scientific progress</b>	<b>Child rights</b>
Research facilitation	Child protection and participation

It is submitted that there is always inherent tension between research facilitation on the one hand and child protection and participation on the other. However, child protection and

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<sup>1177</sup> Article 15 International Convention on Economic, Social and Cultural Rights (note 10 above).

<sup>1178</sup> Constitution of the Republic of South Africa (note 2 above).

child participation rights may in different circumstances either complement each other or compete for dominance. For example, even though the Children’s Act allows children to consent to HIV testing unassisted at the age of 12, an approach which fosters child participation in decision-making, the drafters of this Act tempered their approach and promoted child protection by requiring most forms of HIV testing to be in a child’s best interests.<sup>1179</sup> This approach has ensured that both child protection and participation are promoted without one principle dominating over the other. However, in some instances, the rights may be in conflict and will require balancing, for example, whilst allowing very young female children to consent unassisted to a termination of pregnancy may promote child participation in sexual and reproductive decisions, it may nevertheless place their health at risk given the potential physical and psychological implications of a termination.<sup>1180</sup> In this instance, the legislature had to balance these two rights and in the Choice of Termination of Pregnancy Act it elected to place greater focus on autonomy and child participation rather than protection.<sup>1181</sup>

### *7.2.3 Delineating the concepts of child protection, child participation and research facilitation within an ethical-legal framework*

It is argued that all three concepts, those of child protection, child participation the facilitation of appropriate health research, have the following meaning within the context of health research:

*(i) Child protection*

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<sup>1179</sup> Ss 130–133 Children’s Act (note 4 above). See Chapter Five for further discussion on a child’s rights regarding HIV testing.

<sup>1180</sup> For example, it was argued by the plaintiffs in the *Christian Lawyers Association v Minister of Health and Others (Reproductive Health alliance as Amicus Curiae)* case that girls under the age of 18 did not have the capacity to decide on a termination of pregnancy and accordingly, they should be protected by requirements of mandatory counseling and parental consent (note 542 above) 512.

<sup>1181</sup> S 5(2) Choice of Termination of Pregnancy Act (note 823 above). See Chapter Five for further discussion on this Act and the protections developed by parliament to ensure that young girls’ rights to autonomy and participation in the decision-making process were supported.

This thesis uses the term child protection to refer to the obligations on certain adults and the state to protect children from harm. It is argued that this is an obligation to ensure that children do not suffer 'physical or psychological injury or damage'.<sup>1182</sup> The CRC views the protection obligations of parents and the state as broadly requiring steps to be taken to, amongst others, protect children from unfair discrimination,<sup>1183</sup> physical or mental violence<sup>1184</sup> and protect them against economic,<sup>1185</sup> sexual<sup>1186</sup> or any other form of exploitation.<sup>1187</sup>

Our Constitution provides that as an over-arching principle, children have a right to be protected from amongst others, 'maltreatment, neglect, abuse, or degradation'. It also prohibits child labour.<sup>1188</sup> The Children's Act provides further details on child protection. For example, section 6 sets out some general principles to guide the interpretation and implementation of the Act. These principles include a strong focus on protection by providing for the importance of respect for children's rights, respect for a child's dignity, treating children fairly and equitably, and protection from unfair discrimination.<sup>1189</sup> The obligation to protect children also flows from the concept of parental responsibilities and rights. These are duties owed by certain persons, such as parents to children, and include an obligation to care for and to act as a guardian of the child.<sup>1190</sup>

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<sup>1182</sup> <http://www.thefreedictionary.com/harm> [Accessed: 19 January 2013]. Also see Chapter One for further discussion on this point. S 28 of the Constitution provides that parents are primarily responsible for protecting their children but if they cannot meet this obligation the duty falls to the state: Constitution of the Republic of South Africa (note 2 above). Ss 18–21 of the Children's Act (note 4 above) elaborate on this point by providing that certain persons have parental responsibilities and rights towards a child. These include the obligation to care, remain in contact with, maintain the child and act as their guardian: s 18(2) *ibid*.

<sup>1183</sup> Article 2(2) Convention on the Rights of the Child (note 48 above).

<sup>1184</sup> Article 19(1) *ibid*.

<sup>1185</sup> Article 32(1) *ibid*.

<sup>1186</sup> Article 34 *ibid*.

<sup>1187</sup> Article 36 *ibid*.

<sup>1188</sup> S 28 Constitution of the Republic of South Africa (note 2 above).

<sup>1189</sup> S 6 Children's Act (note 4 above).

<sup>1190</sup> S 18(2) *ibid*.

The Children's Act also places special obligations on various individuals to act positively to protect a child where there is a possibility that they are in need of care or protection. This includes mandatory reporting obligations if, for example, they are being abused or neglected.<sup>1191</sup> These principles recognise the vulnerability of children and the need for special measures to be taken to ensure that their best interests are promoted.

It is submitted that in the specific context of research, the term 'child protection' means special obligations should be placed on researchers, sponsors and regulators to ensure that children are not physically or psychologically harmed by participating in the study.<sup>1192</sup> This can be achieved through measures such as:

- Requiring parental, guardian or care-giver consent for research participation involving children under the age of 12;
- Ensuring their rights to dignity, equality and privacy are not infringed;
- Obligating researchers to comply with mandatory reporting requirements;
- Setting upper limits on the risks that children may be subjected to in health research; and
- Requiring researchers to demonstrate that children are indispensable to the study.

(ii) *Child participation*

The term 'child participation' refers to the active involvement of children in decision-making according to their evolving capacity. As stated above, the principle is one of the four fundamental pillars underlying the CRC<sup>1193</sup> which recognises that children are the bearers of rights and, as such, ought to participate in decisions that affect them in accordance with their evolving capacity:<sup>1194</sup>

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<sup>1191</sup> S 110 Children's Act *ibid*. See Chapter Five for the definitions of these terms.

<sup>1192</sup> Abdool Karim et al (note 24 above)

<sup>1193</sup> Human (note 132) above.

<sup>1194</sup> Article 12 Convention on the Rights of the Child (note 48 above).

‘States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.’<sup>1195</sup>

This requires a consideration of how children can be involved in decision-making, both when they have capacity and in circumstances where they require assistance.<sup>1196</sup> Children’s right to participate is defined broadly to include not only decision-making by the state and at community level, but also the day-to-day decisions that adults make on children’s behalf. As children grow and develop, they should take greater responsibility for decision-making in matters that affect them.<sup>1197</sup>

The principle has been recognised in section 10 of the Children’s Act which provides that every ‘child that is of such an age, maturity and stage of development as to be able to participate in any matter concerning that child has the right to participate in an appropriate way and views expressed by the child must be given due consideration’.<sup>1198</sup> It has been argued that this means that adults must at a minimum listen to the views expressed by children, take them seriously, weight them according to the child’s evolving capacity and advise children of the outcome of their decision, if it is being made on behalf of the child.<sup>1199</sup>

This thesis argues that child participation in research decision-making is particularly important given the general shift within health relationships away from paternalism to

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<sup>1195</sup> *Ibid.*

<sup>1196</sup> McClure et al (note 78 above) 728 where the authors argue that in a research context children who have capacity should participate through the consent process whilst those who do not should still be engaged through giving their assent provided that they are over the age of seven.

<sup>1197</sup> L Jamieson, R Bray, A Viviers, L Lake, S Pendlebury & C Smith *South African Children’s Gauge 2010–2011* (2012) University of Cape Town 20, 23

<sup>1198</sup> Children’s Act (note 4 above).

<sup>1199</sup> *South African Children’s Gauge 2010–2011* (note 1166 above) 27.

patient autonomy.<sup>1200</sup> In the context of research it is submitted that this means involving children in deciding whether to participate in the study, obtaining their consent or assent, and ensuring their wishes are respected should they wish to withdraw from the research at any point. This can be achieved through measures such as:

- Involving children in consent and assent procedures;
- Allowing children of a certain age and capacity to consent independently to health research;
- Providing that if a child does not wish to participate in research this opinion should be respected;
- Allowing children to withdraw from a study at any point; and
- Encouraging child participation in research policy-making forums.

*(iii) Benefiting from scientific progress – facilitating health research with children*

The term ‘research facilitation’ refers to the steps that ought to be taken to ensure that laws, policies and ethical guidelines do not unreasonably prevent health research from taking place.<sup>1201</sup> It is based on an acceptance that children have a right to benefit from scientific progress. However, they can do so only if appropriate child research takes place. Thus, it is argued that within the parameter of this right is an underlying acceptance that health research has to meet certain standards if it is to be justifiable. In other words, it is submitted that the promotion of appropriate health research with children is an inherent element of their right to benefit from scientific progress. Although our Bill of Rights does not include a positive right to benefit from scientific progress within the right to freedom of expression it refers to the right to ‘academic freedom and freedom of scientific research’.<sup>1202</sup> Following on from the arguments above it is submitted that the freedom to undertake scientific research implies a recognition of the importance of research as an activity. Furthermore, given that

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<sup>1200</sup> *Castel v de Greef* (note 138 above) 426B.

<sup>1201</sup> *Strode* (note 1132 above) 742.

<sup>1202</sup> S 16(1)(d) Constitution of the Republic of South Africa (note 2 above).

children have the right to ‘basic health care services’<sup>1203</sup> and everyone has the right to ‘access health care services’<sup>1204</sup> it can be argued that realising these rights requires research to promote the development of effective health prevention and treatment services. The thesis argues that children thus have a right to participate in research and to benefit from its outcomes. In other words, structures and norms are needed which do not exclude children from research participation, but rather facilitate it in a protective and participatory manner.<sup>1205</sup> Nevertheless, it must be research which can be justified on objective, scientific grounds. Furthermore, it must be demonstrated that children are indispensable to the study.

#### 7.2.4 Using children’s rights intertwined with ethical principles to create a set of legal norms to regulate health research

The principles underpinning children’s rights do not deal directly with issues relating to health research. Accordingly, it is argued that the norms underpinning children’s rights ought to be linked to well-established ethical norms in order to articulate appropriate legal standards for the regulation of health research with children.<sup>1206</sup>

Table 18 below demonstrates how this approach could be used when the three interests of protection of research participants, child participation and the facilitation of research need to be continually balanced to ensure that the best interests of children are served.

**Table 18: Using children’s rights and ethical norms to develop a legal framework for regulating research with children**

Principle	Corresponding ethical	Nature of the norm:	Implication for the
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<sup>1203</sup> S 28(1)(c) *ibid.*

<sup>1204</sup> S 27(1)(a) *ibid.*

<sup>1205</sup> For example, Storde and Slack argue that ethical guidelines should be revised so as to recognise that in certain circumstances in the absence of a parent or guardian, proxy consent could be provided by a care-giver as defined in the Children’s Act: Storde & Slack (note 139 above) 56–57.

