ETHICAL-LEGAL PROTECTION FOR VULNERABLE RESEARCH PARTICIPANTS IN SOUTH AFRICA

AN AUDIT OF RELEVANT LAWS AND ETHICAL GUIDELINES

National Health Research Ethics Council (NHREC)

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DRAFT FOR COMMENT

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1. INTRODUCTION

Most human rights law, ethical codes and related documents include the concept of vulnerable groups made up of individuals who are particularly in need of protection from research-related harm and exploitation. In the context of research, the recognition of vulnerable groups requires that research-related norms provide special protection for research participants considered to be vulnerable.

Current ethical guidelines (MRC, 2001, 2003, DOH, 2004) set out various protections for vulnerable research participants; however, these may not be completely harmonized (Stobie, Strode & Slack, 2005). There are limited research-specific laws to support these national ethical standards. This means that RECs are often compelled to seek guidance from general principles of non-research law (e.g. principles of health law relating to medical treatment of a patient) in order to identify protection for vulnerable groups.

1.1 Objectives

This ethical-legal Audit has been undertaken on behalf of a working group on vulnerable groups established by the National Health Research Ethics Council (NHREC) in 2008. It aims to:

- Identify the nature and extent of protection for vulnerable research participants in relevant South African legislation, policies and ethical guidelines
- Identify strengths and weaknesses of the legal-ethical framework protecting vulnerable research participants
- Determine the national minimum standards for the protection of vulnerable research participants within the current legal-ethical framework, and
- Make recommendations for addressing gaps and weaknesses within the current legal-ethical framework.

1.2 Methodology

This report was prepared by conducting a desk review for any provisions that may apply to health research with vulnerable groups in current and future, including:

- *National legislation*, with a special focus on research and health specific legislation, and laws governing individuals commonly considered vulnerable (such as children, prisoners and the mentally disabled) (See Appendix A for a list of all legislation reviewed),
- *Regulations and other forms of subordinate legislation*, with a special focus on research and health specific regulations as well as those governing vulnerable groups, (See Appendix B for a list of all subordinate legislation reviewed),
- *National and institutional ethical guidelines governing research* (See Appendix C for the list of ethical guidelines reviewed), and
- *Health policies* (See Appendix D for a list of policies reviewed).

Within each law, regulation, guideline or policy, the Audit sought to identify not only **who** was protected as a 'vulnerable group', but **how** they were protected in terms of the relevant

norms and standards. The findings were used to develop an overall picture of the protection afforded to vulnerable groups within the South African legal-ethical framework.

1.3 Background

The Belmont Report (National Commission, 1979), one of the landmark ethical milestones in the US, does not explicitly use the term 'vulnerable groups'. However, it identifies 'certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalised' as having 'dependent status' and 'compromised capacity for free consent'. The Report is concerned that these groups were more likely to be recruited into studies without enjoying the benefits of the study findings. Specific mention is made of children, the profoundly retarded, the seriously mentally ill, the demented and the unconscious, although this did not claim to be a definitive list. The Report coined the term 'diminished autonomy', and as a result this became the basis for identifying various groups as vulnerable and deserving of special measures for their protection. The two main criteria for diminished autonomy here appear to be the *dependent status* of the individuals, and the *inability or limited capacity to provide free consent*.

The National Bioethics Advisory Commission frames vulnerability in terms of circumstances that render participants more vulnerable. Here, the implication is that vulnerability is related to persons being *more open to harm* (such as children) or *more subject to coercion* (such as institutionalised persons). The Commission also attends to situational conditions that make certain groups less likely to be included in a study, because they were *more complicated biologically* (such as in the case of women) or *more inconvenient.* As a result, the Commission asserts that while vulnerable groups need added protection, it is unethical to simply exclude vulnerable groups from studies because of additional barriers to their involvement.

The Helsinki Declaration of the World Medical Association (2008) frames vulnerability both in terms of examples (economically disadvantaged, patients in care) and in terms of criteria (*cannot give consent*, *refuse consent*, *pressured to give consent*, *those who will not benefit personally from research*).

The CIOMS (2002) declaration defines vulnerable persons as 'those who are relatively (or absolutely) *incapable of protecting their own interests* … they may have insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interests." Like the US standards, this definition revolves around *limited capacity or freedom to give or decline consent* (Macklin, 2003). CIOMS goes on to provide a list of examples of vulnerable groups including subordinate members of hierarchies (students, military personnel), elderly people with dementia, nursing home residents, people on welfare or social assistance, poor people, the unemployed, patients in emergency rooms, ethnic and racial minorities, homeless, nomads, refugees, displaced persons, prisoners, patients with incurable diseases, politically powerless persons, members of communities unfamiliar with modern medical concepts.

Recent publications acknowledge traditional definitions of 'vulnerability' as persons that lack decisional capacity/ have inadequate capacity to consent, or have dependant status, or are at increased risk of harm/ especially susceptible to research harms, but also argue that the term has become rather expansive (c.f. Levine et al., 2001).