<sup>1206</sup> 446 *ibid.* Similar views are expressed in N Bell ‘Ethics in child research: rights, reason and responsibilities’ (2008) Vol 6(1) *Children’s Geographies* 7–20. In this article, the author argues that ethical codes guiding research ethics must be based on human rights principles. This approach formalises the symbiosis between these concepts 11 *ibid.*

<b>underpinning children's rights</b>	<b>norm</b>	<b>protection/participation/facilitation of research</b>	<b>development of research norms</b>
Children are protected from their lack of experience and knowledge	Children are a vulnerable group which requires special protection through additional ethical scrutiny. Researchers must demonstrate that children are indispensable to the study	Protection	Consent laws require younger children, and children participating in research with some risk, to be assisted by a parent, guardian or care-giver
Child participation – respecting the views of the child	Minors participating in low risk research who have sufficient capacity may consent independently to participate in the study	Participation	Research laws must ensure that the evolving capacity of children is recognised in relation to informed consent by specifying the circumstances in which children can consent independently to research
Children have the right to benefit from scientific advances	Protocols must meet the ethical standards of the REC	Facilitation	Not all research is alike. Research carrying a greater risk must be accompanied by more detailed protections. For example, proxy consent may be dispensed with in research with no risks

Furthermore this thesis finds that legislation regulating research with children should also be premised on the following more general principles:

- 'Risky' research must face greater ethical-legal scrutiny;<sup>1207</sup>
- The recognition of the evolving capacity of children;<sup>1208</sup>

<sup>1207</sup> Points 2.9 and 5.2 NHREC Guidelines (note 56 above). See the law reform proposals below

- Some flexibility should be available to RECs, which are aware of the local context;<sup>1209</sup>  
and
- The development of broad norms consistent with those in the Children’s Act.<sup>1210</sup>

### **7.3 Proposals for law and policy reform based on the principles of protection, participation and research promotion**

It is argued that the approach described above needs to be applied to the following four research-related rights and three obligations to create a framework which effectively balances the competing interests of society, science and individual children:

#### *(i) Informed consent*

Informed consent is one of the most well-established rights of research participants. It has its roots in the Nuremburg Code and the Helsinki Declaration.<sup>1211</sup> It is based on the ethical principle of respect for a person’s autonomy.<sup>1212</sup> In South Africa, it is also a constitutional right.<sup>1213</sup> It is highly developed in both international and local ethical codes.<sup>1214</sup>

Protections should include ensuring that informed consent is obtained from participants and that researchers are obligated to provide a minimum level of information to potential participants. However, the doctrine of informed consent and assent also provides an opportunity for children to participate in research-related decisions. A child’s refusal to

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<sup>1208</sup> The CRC is based on an acceptance of this principle and our Children’s Act (note 4 above) has followed suit in recognising that children may have capacity to consent to certain health interventions before adulthood, see Table Two in Chapter One.

<sup>1209</sup> S 73(2)(b) National Health Act (note 57 above). RECs are simply required to determine whether the protocol meets the ethical standards of that committee.

<sup>1210</sup> It is submitted that as the Children’s Act is the primary piece of legislation dealing with the rights of children there ought to be a synergy with the approaches, principles, norms and language in this Act so as to ensure that there are not divergent approaches between this Act and the National Health Act.

<sup>1211</sup> London et al (note 156 above) 288.

<sup>1212</sup> Lee, Havens, Sato, Hoffman & Leuthner (note 381 above) 724.

<sup>1213</sup> S 12 Constitution of the Republic of South Africa (note 2 above).

<sup>1214</sup> Helsinki Declaration (note 41 above) and NHREC Guidelines (note 56 above).

participate, or their decision to withdraw from a study should always be respected. Finally, research can be facilitated through ensuring that consent norms provide:

- (a) RECs with some flexibility and allowing them to authorise deviations from consent norms where this is appropriate and in line with the NHREC Guidelines, for example, allowing verbal consent in certain situations such as no or low risk telephone interviews;
- (b) Children over the age of 12 with the capacity to consent independently to minimal risk research; and
- (c) Care-givers with the authority to provide proxy consent to minimal risk research.

It is argued that balancing the three principles in this instance means that parental or guardianship consent for all forms of health research is not always possible as, although this creates a highly protective framework, it limits child participation and makes it difficult to undertake certain studies such as low-risk, school-based adolescent sexuality studies.<sup>1215</sup> These protections should therefore be tempered by allowing, in certain circumstances, independent consent by children; care-givers to act as proxy consenters to minimal risk research and RECs some flexibility to fulfil their obligations in terms of section 73(2)(b) of the NHA which requires them to ‘grant approval for research . . . in instances where research proposals and protocols meet the ethical standards of that health research ethics committee’.

**Table 19: Balancing the right to participate in health research with informed consent**

Protection	Participation	Facilitation of research
Consent should be required for all research involving the direct use of human subjects, unless the REC has provided an express waiver of consent	Children over 12 with capacity should be able to consent independently to certain forms of health research Children under 12 who do not have the capacity to consent should be invited to assent to	Parents, guardians and care-givers should be able to provide consent

<sup>1215</sup> Zuch, Mason-Jones, Mathews & Henley (note 121 above) 4.

	health research A child's decision not to participate in the study or to withdraw from it should be respected	
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*(ii) Privacy*

The right to privacy is well established in international law.<sup>1216</sup> A number of international ethical codes apply this right to a research context and provide that research participants are entitled to confidentiality when they participate in research.<sup>1217</sup> Although not research-specific there is also a constitutional right to privacy in South Africa.<sup>1218</sup>

The protection of the rights of research participants to privacy should be expressly provided for in law. Child participation should also be encouraged by recognising a child's right to privacy regarding their research participation when they (a) have the capacity to consent independently to the research, or (b) are able to consent on their own to certain therapeutic intervention being offered as part of the study.

These norms of protection and participation can be balanced by protecting the privacy rights of all child research participants as they have a right to confidentiality regarding their status as research participants and for any information they disclose or provide to researchers. This is a right accorded to all research participants, adults and children alike, and is not linked to their capacity to consent. Although, if proxy consent is required, child participants will not have the right to privacy regarding research participation. Participants who have provided independent consent to research participation should be entitled to privacy regarding their participation in the study, provided that their rights may be limited if this is not in the best

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<sup>1216</sup> Article 17 International Convention on Civil and Political Rights (note 170 above).

<sup>1217</sup> Guidance Point 6 Declaration of Helsinki (note 41 above) and Guidance Points 4 and 5 CIOMS (note 182 above).

<sup>1218</sup> S 14 Constitution of the Republic of South Africa (note 2 above) and *NM and Others v Smith and Others (Freedom of Expression Institute as Amicus Curiae)* (note 357 above).

interests of the child.<sup>1219</sup> Child participation is promoted by allowing older children to keep knowledge of their research participation private from their parents and if they so choose to keep certain information regarding therapeutic interventions in the study from the person providing proxy consent.

**Table 20: Balancing the right to privacy in health research**

<b>Protection</b>	<b>Participation</b>	<b>Facilitation of research</b>
<p>All research participants have the right to privacy regarding information they provide to researchers and regarding their status as research participants</p> <p>A child's right to privacy may be limited when it is in the best interests of the child</p>	<p>Child research participants have the right to privacy regarding therapeutic interventions to which they have consented independently</p> <p>Child research participants have the right to privacy regarding their participation in research if they consent to such a study without assistance</p>	<p>No specific issues regarding research facilitation</p>

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<sup>1219</sup> For example, it may not be in the best interests of the child to keep information on their HIV status private in an HIV prevention trial. See Strode & Slack (note 822) above for further discussion on this issue.

### *(iii) Dignity and Equality*

The rights to dignity and equality are also well established in international law.<sup>1220</sup> However, fewer legal instruments link these rights to research.<sup>1221</sup> In South Africa both dignity and equality are rights entrenched in the Bill of Rights.<sup>1222</sup> The right to dignity is also clearly recognised in the national ethical guidelines.<sup>1223</sup>

The rights of all research participants to dignity and equality should be protected in law. Acknowledging children's right to participate in research-related decisions is a recognition of their inherent dignity and entitlement to respect for their views. There is no balancing which is required with these rights as research which undermines these rights, even though they be in the public good, cannot outweigh children's entitlement to these rights.

### *(iv) Appropriate risk standards*

It is an international ethical norm that the risks in health research should be appropriate given that in many instances participants will accept them altruistically for the benefit of others.<sup>1224</sup> In South Africa, risk standards are established in the national ethical guidelines.<sup>1225</sup> There are also references to risk standards in the draft Regulations on Human Subjects.<sup>1226</sup> It is argued that children should be protected from participating in research with an unacceptable level of risk. Nevertheless, research should be facilitated by allowing

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<sup>1220</sup> Articles 10, 2 and 3 International Convention on Civil and Political Rights (note 172 above).

<sup>1221</sup> The right to dignity is recognised in Guidance Point 2 Helsinki Declaration (note 41 above) and Guidance Point 4 CIOMS (note 182 above). The right to equality has only recently been recognised in a research context in the International Declaration on the Human Genome and Human Rights. See Chapter Two for more detail on these points.

<sup>1222</sup> Ss 10 and 9 Constitution of the Republic of South Africa (note 2 above).

<sup>1223</sup> NHREC Guidelines (note 56 above).

<sup>1224</sup> Wendler & Grady (note 397) above) 203.

<sup>1225</sup> The NHREC Guidelines (note 56 above) 21 provide that the risks cannot place the child at more than minimal risk; or if it poses more than minimal risk but provides the child with direct benefit; or if it poses greater than minimal risk and does not hold out the prospect of direct benefit but has a high probability of generating generalised knowledge. In such a case the risk must be justified by the knowledge ratio.

<sup>1226</sup> Draft Regulations on Human Subjects (note 13 above).

children to participate in studies which entail some risk, provided that this is not disproportionate to the potential outcome.

It is submitted that the upper level of risk to which children can be subjected should be specified in law. This should be premised on the standard of minimal risk, which is a well-established ethical principle. In other words, the risks of the research should be equivalent to the risks children ordinarily encounter in their ‘daily life or routine medical or psychological examinations’.<sup>1227</sup> It is submitted that given that ethical guidelines equate these risks to the risks children encounter in routine medical care and not the general risks that they may face in their daily lives, it is a clear indication that the drafters envisaged a relative risk standard.<sup>1228</sup> Furthermore, the law should provide:

- Health research should not place children at more than a minimal risk of harm;
- If the study poses more than minimal risk of harm but provides the child with direct benefit, it may nevertheless be approvable; or
- If the research poses greater than a minimal risk of harm and it does not hold out the prospect of any direct benefit, it may be approved only if there is a high probability of generating generalised knowledge.

In this instance, child protection must be balanced with research facilitation, as research will generally carry some risks but the principle of child protection requires them to be lower than set benchmarks.

**Table 21 Balancing the risks that children can be exposed to in health research**

Protection	Participation	Facilitation of research
Risk standards are set to an appropriate level in law	-	Children can participate in research with some risk

<sup>1227</sup> NHREC’s Ethical Guidelines (note 56 above) 21.

<sup>1228</sup> See Chapter Two where the debates regarding minimal risk are described in more detail.



*(v) Scientific indispensability*

It is an international ethical principle that children should not be enrolled in research unless it has been demonstrated that they are scientifically indispensable to the study.<sup>1229</sup> In South Africa this principle is established in the national ethical guidelines and the draft Regulations on Human Subjects.<sup>1230</sup>

All child research participants should be protected by laws stating that RECs may not approve research unless scientific indispensability has been shown. There is no balancing required with this principle as protection ought to outweigh both child participation and research facilitation in this instance.

*(vi) Mandatory reporting of abuse*

There is no international ethical-legal principle on the mandatory reporting of abuse in health research with children. Nevertheless, there are a number of legal provisions in South African law which ensure that children in need of care or protection are identified, and steps taken to protect them from further harm. This is done primarily by requiring certain people, particularly those in special relationships with children, such as medical practitioners to report children who are being abused, neglected or who are in need of care and protection.<sup>1231</sup>

This is an ethical principle which protects children and it is submitted that in this instance it should outweigh the principles of child participation and research facilitation.

It is submitted that policy guidance is needed on how to apply this legal framework to health research with children.

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<sup>1229</sup> Helsinki Declaration (note 41 above) and CIOMS Guidelines (note 182 above).

<sup>1230</sup> NHREC Guidelines (note 56 above) and the draft Regulations on Human Subjects (note 573 above).

<sup>1231</sup> S 110 Children's Act (note 4 above). See Chapter Five for definitions of these terms.

#### **7.4 Recommendations for law reform**

Based on the arguments for the development of a new normative framework founded on the principles underpinning ethics and children's rights which are set out above, a number of recommendations are proposed below. In some instances, where possible, draft amendments to the current legislation are described. The recommendations are as follows:

##### *7.4.1 Strengthening the ethical-legal framework to enhance its capacity to regulate health research with children*

Recommendation One: It is recommended that the ethical-legal framework for regulating health research with children be premised at a macro-level on the principle of the best interests of the child. Furthermore, in order to promote the best interests of the child in health research, three other principles ought to inform all other law and policy development: that of ensuring that child research participants are protected, their ability to participate in research-related decisions is promoted, and appropriate health research is facilitated. The Department of Health in consultation with the NHREC should develop a health policy which describes these fundamental principles and how they are to be used to guide the regulation of health research with children.

Recommendation Two: It is recommended that the Minister of Health publish a revised version of the draft Regulations on Human Subjects which were released for public comment in 2007. The public should have an opportunity to comment on the new draft regulations and thereafter, they should be finalised before the end of 2013. This revised draft should take note of the proposals for reform made in Table 23 below.

*7.4.2 Strengthening the institutional aspects of the ethical-legal framework to enhance its capacity to regulate research with children*

Reforms of the institutional framework are required to (a) strengthen its independence from the executive, (b) ensure that there is more effective co-operation between the various institutions, (c) ensure that community participation in research-related decisions is enhanced, and (d) establish better enforcement mechanisms.

Recommendation Three: Strengthening the independence of the ethical-legal institutions. It is recommended that sections 69 and 72 of the NHA and sections 2 and 3 of the Medicines Act be amended in order to guarantee the independence of the NHRC, the NHREC and the MCC. It is proposed that the re-wording prohibit any person or organ of state from interfering in the work of these statutory bodies, as well as requiring its members to act independently and impartially. It should also expressly provide that the MCC is accountable to parliament. Sanctions should be included to respond to conduct which undermines the independence of these institutions (See Table 20 below reflecting the proposed amendments underlined).<sup>1232</sup>

**Table 22: Law reform to enhance the independence and accountability of the NHRC, NHREC and the MCC**

<p>NHA: National Health Research Council</p> <p>69. (1) The Minister must establish a committee to be known as the National Health Research Committee.</p> <p>(2) (a) The National Health Research Committee consists of not more than 15 persons, appointed by the Minister after consultation with the National Health Council.</p> <p>(b) A person appointed in terms of paragraph (a)–</p> <p>(i) serves for a term of not more than three years and may be reappointed for one or more terms; and</p> <p>(ii) ceases to be a member on resignation or if requested by the Minister for good cause</p>
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<sup>1232</sup> Deleted text is in square brackets and insertions are underlined.

to resign;

(c) A vacancy in the National Health Research Committee must be filled by the appointment of a person for the unexpired portion of the term of office of the member in whose place the person is appointed, and in the same manner in which the member was appointed in terms of paragraph (a).

(3) The National Health Research Committee must—

(a) determine the health research to be carried out by public health authorities;

(b) ensure that health research agendas and research resources focus on priority health problems;

(c) develop and advise the Minister on the application and implementation of an integrated national strategy for health research; and

(d) co-ordinate the research activities of public health authorities.

(4) The Minister must prescribe the manner in which the National Health Research Council must conduct its affairs and the procedure to be followed at meetings of the Committee, including the manner in which decisions must- be taken.

(5) A member of the National Health Research Committee who is not in the full-time employment of the State must in respect his or her service as a member be paid such remuneration as the Minister may determine with the concurrence of the Minister of Finance.

(6) A member of the National Health Research Committee shall serve impartially and independently and exercise or perform his or her powers, duties and functions in good faith and without fear, favour, bias or prejudice and subject only to the Constitution and the law.

(7) No organ of state and no member or employee of an organ of state nor any other person shall interfere with, hinder or obstruct the National Health Research Committee in the exercise or performance of its, his or her powers, duties and functions.

(8) Any conduct which interferes with or hinders the work of the National Health Research Committee shall be punishable by law.

NHA: National Health Research Ethics Council

72. (1) A council to be known as the National Health Research Ethics Council is hereby established.

(2) The Minister must—

(a) after consultation with the National Health Council, appoint as members the National Health Research Ethics Council not more than 15 persons nominated by interested parties at the invitation of the Minister by notice in the *Gazette*; and

(b) publish the list of appointees in the *Gazette*.

(3) A member of the National Health Research Ethics Council is appointed for three years but may be reappointed for one or more further terms of office.

(4) A member of the National Health Research Ethics Council must vacate his or her office if he or she resigns or if requested by the Minister to resign for good cause;

(5) If a member of the National Health Research Ethics Council vacates office or dies, the Minister may fill the vacancy by appointing a person in accordance with subsection (2) for the unexpired portion of the term of office of his or her predecessor.

(6) A member of the National Health Research Ethics Council shall serve impartially and independently and exercise or perform his or her powers, duties and functions in good faith and without fear, favour, bias or prejudice and subject only to the Constitution and the law.

(7) No organ of state and no member or employee of an organ of state nor any other person shall interfere with, hinder or obstruct the National Health Research Ethics Council in the exercise or performance of its, his or her powers, duties and functions.

(8) Any conduct which interferes with or hinders the work of the National Health Research Ethics Council shall be punishable by law.

[(6)] (9) The National Health Research Ethics Council must–

(a) determine guidelines for the functioning of health research ethics committees;

(b) register and audit health research ethics committees;

(c) set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials;

(d) adjudicate complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee;

(e) refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider;

(f) institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conducting of research in terms of this Act. Impose an appropriate sanction where a member of a research team is found to have committed a violation of ethical norms and standards including issuing a reprimand, requesting an institution to take disciplinary action against an employee or order an REC to take steps to either revoke ethical approval for a study or to place limitations on the nature of the research being done;

(g) advise the national department and provincial departments on any ethical issues concerning research.

[(7)] (10) For the purposes of subsection (6)(c), “clinical trials” means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

Medicines Act: 2. Establishment, powers and functions of Medicines Control Council

(1) There is hereby established a council to be known as the Medicines Control Council, which may exercise the powers and shall perform the functions conferred upon or assigned to the council by this Act.

(2) The Council may advise the Minister or furnish a report to the Minister on any matter referred to the council by the Minister for consideration and arising from the application of this Act.

(3) The council shall be a juristic person.

(4) No organ of state and no member or employee of an organ of state nor any other person shall interfere with, hinder or obstruct the Medicines Control Council in the exercise or performance of its, his or her powers, duties and functions.

(5) The Council is accountable to and shall report on an annual basis to parliament.

(6) Any conduct which interferes with or hinders the work of the National Health Research Committee shall be punishable by law.

3. Constitution of council

(1) The council shall consist of so many members, but not more than 24, as the Minister may from time to time determine and appoint.

(2) Not less than three of the members appointed to the council shall be persons representing the community.

(3) The chair of the council shall designate one member to sit on the National Health Research Committee and to act as a liaison person between these two bodies.

(4) The chair of the council shall designate one member to sit on the National Health Research Ethics Council and to act as a liaison person between these two bodies.

(5) A member of the Medicines Control Council shall serve impartially and independently and exercise or perform his or her powers, duties and functions in good faith and without fear, favour, bias or prejudice and subject only to the Constitution and the law.

(6) Any conduct which interferes with or hinders the work of the Medicines Control Council Committee shall be punishable by law.

Recommendation Four: Regulations 4 and 5 of the Regulations establishing the National Health Research Committee should be amended so as to ensure that the powers given to the Minister of Health to appoint members to the NHRC in the event of no or limited nominations are removed. Likewise, the Minister's powers to appoint the chairperson and vice-chairperson of the NHRC should be replaced with provisions which enable the members

of the Committee to elect from their own ranks persons into these two positions. Finally, a new Regulation 6 should be inserted into the Regulations establishing the National Health Research Committee which provides that the Committee is accountable to parliament (See the proposed amendments, underlined, below).

**Table 23: Law reform to enhance the independence and accountability of the NHRC**

Regulations relating to the establishment of the National Health Research Committee

**Constitution of the Committee**

3.(1) The members of the Committee appointed by the Minister in terms of section 69(2) (a) of the Act shall comprised the following:

- (a) a person with extensive experience and knowledge in health research;
- (b) a person representing the Department;
- (c) a person representing the community;
- (d) a person appointed on account of his/or her knowledge of the law;
- (e) a person representing the Medicines Control Council; and
- (f) a person representing the National Health Research Ethics Council.

**Nomination and appointment of members of the Committee**

4.(1) A notice relating to nominations of members of the Committee shall be published in the Government Gazette and at least one newspaper enjoying circulation in the entire Republic for appointment referred to in section 69(2) of the Act and shall include-

- (a) the closing date and time for the receipt of nominations, and
- (b) an address to which the nominations should be sent or delivered.

(2) A nomination of members of the Committee must be in a form substantially similar to Annexure "A" and must be accompanied by a curriculum vitae signed by the nominated person.

(3) If the Minister receives no nomination or receives an insufficient number of nominations within the period specified in the invitation, he or she must re-advertise the positions calling for further nominations. [the Minister may appoint the required number of persons who qualify to be appointed in terms of section 69(1) and such an appointment shall be deemed to have been appropriately made.]

[(4) If the Minister receives no nomination, the Minister shall make the necessary nomination, and any nomination so made by the Minister shall be deemed to have been properly made in terms of the appropriate provisions of these regulations.]

#### **Appointment of the chairperson and the vice-chairperson**

5.(1). For every newly constituted Committee members of the Committee shall at their first meeting elect from among themselves a [the Minister shall appoint the] chairperson and a vice-chairperson.

(2) The chairperson and vice-chairperson shall hold office during the term of office of the members of the Committee unless the chairperson and the vice chairperson shall sooner resign or cease to be a member of the Committee.

(3) The vice-chairperson may, if the chairperson is absent or for any reason unable to act as chairperson, perform all the functions and exercise all the powers of the chairperson.

(4) If both the chairperson and vice-chairperson are absent from any meeting, the members present shall elect one of their number to preside at that meeting and the person so presiding may, during that meeting and until the chairperson resumes duty or vacates office.

(5) If both the chairperson and the vice-chairperson have been given leave of absence, the [Minister shall appoint] members shall elect one of the members to act as chairperson until the chairperson and the vice-chairperson resumes duty or vacates office.

(6) If the office of chairperson and the vice-chairperson become vacant, [the Minister shall appoint] the members shall elect a new chairperson and the vice-chairperson, as the case may be, and the member so elected shall hold office for the unexpired portion of the period for which his or her predecessor was appointed.

#### **Accountability of the Committee**

(6)(1) The Committee shall be accountable to parliament.

(2) The Committee shall report on its activities to parliament on an annual basis.

Recommendation Five: Regulation 3 dealing with appointments and Regulation 4 setting out the process for appointing the chairperson and vice-chairperson of the NHREC in the Regulations Relating to the National Health Research Ethics Committee should be amended to strengthen its independence from the executive. A new Regulation 5 should be inserted into these Regulations providing that the NHREC is accountable to parliament (See the proposed amendments, underlined, below).

**Table 24: Law reform to enhance the independence and accountability of the NHREC**

Regulations relating to the National Health Research Ethics Council

**Constitution of the Council**

2. The members of the Council appointed by the Minister in terms of section 72(2)(a) are constituted as follows:

- (a) nine with extensive experience and knowledge in health research ethics;
- (b) A representative from the community;
- (c) A representative from the Department;
- (d) A representative of the pharmaceutical industry;
- (f) A representative from the Medicines Control Council;
- (g) A representative of the National Health Research Committee;
- (h) A person with extensive knowledge in animal health research ethics; and
- (g) A person with extensive knowledge in law.

**Nomination and appointment of members of the Council**

3.(1) A notice relating to nominations of members of the Council shall be published in the Government Gazette and at least one newspaper enjoying circulation in the entire Republic for appointment referred to in section 72(l)(a) of the Act and shall include—

- (a) the closing date and time for the receipt of nominations; and
- (b) an address to which the nominations should be sent or delivered.

(2) A nomination of members of the Council must be in a form substantially similar to Annexure “A” and must be accompanied by a curriculum vitae signed by the nominated person, and in the case of a candidate referred to in regulation 2(b) above, signed by two other persons who are members of a functioning Committee.