2 LEGAL PROTECTIONS: VULNERABLE PARTICIPANTS

South Africa's current legal framework does **not contain any specific laws addressing health research**. There are, however, some legal provisions regulating aspects of health, for example, section 73 of the National Health Act requires all institutions and health establishments at which health research is conducted, to establish or have access to an ethics committee. There are also some provisions which could be applied to research, for example, section 129 of the Children's Act (No 38 of 2005) provides for a child of 12 years or older to consent independently to medical treatment. This means that a child of 12 years and older could consent independently to health interventions within a research project (Strode, et al., 2009). Additionally, there are various pieces of legislation that protect the rights and welfare of vulnerable persons generally, which would apply to those persons as research participants.

The legal situation is currently in a state of flux. The National Health Act No 61 of 2003 contains research-specific provisions (s71); however these provisions have *yet to be put into operation*. Accordingly references to the future ethical-legal framework are highlighted in grey within this report.

2.1 Health law

Prior to the recent promulgation of the National Health Act No 61 of 2003, there was no legal provision for the regulation of research in South Africa. The Act contains a number of provisions relevant to the regulation of research in general, as well as some provisions specifically pertinent to the protection of vulnerable research participants. However s71 of the Act which deals with health research *is not yet in operation* and accordingly none of its provisions are binding on researchers or Research Ethics Committees.

2.1.1 Who is protected?

Section 2(c)(iv) of the National Health Act (2003) makes reference to the following vulnerable groups:

- Women
- Children
- Older persons
- Persons with disabilities

Section 5 of the Act also provides specific protection for a user (patient) requiring emergency medical treatment.

The *Patients' Rights Charter (*Department of Health , 2002) also provides for the special needs of vulnerable patients including newborn infants, children, pregnant women, the aged, the disabled, patients in pain, and patients with HIV/AIDS. Furthermore the *HIV and AIDS and STI Strategic Plan for South Africa 2007 – 2011* recognises the need to protect the rights of people affected by HIV and AIDS.

Future law

The draft *Regulations relating to Research on Human Subjects,* 27 February 2007 provide specific protection for the following vulnerable groups in research:

- Children
- Persons with intellectual or mental impairments
- Persons in dependent relationships or comparable situations (including older persons and their caregivers, patients and health care professionals, students and teachers, persons with life-threatening diseases, prisoners and prison authorities); and
- Women (including pregnant women and their foetuses).

2.1.2 How are they protected?

The National Health Act (2003) provides for the following protection for vulnerable groups:

- *Prioritisation of the health needs of vulnerable groups:* The objectives of the Act in s 2(c)(iv) include to protect, respect, promote and fulfil the rights of vulnerable groups such as 'women, children, older persons and persons with disabilities'. Persons requiring emergency medical treatment may not be denied treatment in terms of s 5. In terms of research, the National Health Research Committee is given the power in s 70(2) to identify health research priorities for the country, with due regard to the health needs of these vulnerable groups. Furthermore the *Health Research Policy in South Africa (*Department of Health, 2001) provides for mechanisms to address priority health needs in research and to ensure that health research addresses the health concerns of vulnerable groups such as the 'rural poor, women and people with disabilities'.
- *Provision for informed consent for all persons:* The principle of providing informed consent to medical treatment or an operation is a well-established principle of our common law, and is also now set out in s 7 and 8 of the National Health Act. While this principle certainly applies to, and is important for, all people including those considered particularly vulnerable, it is not a protection specific to vulnerable groups, nor is it specific to research. The Act provides further in s 11 that, if research is to be conducted at a health establishment, the patient must be informed that the service is part of a study. Furthermore consent must be obtained from the user, their health care provider, the head of the health establishment and the relevant health research ethics committee.

Furthermore, in terms of common law, in order for consent to be *valid, the following factors need to be present:*

- The patient must have knowledge of the nature and extent of the harm or risk involved in a medical procedure;
- The patient must appreciate and understand the nature of the harm or risk;
- The patient must have consented to the harm or assumed the risk (*Lambert v Hefer NO* 1995 (2) SA 507 G-H);
- The medical treatment provided must be lawful and not something considered to be against the values of our community; and
- The person consenting must have capacity (Dada & McQuoid Mason, 2001).

Future law

Consent norms. Consent may only be obtained after the participant has been informed of any negative or positive consequences the research may have for his/her health (s 71(1)(b) National Health Act No. 61 of 2003).

Minor's participation in research: Section 71(2) and (3) of the Act provide for the circumstances in which a minor may participate in research. The section requires a

justification for research on a minor (particularly in the case of 'non-therapeutic research', where strict risk-benefit standards apply), proxy consent by a parent or guardian, and the consent of the minor where he or she is capable of providing it. This section is not yet in operation. There are also several criticisms of the Act. It has been argued that the Act is overly protectionist, for example, the requirement that ministerial consent be obtained for all non therapeutic research with minors is very broad and will in all likelihood deter low risk research with children (Strode, Slack, Wassenaar and Singh, 2007).