(3) If the Minister receives no nomination or receives an insufficient number of nominations within the period specified in the invitation, he or she must re-advertise the positions calling for further nominations. [the required number of persons who qualify to be appointed in terms of section 72(2) and such an appointment shall be deemed to have been appropriately made.]

**Appointment of the chairperson and the vice-chairperson**

4.(1). For every newly constituted Council the members of the Council shall at their first meeting elect from among themselves a [Minister shall appoint the] chairperson and a vice-chairperson.

(2) The chairperson and vice-chairperson shall hold office during the term of office of the members of the Council unless the chairperson and the vice-chairperson shall sooner resign or cease to be a member of the Council.

(3) The vice-chairperson may, if the chairperson is absent or for any reason unable to act as chairperson, perform all the functions and exercise all the powers of the chairperson.

(4) If both the chairperson and vice-chairperson are absent from any meeting, the members

present shall elect one of their number to preside at that meeting and the person so residing may, during that meeting and until the chairperson and the vice-chairperson resumes duty, perform all the functions and exercise all the powers of the chairperson.

(5) If both the chairperson and the vice-chairperson have been given leave of absence, the [Minister shall appoint] members shall elect one of the members to act as chairperson until the chairperson and the vice-chairperson resumes duty or vacates office.

(6) If the office of chairperson and the vice-chairperson becomes vacant, the [Minister shall appoint] members shall elect a new chairperson and the vice-chairperson, as the case may be, and the member so elected shall hold office for the unexpired portion of the period for which his or her predecessor was appointed.

#### **Accountability of the Council**

(5)(1) The Council shall be accountable to parliament.

(2) The Council shall report on its activities to parliament on an annual basis.

Recommendation Six: Enhancing co-operation between the institutions functioning within the ethical-legal framework. In order to ensure co-ordination between the various institutions within the ethical-legal framework, amendments will be required to (a) Regulation 4 of the Regulations relating to the Establishment of the National Health Research Committee,<sup>1233</sup> (b) Regulation 2 of the Regulations relating to the National Health Research Ethics Council, and (c) section 3 of the Medicines Act, in order to ensure that a representative of each institution sits on the other structures. This will facilitate greater co-operation between the various ethical-legal institutions (See the proposed amendments, underlined, in Tables 20, 21 and 22 above).

Recommendation Seven: Facilitating greater community engagement on research-related decisions. It is recommended that section 3 of the Medicines Act be amended to provide expressly for a community representative on the MCC (See the proposed amendments which are underlined where necessary in Table 20 above).

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<sup>1233</sup> Regulations relating to the establishment of the National Health Research Committee (note 599 above).

Recommendation Eight: Enhancing the sanctions available to the NHREC in terms of section 72 of the NHA, as this will create a broader range of remedies that can be used by the NHREC and will facilitate effective relief by research participants (See the proposed amendments which have been underlined in Table 22 above).

#### *7.4.3 Strengthening the normative aspects of the ethical-legal framework to enhance its capacity to regulate health research with children*

This thesis argues that given the fundamental flaws with section 71, described in Chapters Five and Six, it would be very difficult to make proposals for amendments to the section. Although it would be possible to minimise some of the negative impact of the section through minor amendments<sup>1234</sup> it would be very difficult to address the problems which flow from the fact that the section is based on the flawed distinction between therapeutic and non-therapeutic research.

Recommendation Nine: This thesis proposes that section 71 be replaced with a new section which is based on the principles described above, rather than attempting to rectify the current section in the NHA.<sup>1235</sup> The revised section should:

- (a) Expressly require informed consent from all research participants unless an express waiver of consent is issued by an REC;<sup>1236</sup>

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<sup>1234</sup> For example, it would be possible to minimise the impact of ministerial consent by amending s 71(3)(a) as follows: 'Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted . . . (ii) With the consent of the Minister, if the risk of the study exceeds a minor increase over minimal risk and is otherwise not approved by an REC'. This would narrow the scope of ministerial consent to exceptional studies and would bring it in line with the Code of Federal Regulations in the USA. See Strode, Slack, Wassenaar & Singh (note 119 above) 201 for more detail on the US approach.

<sup>1235</sup> Although it could be argued that law reform could also be inserted within the Children's Act (note 4 above) as that deals with a number of a child's other health rights, this approach was rejected by this thesis as (a) it could result in a divergent approach between the norms for health research with adults and children; (b) it could result in a lack of clarity as stakeholders would have to consult both pieces of legislation with designing or regulating studies; and (c) it may result in complexities when research involves both child and adult participants.

- (b) Allow children from the age of 12 who have sufficient maturity and mental capacity to understand the benefits, risks, social and other implications of minimal risk research to consent independently to such a study. Children below this age or those without capacity should, where possible, assent to research;<sup>1237</sup>
  - (c) Give parents, guardians or care-givers the authority to consent alongside their children's assent for all research which is classified as bearing more than minimal risk or where the child is under the age of 12;<sup>1238</sup>
  - (d) Allow children who do not have the capacity to consent to assent to research;
  - (e) Ensure a child's decision to decline to participate or withdraw from a study is respected;<sup>1239</sup>
  - (f) Provide that research participants have the right to privacy regarding research participation. Children who have consented independently to participation should have the right to privacy regarding this choice. Children should also have the right to privacy regarding therapeutic interventions within a study to which they have consented independently. A child's privacy rights may be limited when maintaining confidentiality is not in their best interests;
  - (g) Stipulate that all research participants have the right to dignity and equality;
  - (h) Specify risk standards. Accordingly, the current risk standards in the draft Regulations which conflict with the standards in the NHREC ethical guidelines should be deleted;
- and

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<sup>1236</sup> This proposal is a deviation from the current approach in s 71 of the National Health Act (note 57 above) as it does not require written consent but rather leaves the flexibility in the hands of the REC to determine the nature of the informed consent process.

<sup>1237</sup> This brings the circumstances in which children can consent to health research in line with other similar health interventions in the Children's Act (note 4 above). It requires that children reach the age of 12 and demonstrate that they have capacity in order to consent to health research.

<sup>1238</sup> This norm will enable children to provide independent consent to studies which are considered to pose no more than minimal risk and to which an REC has waived the need for proxy consent. It will mean nevertheless that proxy consent will still be required for, amongst others, clinical trials.

<sup>1239</sup> This proposed norm promotes active child participation as the child's decision regarding participation trumps a choice made by their proxy consentor.

- (i) Ensure that research is not approved unless it is shown that the participation of children is scientifically indispensable to the study.

See the proposed amendments in Table 23 below.

**Table 25: Law reform to enhance the protection, participation of child research participants in appropriate research (new section 71)**

<p><b>NHA Research on or experimentation with human subjects</b></p> <p><u>71(1) Health research with human subjects shall only take place in the following circumstances:</u></p> <ul style="list-style-type: none"><li><u>(a) Informed consent has been obtained from all research participants unless an express waiver of consent is issued by a Research Ethics Committee;</u></li><li><u>(b) The right of all research participants to privacy is respected;</u></li><li><u>(c) The right of all research participants to dignity and equality is respected;</u></li></ul> <p><u>(2) A Research Ethics Committee may only approve research with children in the following circumstances:</u></p> <ul style="list-style-type: none"><li><u>(a) Where the research poses acceptable risk standards. No child may participate in research which poses more than a minimal risk unless:</u><ul style="list-style-type: none"><li><u>(i) The research poses more than minimal risk but provides the child with direct benefit; or</u></li><li><u>(ii) The research poses greater than minimal risk and does not hold out the prospect of direct benefit but has a high probability of generating generalised knowledge. In such a case the risk must be justified by the knowledge ratio;</u></li></ul></li><li><u>(b) Consent has been obtained from the child for the minimal risk study. A child providing consent must be over the age of 12 and have sufficient maturity and the mental capacity to understand the benefits, risks, social and other implications of the research;</u></li><li><u>(c) Assent has been obtained from the child if it is a more than minimal risk study or they are under the age of 12 and have sufficient understanding to assent, or they are over the age of 12 and lack capacity to provide independent consent to minimal risk research;</u></li><li><u>(d) Consent for child research participation in a minimal risk study where the child is under the age of 12, or is over the age of 12 and lacks capacity, has been obtained from the child's parent, legal guardian or care-giver;</u></li><li><u>(e) Consent for child participation in studies with more than a minor increase over minimal risk is provided by the child's parent or legal guardian;</u></li><li><u>(f) Where a child's decision not to participate or to withdraw from a study will be respected;</u></li><li><u>(g) A child research participant's right to privacy regarding participation in the study is respected if they have given independent consent to the study;</u></li><li><u>(h) A child research participant's right to privacy is respected regarding their accessing of or use of therapeutic interventions offered during the study to which they have consented independently;</u></li><li><u>(i) A child research participant's right to privacy may be limited when maintaining confidentiality is</u></li></ul>
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not in the best interests of the child; and

(j) It has been demonstrated that children are scientifically indispensable to the study.

Recommendation Ten: Section 16 of the NHA should be amended to provide that ethical review is required for record reviews by health care providers (See Table 24 below which contains the proposed revised wording (underlined) of section 16 of the NHA).

**Table 26: Law reform to ensure that all forms of health research are submitted for ethical review**

**NHA: Access to health records by health care providers or health researchers**

**16.(1) A health care provider may examine a user's health records for the purposes of**

*(a) treatment with the authorisation of the user; and*

*(b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.*

**(2) If the study, teaching or research contemplated in subsection (1)(b) reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the [authorisations contemplated in that subsection] consent of the user.**

**(3) A health researcher may examine a user's health records for the purposes of study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee; and**

**(4) If the study, teaching or research contemplated in subsection (3) reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisation of the user.**

Recommendation 11: The NHREC should issue policy guidance on the mandatory reporting of abuse by health researchers.

Table 27 below summarises the law and policy reform recommendations.

**Table 27: Summary of Law and Policy Recommendations**

Recommendation Number	Policy reform	Law reform
1	NHREC issue a policy on the principles under-pinning the ethical-legal framework regulating research with children	
2		Revise and re-issue the draft Regulation on Research with Human Subjects
3		Amend sections 69 and 72 of the NHA
4		Amend Regulations 3 and 4 of the NHRC regulations
5		Amend Regulation 3 and 4 of the NHREC Regulations
6		Amend Regulations 4 of the NHRC regulations, Regulation 2 of the NHREC Regulations and s 2 of the MCC Act
7		Amend s 3 of the MCC Act
8		Amend s 72 of the NHA
9		Amend s 71 of the NHA
10		Amend s 16 of the NHA
11	NHREC issue a policy on mandatory reporting in research	

**7.5 Key differences between the proposed approaches based on children’s rights intertwined with ethical principles and the current norms in the National Health Act**

It is submitted that the proposed law and policy reforms described above reflect a new and innovative approach to the regulation of research with children. They differ from the current framework in that:

- (a) These proposals are based on a principled framework which attempts to balance child protection, child participation and research facilitation. No one principle dominates the framework;
- (b) The language and approach have been synchronised with the Children’s Act and the national ethical guidelines in order to ensure consistency. For example, the words ‘child’ and ‘children’ have been used rather than minor.<sup>1240</sup> Likewise, children can consent independently to minimal-risk health research if they are 12 years old and meet the capacity requirement. This approach is substantially similar to the approach the Children’s Act takes to children consenting to medical treatment.<sup>1241</sup> Furthermore, the norms regarding consent and risk standards have been brought in line with the NREC ethical guidelines;
- (c) The outdated approach of distinguishing research as therapeutic and non-therapeutic studies has been removed;
- (d) Protections which had no ethical value, such as the need for ministerial consent for all forms of non-therapeutic research with minors, have been removed;
- (e) RECs have been given greater flexibility to decide whether a study is ethical in line with section 73 of the NHA. For example, they are able to waive informed consent or allow verbal consent;
- (f) Research is facilitated, as highly restrictive provisions, such as the requiring of mandatory written consent, the prohibition on independent consent by children and ministerial consent for non-therapeutic research, have been removed. Research is further facilitated through the broadening of the categories of adults who have the capacity to provide proxy consent for child research participation;
- (g) Research protections have been enhanced through, amongst others, amending the NHA to provide that a child’s refusal to participate or their decision to withdraw from

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<sup>1240</sup> Child and children are the terms used in the Children’s Act (note 4 above) whilst the drafters of the NHA elected to use the term minor in s 71 of the NHA (note 57 above).

<sup>1241</sup> S 129 Children’s Act (note 4 above).

- a study must be respected; rights to privacy, dignity and equality have been added from the draft Regulations to the NHA; and by placing an obligation on researchers to show that children are scientifically indispensable to the study; and
- (h) Child participation has been enhanced by enabling children to consent without assistance in certain circumstances, obliging researchers to obtain assent and respecting a child's views regarding participation in the study.

Table 28 below shows changes to the existing law/policy position in respect of each recommendation.

**Table 28: Changes between the existing law and policy and the proposed reforms**

Recommendation Number	Current situation	Proposed change
1	No policy describing the principles that underpin research regulation with children	NHREC issue a policy on the principles underpinning research regulation with children
2	Draft regulations on human subjects issued in 2007	Finalise regulations
3	Legislation does not expressly protect the independence of the NHRC, NHREC and the MCC	Strengthen the independence of the NHRC, NHREC and the MCC through amendments to the NHA and the Medicines Act
4	Regulations establishing the NHRC allow the Minister of Health to appoint members to the Committee	Amend regulations to prevent the Minister of Health from broad appointment powers
5	Regulations establishing the NHREC allow the Minister of Health to appoint members to the Council	Amend regulations to prevent the Minister of Health from broad appointment powers
6	No mechanisms which enables the members of the NHRC, NHREC and the MCC to meet and co-ordinate their work	Amend the NHRC and NREC regulations and the Medicines Act to facilitate co-operation between the institutions in the ethical-legal framework
7	No community representation	Amend the Medicines Act to ensure that a representative of

	on the MCC	the community sits on the Council
8	Limited sanctions for ethical violations are described in the NHA	Amend NHA to enhance the powers of the NHREC to discipline researchers
9	Section 71 of the NHA over protects child research participants	Amend s 71 of the NHA so that it balances child protection and participation with research facilitation
10	Health researchers doing record reviews do not need ethical approval	Amend the NHA so that all researchers must obtain ethical approval for health research
11	No policy on when researchers must report children in need of care and protection	NHREC to issue a policy on mandatory reporting in health research

It is submitted that the proposed approach balances the three principles rather than allowing protection to dominate. Table 29 shows at a macro level how the proposal works across the three principles, in attempting to balance them in relation to each norm. The table also shows the differences between the law and policy reform proposals and the current situation.

**Table 29: Protection, participation and research promotion in the current and proposed frameworks**

	<b>Protection</b>	<b>Participation</b>	<b>Research promotion</b>
<b>Current framework</b>	<p>Written consent</p> <p>Participants to be informed of certain basic information about the study</p> <p>No express right to privacy, dignity or equality</p>	<p>Ethical guidelines require children to assent to participation</p>	–

	No express risk standards in law		
<b>Proposed new framework</b>	<p>Consent required for research</p> <p>Participants to be informed of certain basic information about the study</p> <p>All research participants have the right to privacy</p> <p>A child's right to privacy may be limited when it is in the best interests of the child</p> <p>Right to dignity and equality</p> <p>Risk standards are set in law</p>	<p>Children can consent independently to minimal risk research from age 12</p> <p>Children who can't consent can assent</p> <p>A child's decision to refuse to participate must be respected</p> <p>Child research participants have the right to privacy regarding therapeutic interventions to which they have consented independently</p> <p>Child research participants have the right to privacy regarding their participation in research if they consent to such a study without assistance</p>	<p>Consent can be verbal or in writing</p> <p>Parents, guardians or care-givers can provide proxy consent for minimal risk research</p> <p>Children can</p>

			participate in research with some risk
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## 7.6 Conclusions

The critique in Chapters One, Three and Six has shown that the current ethical-legal framework cannot effectively regulate health research with children. As it has been stated, albeit in a more general context:

The implementation of the final aspects of the National Health Act should be good news – however, it isn't, as the Minister of Health has ushered in a new legal framework that already lags behind scientific developments, and is strangling much-needed innovation in health. Political commitment is required to look to the future and ensure that there is synergy between unfolding scientific developments, public health and human rights.<sup>1242</sup>

In conclusion this Chapter argues that law and policy reform is needed. Furthermore, it has shown that a principled approach to law and policy reform is possible. Thus the regulation of health research with children can balance both protection and participation with research facilitation. This creates a framework which promotes child health at a macro-level without compromising the need to take special measures to protect children and recognise their evolving capacity.

The law and policy reform proposals described in this Chapter are far-reaching. They suggest reforms to the intuitional and normative framework for regulating health research. Proposals include changes to the NHA and its regulations, as well as the Medicines Act. It is submitted that political commitment will be required tackle this issue, and will need to be coupled with a commitment to ensure that the public and other key stakeholders are engaged in the

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<sup>1242</sup> Strobe (note 1132 above) 741.

development of a new, more appropriate ethical-legal framework for health research with children.

## **Chapter Eight:**

### **Conclusions**

The previous Chapter established a theoretical framework for the development of law and policy reforms. It did so by describing the principles that underpin children's rights, and setting out how these could be balanced, particularly if they were linked to well-established ethical norms. These principles were then used to inform the development of new South African norms relating to informed consent, privacy, dignity, equality, risk standards, ensuring children are scientifically indispensable to research and mandatory reporting of abuse. The Chapter concluded with a range of law and policy reform proposals including specific amendments to the NHA, its accompanying regulations, and the Medicines Act. An elaboration was provided of how the proposed normative reforms to the framework balances the three competing interests which underpin this thesis namely, protection, participation and research facilitation, and how this approach differs from the current one.

This Chapter completes this thesis by drawing a number of conclusions on the extent to which the South African ethical-legal framework protects child research participants, promotes their participation in research-related decisions and facilitates appropriate research. It also makes concluding comments on how a new approach to research regulation could better serve the best interests of children.

#### **8.1 Framing the issue: Walking the tightrope by balancing competing interests**

This thesis has used the analogy of walking on a tightrope to describe the complexity of the ethical-legal regulation of child research. It has submitted that there is an inherent tension between facilitating health research with child participants and the need to both protect children and facilitate their active engagement in research decision-making. Furthermore, if a delicate balance is not struck between these three principles the tightrope walker will fall,

resulting in either limited health research for children or inadequate protection and involvement of children in decision-making. Accordingly, this thesis concludes that:

*(i) As children are at high risk of childhood diseases, health research is required to develop evidence-based interventions to promote their health and well-being*

Many children are at risk of early childhood mortality and illness from preventable or treatable diseases.<sup>1243</sup> Poor child health outcomes have been compounded by a lack of child specific data as historically children were excluded from health research in order to protect them from harm.<sup>1244</sup> Resultantly, they have been subjected to medication or interventions tested only on adults even though they have different biokinetics, metabolism, physiology, and immunological systems.<sup>1245</sup>

Recently, there has been a reversion to the active inclusion of children in research in order to improve our understanding of issues that impact on their health and to develop appropriate new prevention or treatment interventions.<sup>1246</sup> This new approach is premised on an acceptance that health research is critical to the development of drugs/health interventions and to the monitoring and implementation of existing health services. Accordingly, this thesis finds that realising a child's constitutional right to both 'basic health care services' and 'access to health care services'<sup>1247</sup> requires health research involving children as research participants.<sup>1248</sup>

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<sup>1243</sup> *South Africa's Children: A Review of Equality and Child Rights* (note 21 above) 32. See Chapter One for more detail on the health risks facing children. Also see Chapter Four where more detail is provided on the most significant health risks facing South African children these include HIV and AIDS, TB, diarrhoeal disease, low birth weight and protein energy malnutrition.

<sup>1244</sup> Burns (note 6 above).

<sup>1245</sup> Caldwell (note 16 above) 803. See Chapter One for definitions of these terms.

<sup>1246</sup> <http://www.who.int/childmedicines/questions/en/> [Accessed: 7 April 2009] and Jaspens, Cunningham, Tucker et al (note 17 above) 87.

<sup>1247</sup> S 28(1)(c) and s 71(1) Constitution of the Republic of South Africa (note 2 above).

<sup>1248</sup> <http://www.unbrussels.org/agencies/who.html> [Accessed: 15 February 2012].

*(ii) There are competing interests in research and these must be regulated by an ethical-legal framework*

There are competing interests in health research as it frequently requires the use of human volunteers who may bear some risk in order to generate new knowledge.<sup>1249</sup> Given this inherent tension, the regulation of health research should aim at ensuring that the interests of society and of science do not override the individual interests of research participants.<sup>1250</sup>

*(iii) Child research participants are vulnerable and their welfare must be ensured by an ethical-legal framework which protects them, promotes their involvement in research-related decision-making and facilitates appropriate research. Some key principles that ought to underpin an ethical-legal framework can be found in international law and ethical codes*

This thesis concludes that the tensions between the interests of individuals and the interests of science are heightened when children are to be enrolled as research participants due to the constitutional obligation to act in the best interests of the child.<sup>1251</sup> Nevertheless, in the post-World War II period, an increasing number of research-related principles have been established in international law and ethical codes which can be used to guide such decision-making. These norms are found in, amongst others, the Geneva Conventions, the Nuremburg Code, the ICCPRs, the ICESCRs, the Universal Declaration on the Human Genome and Human Rights, the CRC, the EU Convention on Human Rights and Biomedicine, the Helsinki Declaration, the CIOMS Guidelines, the WHO GCP and the ICH Guidelines<sup>1252</sup> (See Table 28

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<sup>1249</sup> Fisher (note 40 above) 195. See Chapter One for further discussion on this point.

<sup>1250</sup> *Ibid and the Helsinki Declaration* (note 41 above). See Chapter Two for a more detailed discussion on this point.

<sup>1251</sup> S 28(2) Constitution (note 2 above). This requires decision-making which affects children to consider a range of factors in determining what is best for children both individually and as a group: Stobie, Strode & Slack (note 59 above) 198–204.

<sup>1252</sup> See Chapter Two for a full description of these documents and the norms that they establish with regard to research with human participants.

below for an overview of these key norms which establish both procedural and substantive protections).

**Table 30: Key principles and rights from international law and ethical codes that ought to underpin an ethical-legal framework regulating health research with children**

<b>Child protection</b>	<b>Child participation</b>	<b>Facilitating research with children</b>
Right to participate in research only if informed consent or assent is provided	Right to participate in research only if informed consent or assent is provided	Clinical trials must be submitted for regulatory approval
Proxy consent may be provided by parents or guardians	Proxy consent may be provided by parents or guardians	
Right to withdraw consent to participation at any time	Right to withdraw consent to participation at any time	
Right to dignity	Right to benefit from scientific progress	Vulnerable groups are entitled to participate in research
Right to privacy	Right to dignity	
Research participants must be informed of their rights		
Protective measures must be taken when vulnerable groups participate in research		
An appropriate balance of risks and benefits must exist		
The inclusion of children in research must be scientifically justified		
All health research must be submitted for ethical review		
Promote and safeguard the health of patients and research participants		

This dissertation finds that the norms established in international law and ethical codes are not comprehensive, and there is a need for a convention dedicated to research participants' rights. Nevertheless, these norms provide a basis for developing laws and policies for protecting and facilitating child participation in national frameworks. Unfortunately, limited

international guidance exists on how these norms can be balanced with facilitating appropriate child research.<sup>1253</sup>

## **8.2 A review of the extent to which the South African ethical-legal framework protects research participants, enables child participation and facilitates health research**

The first research question of this dissertation was: to what extent does the current ethical-legal framework protect research participants, enable child participation in accordance with their evolving capacity and facilitate appropriate health research? This question was answered by firstly, by describing both the international ethical-legal norms for regulating health research with children in Chapter Two and the South African ethical-legal framework in Chapters Four and Five. Secondly, the ethical-legal framework was critiqued in Chapter Six. The analytical framework used for the critique was based both on the extent to which the ethical-legal framework met the international norms and its ability to balance the three principles which underpin this thesis. Based on this approach this thesis concludes that:

*(iv) South Africa has established institutions within its ethical-legal framework. The institutional framework complies with some but not all international norms. Furthermore, it protects child research participants but does not facilitate their active involvement in research policy and regulation or effectively facilitate health research*

It is submitted in Chapter Two that a key element of an ethical-legal framework is the need to protect research participants by setting procedural obligations enforced by institutions.<sup>1254</sup>

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<sup>1253</sup> See for example, the restrictive approach recommended by the Committee on the Rights of the Child General Comment No. 3 (note 174 above) regarding the involvement of children in HIV prevention research. This is in direct contrast with the proposals made by the WHO/UNAIDS/AAVP Expert Group (note 140 above). This appears to reflect divergent approaches between the human rights obligations to protect children and public health imperatives to develop HIV prevention products for at risk adolescents.

<sup>1254</sup> Glantz (note 90 above) 128.

This dissertation finds that the South African institutional framework for regulating health research with children is well established. There are three statutory institutions and two non-statutory bodies which collectively play key roles in the regulation of health research.<sup>1255</sup> These institutions ensure that health research is appropriate by requiring studies to: fit within a national research agenda; comply with scientific and ethical standards; and, in certain circumstances, engage with the community. However, this institutional framework is undermined by:

(a) The lack of defined institutional independence of the NHRC, the MCC and the NHREC undermines their capacity to act impartially

This thesis finds that the institutional framework is undermined by the failure of the NHA and the Medicines Act to (a) guarantee the independence of the NHRC, the NHREC and the MCC, and (b) to ensure that powers given to the Minister of Health do not allow him or her to interfere in the appointment of members or the workings of these institutions. These omissions mean that the relevant institutions are vulnerable to political pressure from the executive. This in turn undermines their authority and ability to work independently.

(b) The participation of children and the community in the development of health research policy and research regulation is limited as the legal framework has adopted a superficial approach to community engagement

Based on the review of the institutions supporting the ethical-legal framework in Chapter Four, this thesis finds that there is only a token involvement of the community in research regulation. Although the community is represented on some statutory bodies this is not linked to obligations on such institutions to engage in broader community consultation or

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<sup>1255</sup> The statutory bodies are the NHRC, the MCC and the NHREC. RECs and CAGs are not statutory bodies however RECs have a specific statutory role described in s 73 of the National Health Act (note 57 above).

debate and, as a result, research policy decisions are still largely in the hands of technical experts.

The introduction of the research norms in section 71 is a good example of this lack of public participation in the development of health research policy. In this instance, the new norms reflect a significant policy shift which occurred silently and without public discourse on the problems with the previous framework and on ways in which it could be strengthened.<sup>1256</sup>

The principles underpinning them were not set out in the White Paper on Transformation of the Health System in South Africa<sup>1257</sup> or in other policy documents issued by the Department of Health. The rights of child research participants were also not an issue raised as part of the extensive consultation process which informed the development of the Children's Act.<sup>1258</sup>

Even the NHREC, a body with a statutory mandate to advise the government on research ethics, appears to have been surprised by the implementation of sections 11 and 71 of the NHA without the Regulations on Human Subjects being finalised.<sup>1259</sup> Given that there have been extensive criticisms of section 71 since it was adopted by Parliament; it is surprising that, at the very least some of the issues of concern were not addressed in regulations.<sup>1260</sup>

This thesis finds that the high-handed manner in which the new research norms were developed and implemented reflects the state's non-commitment to consultations on health research policy, its failure to act in a transparent fashion and the inability of the ethical-legal institutions to impact on the normative framework.

(c) Monitoring and enforcement mechanism exists but research specific enforcement mechanisms are generally weak

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<sup>1256</sup> This issue is discussed further in Chapter Six.

<sup>1257</sup> White Paper for the Transformation of the Health System in South Africa (note 7 above).

<sup>1258</sup> South African Law Reform Commission, 2002, Project 110: Review of the Child Care Act, available from <http://www.justice.gov.za/salrc/reports.htm> [Accessed: 8 February 2012].

<sup>1259</sup> Statement from the Council on Proclamation of s 71 of National Health Act (undated) available from <http://www.nhrec.org.za/wp-content/uploads/2012/letter.pdf> [Accessed: 12 January 2013].

<sup>1260</sup> See Chapter Six for an outline of these criticisms.

It is submitted that although a comprehensive monitoring and enforcement framework exists access to it is limited by structural factors such as costs and in some instances the need for legal representation.<sup>1261</sup> This thesis finds that there is a need for an amendment to the NHA to ensure that the NHREC has broader powers that it can use to act against researchers or institutions that infringe research participants' rights.

(d) Appropriate health research is not facilitated due to the limited co-ordination between regulatory institutions

This dissertation finds that there is only a formal institutional link between the MCC and the NHREC. There is no other mechanism by which all the heads of the various institutions or the institutions themselves can meet and co-ordinate their respective functions within the ethical-legal framework. This is a significant gap which could lead to inconsistent and overlapping approaches.

*(v) South Africa has a normative framework for regulating health research established primarily in the NHA and ethical guidelines. To some extent this normative framework meets the international standards however, it over protects children thus undermining child participation in research-related decisions and hindering appropriate health research*

In Chapter Two of this thesis it is argued that ethical and legal norms are required in order to regulate research. Accordingly, that chapter argued that an ideal legal framework should have laws describing the rights of research participants, and the obligations on the state, researchers, proxy consenters and sponsors in protecting such rights.

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<sup>1261</sup> *Ibid.*

This thesis has described the South African normative framework for regulating health research with children which is created primarily by the NHA in Chapter Five. There are norms established both in law and ethical guidelines on the conduct of health research with children. There are also a number of non-research specific laws which impact on the way in which health research is conducted. Resultantly, there are four rights which set out when and how children can participate in health research.<sup>1262</sup> There are also four research-specific obligations and one non-research specific obligation on researchers to promote the welfare of child research participants.<sup>1263</sup> These ensure that the vulnerability of children in health research is expressly protected within the framework. However, this thesis concludes, these ethical-legal norms are undermined because:

(a) The conflict between the norms in the NHA and those in the Children's Act result in health research with children being treated in an exceptional way which is different from the approach taken to other health interventions. The norms in the NHA are in many instances diametrically opposed to those in the NHREC ethical guidelines.

There are a number of issues regarding the normative approach taken in the NHA. Firstly, the norms in the NHA are also founded on principles which were rejected by the drafters of the Children's Act which is the primary source of law dealing with persons under the age of 18.<sup>1264</sup> The Children's Act is premised on, amongst others, the notion that children have evolving capacity, they have a right to participate in decisions that affect them, and their best interests must be considered.<sup>1265</sup> Secondly, these norms are diametrically opposed to the position adopted in the national ethical guidelines and the GCP. For example, ethical

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<sup>1262</sup> These rights are set out in ss 11, 16 and 71 National Health Act (note 57 above).

<sup>1263</sup> See Chapter Five for a full description of these obligations.

<sup>1264</sup> The drafters of the Children's Act (note 4 above) accepted the principle that children have evolving capacity and accordingly ought to be able to consent to certain health interventions without parental assistance: Strode, Slack & Essack (note 143 above) 218.

<sup>1265</sup> The preamble, ss 10 and 7 Children's Act (note 4 above).

guidelines treat research which may confer a direct benefit to the participants differently from research without a direct benefit. For example, with research conferring the possibility of a direct benefit the ethical guidelines allow for the approval of a higher risk level by an REC. The NHA however, has inverted this principle and requires that this form of research must receive greater scrutiny than research without a direct benefit.<sup>1266</sup> Collectively, this approach acts as a direct barrier to the conduct of certain forms of health research with children which infringes other rights, such as those described in sections 27 and 28 of the Constitution.<sup>1267</sup>

(b) The drafters of the NHA appear to have considered informed consent as one of the primary mechanisms for protecting child research participants

This study finds that although the research norms in the NHA are protective they are nevertheless limited by their focus on informed consent as the primary protection for child research participants. The NHA is conspicuously silent on other rights such as the right to privacy, dignity or equality.<sup>1268</sup> Thus, although the normative framework is highly protective for child research participants, ironically it prioritises a single right of child research participants.

(c) The norms within the ethical-legal framework are based on a single principle, that of child protection, and this has the unintended consequence of excluding children from health research and consequently the benefits of scientific progress in this field

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<sup>1266</sup> See Chapter Four for more discussion on this point.

<sup>1267</sup> See for example, Zuch, Mason-Jones, Mathews & Henley (note 121 above) 4 where the authors describe the impact that s 71 of the National Health Act will have on school-based adolescent health studies.

<sup>1268</sup> These rights are referred to in the draft Regulations on Human Subjects however, given the uncertainty around these draft Regulations there is no assurance that they will be in the final regulations.

The critique of the ethical-legal framework in Chapter Six showed that the framework is based on the over-arching premise of protecting child research participants. However, this approach undermines children's best interests by, amongst others, prohibiting them from providing independent consent in any circumstances, limiting the categories of adults who can provide proxy consent, mandatorily requiring written consent, requiring therapeutic research to be in the best interests of children and obligating researchers to obtain ministerial consent for non-therapeutic research. Cumulatively it could be argued that these norms limit the pool of children eligible for enrolment in research, and thus prevent valuable research from being undertaken. Accordingly, this thesis finds that the norms have the unintended consequence of retarding the development of new health technology, medicine and treatment for children.

(d) The rationale for a number of provisions is unclear and they offer limited protection for child research participants

It is unclear for example, as to why the drafters of the NHA introduced a contested and largely disregarded distinction between therapeutic and non-therapeutic research in the NHA. Furthermore, there is no explanation as to why all forms of non-therapeutic research with children required additional protection by obliging researchers to obtain ministerial consent.

*(vi) South Africa's ethical-legal framework has grappled with the tension between protection, participation and research facilitation. It has moved from a system based largely on self-regulation to one which is highly regulated and restrictive, particularly when the potential research participants are children*

The current ethical-legal framework indicates a radical policy shift away from regulation being vested in institutionally based RECs using ethical guidelines to decide when research was ethical, to one in which there is greater emphasis on substantive and procedural

protections for child research participants (See Table 29 below). Over the three phases of its development, the protectiveness of the ethical-legal framework has been strengthened. Resultantly, the protection of research participants is now the dominant principle underlying the regulation of health research with children. Child participation has not evolved significantly, as it remains focused on the consent and assent provisions within ethical guidelines, although there is some reference to this principle in section 71 of the NHA.<sup>1269</sup> Finally, research facilitation which was a strong element of the first and second phases of the ethical-legal framework, has been undermined by the current system due to its focus on child protection. This thesis finds that these disjunctive approaches reflect a lack of coherence of the principles guiding health research, and do not serve the interests of children or of science.

**Table 29: The evolving nature of protection, participation and research facilitation with children in the South African ethical-legal framework**

	Protection	Child participation	Research facilitation
<b>First phase</b>	Weak	Recognised as a principle through assent and consent processes	Swung between excluding research with children and allowing research in any circumstances
<b>Second phase</b>	Stronger	Strong through assent and consent processes but undermined by a lack of clarity on independent consent	Strong
<b>Third (current) phase</b>	Strong	Exists but is not a strong element of the framework	Weak

*(vii) It is disconcerting that key legal problems with the first and second phases of the ethical-legal framework have not been addressed in the very recent reforms implemented in March 2012*

<sup>1269</sup> For example, s 71 requires children to participate alongside their parents/guardians in the consent process if they are 'capable of understanding': National Health Act (note 57 above). This clearly reflects elements of a child participation approach. See Chapters Five and Six for further discussion on this point.

Chapters One and Three of this dissertation set out the key problems with first and second phases of the ethical-legal framework. In the first phase there wasn't a formal, legally established ethical-legal framework. There were however, a limited number of institutions to regulate research, and some legally binding norms and standards. This was addressed with the introduction of the second stage of the ethical-legal framework which created a formal system consisting of institutions to set the policy agenda, establish norms and standards, and regulate health research. Enforceable ethical norms could also be established and research-specific monitoring and enforcement mechanisms were established. The second phase of the ethical-legal framework addressed (a) the focus on self-regulation by introducing a number of statutory bodies, (b) the disjointed nature of many of the legal provisions by consolidating most of the norms into the NHA, and (c) providing the NHREC with the authority to issue national ethical guidelines binding all health researchers and institutions. However, there were several problems with the second phase of the ethical-legal framework including that the legally binding norms in the NHA were not implemented; there were differing interpretations of the ethical guidelines; and some disharmony between the guidelines. Overall, the previous ethical-legal frameworks failed as they did not adequately protect child research participants or sufficiently promote child participation. They were however, facilitative of health research.

The third or current stage of the ethical-legal framework came into being on 1 March 2012 with the implementation of sections 11 and 71 of the NHA. This completed the introduction of a comprehensive ethical-legal framework by operationalising the legal norms in the NHA on how and when research with human subjects may be conducted. This includes specific provisions on research with minors. Although in the current phase there are now clear legal norms regulating child research these norms tend to over-emphasise protection thereby hindering research.

*(viii) Despite the full implementation of the NHA, the ethical-legal framework remains in a state of limbo. It has been in this state for more than seven years. It is unclear as to when the draft Regulations on Human Subjects will be finalised thus enabling the framework to be fully implemented. This on-going state of limbo results in inconsistent approaches and uncertainty for RECs, statutory institutions, researchers and participants*

This dissertation finds that regulating health research with children is extremely complex due to the on-going state of limbo in the ethical-legal framework.<sup>1270</sup> Currently, although required to do so by law, many RECs are not applying the norms described in section 71 of the NHA because of, firstly, the uncertainty in the way in which the law was implemented without accompanying regulations; and secondly, due to concerns regarding the way it undermines well-established practices which have been developed on the basis of the national ethical guidelines.<sup>1271</sup> Once the regulations have been finalised and the framework is in place, it is possible that compliance with the system may remain low due to this long period of uncertainty and a lack of buy-in of the new norms by researchers, institutions and RECs.

### **8.3 A review of the usefulness of the principles of protection, child participation and research facilitation in developing new norms for the regulation of health research with children**

The second research question in this thesis was: can the three principles of protection, participation and research promotion be used to establish the key legal norms that ought to inform the development of laws regulating health research with children?

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<sup>1270</sup> Slack, Strode, Grant & Milford (note 143 above) 682.

<sup>1271</sup> See the approaches taken by a range of research institutions (note 123 above).

Chapter Seven of this dissertation sets out these three principles and develops a theoretical model showing how they could be used to create ethical-legal norms for regulating research with children. This thesis concludes:

*(ix) In walking the tightrope towards better child health services and treatments, the facilitation of health research must be carefully balanced with both child protection and child participation*

In Chapter Seven it is submitted that there is always an inherent tension between research facilitation and child protection and participation. However, child protection and child participation rights may in different circumstances either complement each other or compete for dominance. It concludes that the right to access health services is premised on health research and thus this must be balanced with child protection and child participation. Furthermore, this approach could be used to develop norms for four research-related rights (consent, privacy, dignity and equality) and three obligations (scientific indispensability, appropriate risk standards and mandatory reporting) to create a framework which effectively balances the competing interests of society, science and individual children.

*(ix) The consideration of and the balancing of each principle can be an effective way of developing research related norms for regulating child research participation*

This dissertation concludes in Chapter Seven that these three principles do create an effective framework for developing new norms provided they are linked to both the principles underlying child rights and those contained in ethical norms. This dissertation demonstrates the usefulness of such an approach by applying it to the current South African ethical-legal framework and proposing new norms based on this principled approach.

#### **8.4 Conclusion**

In conclusion, this thesis has shown that children have a constitutional right to access 'basic' health services. This can most effectively be achieved if there is on-going health research to improve services and treatments offered to children. In many instances, children will need to participate in such studies. Given a history of abusive research practices it is acknowledged that research ought to be regulated by an ethical-legal framework.

In this regard, the South African legislature has responded by moving from self-regulation to a highly sophisticated system with three levels of controls. Firstly, policy controls which ensure that appropriate and relevant research is undertaken; secondly, institutions which regulate research; and thirdly, norms which describe enforceable rights and duties of key stakeholders. These are created by amongst others the NHA and the Medicines Act.

On the face of it, the South African system appears to be an excellent case study of a developing country that has effectively used the law to create a framework for regulating health research, a framework which is comparable to any developed country. However, this thesis has shown through its critique that, although the system has a solid institutional foundation, norms have been haphazardly introduced into the system without any principled basis. These norms are not relevant in that they do not address the key issues facing research regulation and they are not coherent as they conflict with children's rights and ethical principles. Resultantly, the overly-restrictive new normative framework undermines the institutional gains in the system. The over-focus on protection also has a disparate impact on children as the framework severely limits when and how children can participate in research. Consequently, it will be difficult to undertake both social science studies and clinical trials with children in the future.

This thesis has argued for law and policy reform to address the key weaknesses in the institutional framework. It has also described three principles which when entwined with ethical norms are able to develop a normative framework which will balance child protection/participation with research facilitation. It has concluded with a description of these proposals.

It is submitted that the key lessons that have emerged from the South African experience and the proposed model for law reform could be applied in other jurisdictions as a framework for developing locally relevant research norms for regulating research with children. Children should not die or suffer needlessly of preventable health conditions, and research should be employed strategically to improve health services and serve their best interests. Nevertheless, such research should be regulated in a way that ensures their rights are not infringed and their welfare is promoted. This can be achieved through carefully balancing the three key principles of protection, participation and research facilitation, thus effectively walking the tightrope.

## **Addendum**

### **The impact of the draft Regulations Relating to Research on Human Subjects, published on 29 May 2013, on the regulation of health research with children in South Africa**

In 2007 the Minister of Health published draft Regulations relating to research on human subjects for public comment (the 2007 draft Regulations).<sup>1272</sup> A further set of regulations presumably based on the public comments and dated 2009 (the 2009 revised Regulations) is available on the NHREC website.<sup>1273</sup> However, no further information was made available regarding the status of these revised Regulations. Following the promulgation of section 71 of the NHA on 1 March 2012<sup>1274</sup> there was much speculation on whether the 2007 draft or the 2009 revised Regulations would be gazetted, particularly as some aspects of section 71 are not implementable without more detailed guidance being provided. It was therefore not unexpected that on 29 May 2013 a further set of draft Regulations titled ‘the Regulations relating to Research with Human Subjects’ (the 2013 draft Regulations) was gazetted for public comment. The closing date for submissions is 29 July 2013. These revised draft regulations impact on the discussion on the current normative framework in Chapters One, Three, Five, Six and Eight of this dissertation. Given, that they are still in draft form and it is unclear as to whether (a) they will undergo significant revisions based on the public comments, and (b) their deadline for completion, it was decided not to change the content of this thesis but to add this explanatory addendum.

This addendum (a) sets out the sections of the 2013 draft Regulations which deal with or impact on research with children and compare it with the approach taken in the 2007 draft regulations; (b) discusses the implications that the 2013 draft Regulations will have for

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<sup>1272</sup> 2007 draft Regulations relating to research on human subjects (note 13 above).

<sup>1273</sup> 2013 draft Regulations relating to research on human subjects (note 572 above).

<sup>1274</sup> *Government Gazette* No. 35081 (note 96 above).

research regulation with children including issues not addressed by them; and (c) conclude with the implications they will have for the law reform proposals made in this thesis.

### **An overview of the content of the 2013 draft Regulations relating to Research with Human Subjects**

There are a number of areas in which the regulations may impact on the future regulation of health research with children. The key content areas are each discussed in turn:

*(i) Clarifying key terms used in the National Health Act through new or revised definitions*

The 2013 draft Regulations set out a number of key definitions in Regulation 1. Those that will impact on research with children include:

The term ‘best interests’ of the child is a term used in section 71(2) of the NHA with regard to therapeutic research with minors.<sup>1275</sup> It was not defined in the NHA or the 2007 draft Regulations. The 2013 draft Regulations provide some clarity by stating that it means ‘significant decisions affecting a minor’s life should aim to promote amongst others the minor’s physical, mental, moral and emotional welfare’.<sup>1276</sup>

The 2013 draft Regulations also define the word ‘condition’ which is used in section 71 of the NHA. The Act provides that the Minister of Health may not give his or her consent to non-therapeutic research with minors unless, amongst others, it can be demonstrated that the study will result in a significant improvement in the understanding of the minor’s condition or disorder.<sup>1277</sup> The term was not defined in either the NHA or the 2007 draft Regulations.

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<sup>1275</sup> National Health Act (note 56 above).

<sup>1276</sup> Regulation 1 2013 draft Regulations relating to research on human subjects (note 13 above).

<sup>1277</sup> S 71(3)(b) National Health Act (note 57 above).

The 2013 draft Regulations state that in this context ‘condition’ means ‘physical and psychosocial characteristics shown to affect health’.<sup>1278</sup>

The term ‘human subject’ has been defined as ‘a living person about whom an investigator obtains data or specimens of identifiable private information through intervention or interaction with that person’.<sup>1279</sup> This is significant as the obligations in section 71 of the NHA relate to ‘research or experimentation on a living person’<sup>1280</sup> yet the term human subject was not defined in the Act. This definition now clearly indicates that these norms only apply to health research involving an actual interaction with a living research participant. This definition also ensures synergy with the NHREC ethical guidelines which have a similar definition.<sup>1281</sup>

‘Minimal risk’ is not a term that is used in the NHA. However, the 2013 draft Regulations have a specific section on risk standards in Regulation 4, and this term is important for establishing the parameters of such risk standards. The term is defined as ‘the probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life including routine medical, dental or psychological tests or examinations’. Again, this definition is in line with the approach to minimal risk as described in the NHREC ethical guidelines.<sup>1282</sup>

The type of research which falls within the ambit of the term ‘non-therapeutic research’ is important as there are a number of specific obligations set out in section 71 of the NHA if such a study includes persons under the age of 18.<sup>1283</sup> This term is not defined in the NHA

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<sup>1278</sup> Regulation 1 2013 draft Regulations relating to research on human subjects (note 13 above).

<sup>1278</sup> S 71(3)(b) National Health Act (note 57 above).

<sup>1279</sup> *Ibid.*

<sup>1280</sup> National Health Act (note 56 above).

<sup>1281</sup> NHREC Guidelines (note 56 above) 59. See Chapter Four for further discussion on this point.

<sup>1282</sup> *Ibid.*

<sup>1283</sup> National Health Act (note 57 above).

but a similar definition was included in the 2007 draft Regulations which provided that it entailed ‘any research not directed towards the benefit of individual but rather towards improving scientific knowledge or technical application and developing generalisable knowledge’.<sup>1284</sup> The 2013 draft Regulations re-define this form of research so that there is greater synchronicity with the NHREC ethical guidelines, stating that it is ‘research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalisable knowledge’.<sup>1285</sup>

A definition of ‘significant risk’ is also provided in Regulation 1 of the 2013 draft Regulations. This new risk standard introduced in section 71 of the NHA in relation to so-called non-therapeutic research was not defined in either the NHA or the 2007 draft Regulations. The 2013 draft Regulations now define it as a ‘substantial risk of serious harm’.

The term ‘therapeutic research’ is also of importance as there are a number of obligations on researchers who undertake this form of research with minors, in terms of section 71 of the NHA. Neither the NHA nor the 2007 draft Regulations defined this term. The 2013 draft Regulations state that it refers to ‘research that holds out the prospect of direct benefit to the participant’.<sup>1286</sup> Again, this definition is in line with the terminology used in the NHREC ethical guidelines.<sup>1287</sup>

*(ii) Describing key principles that must underpin the way in which health research is conducted*

Regulation 2 of the 2013 draft Regulations sets out 10 principles that should underpin the way in which research is conducted. These are very similar to the principles contained in the

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<sup>1284</sup> Regulation 1 draft Regulations 2007 (note 13 above).

<sup>1285</sup> Regulation 1 draft Regulations 2013 *ibid.*

<sup>1286</sup> *Ibid.*

<sup>1287</sup> NHREC ethical guidelines (note 56 above).

2007 draft Regulations. They include, amongst others, that the research must be relevant, be based on a valid scientific methodology, protect the rights of research participants to dignity, equality, bodily integrity and privacy and be submitted for ethical review.<sup>1288</sup>

*(iii) Setting out the obligations on researchers*

Regulation 3 of the 2013 draft Regulations sets out seven obligations imposed on researchers. Although the 2007 draft Regulations also included a number of obligations, some changes have been made to those listed in the 2013 version. The obligations now include responsibilities to meet procedural requirements such as ethical approval, consultations with certain stakeholders, and ensuring that participants, if harmed, are provided with assistance and compensation.<sup>1289</sup>

*(iv) Setting additional norms for the participation of minors in research*

Regulation 4 deals with the participation of special classes of persons in research including minors. The approach in the 2013 draft Regulations is considerably different from that set out in the 2007 draft Regulations. The current Regulation 4 sets maximum risk standards for research involving children and requires researchers to demonstrate that children are indispensable to the study.<sup>1290</sup> Like the 2007 draft Regulations, the 2013 version also requires an REC to pay special attention to persons in special relationships, such as those in a doctor-patient or student-teacher relationship.<sup>1291</sup> The new approach is now consistent with the approach in the national ethical guidelines.<sup>1292</sup>

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<sup>1288</sup> Regulation 2 draft Regulations 2013 (note 13 above).

<sup>1289</sup> Regulation 3 *ibid.*

<sup>1290</sup> Regulation 3 *ibid.*

<sup>1291</sup> *Ibid.*

<sup>1292</sup> NHREC Guidelines (note 56 above).

*(v) Describing the informational aspect of informed consent*

Regulation 6 of the 2013 draft Regulations sets out 14 areas in which research participants must be provided with information as part of the informed consent process.<sup>1293</sup> The most significant difference between the two sets of draft regulations is that the 2013 version now requires participants to also be informed of ‘their freedom to decline or withdraw from the research without prejudice’.<sup>1294</sup>

*(vi) Providing guidance on applications for ethical approval*

Regulation 7 requires researchers to obtain ethical approval from a registered REC, to satisfy any requirements set by the Committee, and to ensure they comply with its obligations.<sup>1295</sup> Similar provisions were set out in Regulation 8 of the 2007 draft Regulations.<sup>1296</sup>

*(vii) Describing the manner and form in which an application must be made for ministerial approval of non-therapeutic research with minors*

The 2007 draft Regulations were silent on the process for applying for ministerial consent for non-therapeutic research with minors. The 2013 draft Regulations deal with this issue in Regulation 8. They provide that an application for ministerial approval must be made on a standard form (Form A).<sup>1297</sup> They also describe the process that must be followed in obtaining ministerial consent. Researchers must obtain ethical approval and thereafter apply to the Minister on the standard form.<sup>1298</sup> The Minister, in making his or her decision, may ‘consult relevant bodies including the National Health Research Ethics Council, registered

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<sup>1293</sup> *Ibid.*

<sup>1294</sup> Regulation 6 *ibid.*

<sup>1295</sup> Regulation 7 *ibid.*

<sup>1296</sup> Regulation 7 draft Regulations 2007 (note 13 above).

<sup>1297</sup> A draft of Form A is attached to the 2013 draft Regulations (note 13 above).

<sup>1298</sup> Regulation 8(1)(a)–(b) *ibid.*

research ethics committees or relevant experts'.<sup>1299</sup> The draft Regulations also provide that researchers must be informed of the outcome of the Minister's decision 'in a timely manner'.<sup>1300</sup>

Finally, the draft Regulations allude to the possible delegation of the Minister's power to another body which would then provide consent for non-therapeutic research when it states that this decision may be made by the Minister or a 'duly appointed delegated authority in terms of s92(a) of the Act'.<sup>1301</sup>

### **The implications of the 2013 draft Regulations relating to Research with Human Subjects on future studies involving children**

It is argued that if the new 2013 draft Regulations are finalised in their current form they will impact on the regulation of health research with children in a number of ways.

In many respects, the 2013 draft Regulations will enhance the regulation of research with children in that they firstly, provide clarity on a number of key terms used in section 71 of the NHA and this will assist in the implementation of these norms. For example, by providing a definition of 'significant risk' there is now clarity on this term. This thesis had identified this lacuna as a key concern as academics were divided on whether it implied minimal or a higher level of approvable risk.<sup>1302</sup> The definition provided in the 2013 draft Regulations makes it clear that significant risk cannot be compared with minimal risk which is linked to the concept of 'everyday risks'. Instead the term refers to a higher level of risk through the use of words such as 'substantial risks' which may result in 'serious harm'.

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<sup>1299</sup> Regulation 8(1)(c) *ibid.*

<sup>1300</sup> Regulation 8(1)(e) *ibid.*

<sup>1301</sup> Regulation 8(1) *ibid.*

<sup>1302</sup> See Chapters Five and Six for further discussion on this point.

Secondly, the 2013 draft Regulations address some of the concerns raised regarding discordant approaches between the NHA and the national ethical guidelines.<sup>1303</sup> The 2013 draft Regulations have addressed some of the issues relating to inconsistent terminology between the NHA and ethical guidelines through a revision of some key terms. Furthermore, the norms in the 2013 draft Regulations relating to risk standards and the informational aspects of informed consent are now consistent with those in ethical guidelines.

Thirdly, the 2013 draft Regulations address some of the weaknesses in the current normative framework by (a) providing that research participants have rights to dignity, equality and privacy; (b) placing an obligation on researchers to inform research participants on 14 issues which inform research decision-making; (c) setting maximum risk standards that children may be subjected to in law; and (d) placing a legal obligation on researchers to demonstrate that children are scientifically indispensable to a particular study.

Fourthly, the 2013 draft Regulations have provided clarity on the procedural aspects of applying for ministerial consent in section 71 of the NHA. They describe the process that must be followed and contain a form that must be used for this application.

There are, however, a number of weaknesses in the ethical-legal framework which are not addressed by the draft Regulations. Resultantly, the most significant principled issues plaguing the ethical-legal framework remain unaddressed. This was to be expected as regulations are a form of delegated legislation, and accordingly the Minister of Health did not have the statutory authority to establish new legal norms which are not provided for in the empowering legislation. It could not therefore be expected that the draft Regulations would change the principles which underpin our normative framework for research regulation with children. Accordingly, this thesis has argued that law reform of the NHA is

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<sup>1303</sup> See Chapter Six for further discussion on this point.

required to address these key issues. Irrespective of this limited opportunity offered by the regulations for reform it is submitted that there were some issues which could have been resolved in the regulations but which have remained unanswered. Outstanding issues include:

- (i) There is still no clarity on how to apply section 71(2)(a) of the NHA. This section requires all therapeutic research with minors to be in the best interests of the minor. Currently, it is unclear whether this principle must be used in an individual or collective manner and both the NHA and the regulations are silent on this issue. In other words, whether therapeutic research must promote the best interests of children as a class or the best interests of individual child research participants is open to debate. It is submitted that clarity could be provided in the regulations on how to apply this principle.
- (ii) The word 'condition' requires a broader meaning if it is to give effect to section 71(3) of the NHA. The NHA provides that the Minister of Health may not give his or her consent to non-therapeutic research with minors unless amongst others it can be demonstrated that the study will result in a significant improvement in the understanding of the minor's condition or disorder. This term was not defined in the NHA and some academics questioned whether this factor had any meaning as participants in a so-called non-therapeutic study would be healthy and not generally have the condition under study.<sup>1304</sup> The 2013 draft Regulations attempt to rectify this issue by defining the term as the 'physical and psycho-social characteristics shown to affect health'. Although defining this term does assist to some extent, it is submitted that this particular definition fails to address the core issue – that of the need for the term to be used broadly so that it includes conditions to which the participant may be at risk of acquiring.

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<sup>1304</sup> Strode, Slack, Wassenaar & Singh (note 119 above).

(iii) The lack of clarity between Regulation 2 (principles underpinning health research) and Regulation 3 (obligations on researchers) should be addressed. There does not appear to be any clear distinction between what is considered to be a principle which underpins the way in which research is conducted and the obligations on researchers. A principle has been defined as a ‘fundamental truth or proposition that serves as the foundation for a system of belief or behaviour’.<sup>1305</sup> Whilst an obligation has been defined as an ‘act or course of action to which a person is morally or legally bound; a duty or commitment’.<sup>1306</sup> In this set of draft Regulations it is unclear how these terms have been used since although Regulation 2 ought to set out the broad propositions which give rise to various obligations in Regulation 3 this does not appear to be the case. For example, a principle would be the need to respect the autonomy of research participants and this could be translated into the dual obligations of ensuring that participants are well informed and participate in health research only after having provided consent. In the current draft of the regulations in Regulation 2 the language used seems to refer to obligations rather than ‘fundamental truths’ which guide the way health research is conducted. It is recommended that the following provisions in Regulation 2 are principles and should be retained; the need for research to be relevant, the importance of a valid methodology, effective management of studies, the importance of individual autonomy, respect for rights. It is recommended that firstly, all remaining principles should be phrased as principles; secondly, the principles which are in fact obligations such as the points on obtaining informed consent, fair recruitment, risks, obtaining ethical approval and registering on the SANCTR, should be moved to Regulation 3; and thirdly, there should be a

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<sup>1305</sup> [http://www.google.co.za/search?sourceid=navclient&aq=&oq=definition+of+principle&ie=UTF-8&rlz=1T4ADSA\\_enZA464ZA464&q=definition+of+principle&gs\\_l=hp...015.0.0.0.5951.....0.YFPWUHkSyso](http://www.google.co.za/search?sourceid=navclient&aq=&oq=definition+of+principle&ie=UTF-8&rlz=1T4ADSA_enZA464ZA464&q=definition+of+principle&gs_l=hp...015.0.0.0.5951.....0.YFPWUHkSyso)  
[Accessed: 11 June 2013].

<sup>1306</sup> [http://www.google.co.za/search?sourceid=navclient&aq=&oq=Definition+of+an+obligation&ie=UTF-8&rlz=1T4ADSA\\_enZA464ZA464&q=Definition+of+an+obligation&gs\\_l=hp...015.0.0.1.544720.....0.LhMKMLDltPU](http://www.google.co.za/search?sourceid=navclient&aq=&oq=Definition+of+an+obligation&ie=UTF-8&rlz=1T4ADSA_enZA464ZA464&q=Definition+of+an+obligation&gs_l=hp...015.0.0.1.544720.....0.LhMKMLDltPU) [Accessed: 11 June 2013].

synergy between the principles and obligations, in other words, there ought to be obligations which correlate with each principle;

**The implications of the 2013 draft Regulations relating to Research with Human Subjects on the law reform recommendations made by this thesis**

The 2013 draft Regulations do not have a significant impact on the proposed law reform proposals made in this dissertation as most of the proposed normative changes were to the text of the NHA itself. There are however, three instances in which the draft Regulations do affect the recommendations made. These are firstly, that this thesis recommended that research participants should have an express right to privacy, dignity and equality in the NHA, and these rights are now included in the draft Regulations. Secondly, it was proposed that the NHA provide that participants may withdraw from a study at any point and this is now also provided for in the Regulations. Thirdly, the Regulations also require researchers to demonstrate that children are scientifically indispensable to the study, and again this thesis had proposed that such a principle be included in a revised section 71 of the NHA. In all three cases it is arguable that reform of the NHA is now not required on these issues as they are provided for adequately in the 2013 draft Regulations.

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