The draft *Regulations relating to Research on Human Subjects,* 2007 provide further, detailed protection for children, the mentally ill, people in dependent relationships, and women. When the regulations are finalised, the following legal protection will exist for these vulnerable groups:

- *Selection and Recruitment:* The exclusion of women from research will have to be scientifically justified
- *Risk-benefit standards:* Stringent risk-benefit standards are set for the participation of children, the mentally ill and pregnant women in research
- *Justification for research:* Research may only be conducted with children, the mentally ill and pregnant women where the research is justifiable (that is, the research can only be done on this population, the research will meet the health needs of this population)
- *Informed Consent:* Detailed provision is made for informed consent in the case of children (in order to provide for proxy consent by a parent / guardian and the right of the child to refuse consent) and the mentally ill (in order to provide for evaluations of capacity to consent independently, and that appropriate proxy consent is provided).
- *Special attention to persons in dependent relationships or comparable situations:* The Regulations oblige researchers to pay special attention to this vulnerable group of participants.

2.2 Anti-Discrimination law

2.2.1 Who is protected?

The Constitution of the Republic of South Africa, 1996 and the Promotion of Equality and Prevention of Unfair Discrimination Act No 4 of 2000 ('the Equality Act'), protect the rights and welfare of various vulnerable groups. Grounds for non-discrimination include gender, sex, pregnancy, ethnic or social origin, age, disability, language and birth. In effect, this gives protection to, amongst others:

- Women (including pregnant women)
- Children
- People with Disabilities
- People for whom English is not their first language; and
- Ethnic minority groups, homeless persons, refugees, nomads.

The Equality Act provides specific protection for non-discrimination on the grounds of race, gender and disability, over and above the general prohibition against discrimination. Furthermore it places positive obligations on the state to promote equality i.e. this obliges the state to take steps to ensure that unfair discrimination does not occur.

2.2.2 How are they protected?

The Constitution and the Equality Act protect vulnerable groups from being unfairly discriminated against on various grounds, such as their age in the case of children, or their gender in the case of women. The Equality Act provides specific protection from discrimination on the basis of race, gender and disability. Applied to research, the legal provisions provide the following protection for vulnerable research participants:

- *Protection from unfair discrimination in terms of research participation:* The Constitution and Equality Act protections from unfair discrimination would help to protect vulnerable participants from being unfairly excluded from research simply because of their status as, for example, a women or a child;
- *Protection from stigma and discrimination as research participants:* Vulnerable and socially marginalised groups may be at increased risk of stigma and discrimination from research participation. Researchers would be obligated to protect vulnerable research participants from stigma and discrimination related to research.

2.3 Laws for vulnerable groups

2.3.1 Who is protected?

There are a number of laws specific to particular vulnerable groups. For example, in South Africa there are children's laws, laws relating to the mentally ill and laws providing for prisoners (see table below for examples of 'vulnerable groups' and relevant laws). Although these laws do not generally deal with research participation, they nevertheless give some indication of who is viewed as in need of additional protection by law.

Table 1: Legal protection for vulnerable groups

Vulnerable Group	Source of law	Legal protection
Children	Children's Act Domestic Violence Act Sexual Offences Act Choice of Termination of Pregnancy Act Equality Act Basic Conditions of Employment Act	Decisions affecting children must consider their best interests Children may not be discriminated against on the basis of their "health status" Children who are identified as being abused or neglected must be reported to appropriate authorities Children may only be treated with informed consent Children have the right to privacy regarding their health status
Women (including pregnant and nursing women)	Choice of Termination of Pregnancy Act Equality Act Domestic Violence Act Employment Equity Act Basic Conditions of Employment Act Sexual Offences Act	Women have the right to equality Women have the right to reproductive health choices including terminations of pregnancy
Persons with mental illnesses	Mental Health Care Act	Decisions regarding patients with mental illness must be taken with regard to their best interests

Vulnerable Group	Source of law	Legal protection
		They are protected against exploitation and abuse. This includes mandatory reporting of any identified abuse Patients with mental illnesses may not be discriminated against
Persons with restricted freedom	Youth Justice Act Correctional Services Act	Prisoners rights must be respected They may not receive medical treatment without informed consent
Members of hierarchical structures	Schools Act South African National Defence Force Act Labour Relations Act Employment Equity Act Basic Conditions of Employment Act	Learners rights are protected Members of the military have defined rights regarding their employment and the circumstances in which they may for example, join trade unions Employees have rights which protect them against for example, unfair dismissal and unfair discrimination
Persons in dependant relationships	Domestic Violence Act	Persons in abusive relationships may apply for protection orders from a magistrate to prevent their abuser from physically or emotionally abusing them
Refugees	Refugees Act	Refugees have rights of residence in South Africa within defined circumstances

Children:

Children are given similar protections to those provided to all patients (such as the right to confidentiality with regard to health information(s 13, Children's Act, 2005). They are also given additional protection in, for example, child care and criminal law, to protect them from harm. There are currently limited research-specific provisions in place. Relevant protections include the following:

- *Best interests of the child:* The best interests of the child are paramount in all matters concerning children. Applied to research, this means that decision-making regarding research participation must take into account the 'best interests' of the child standard (s 28(2), Constitution of the Republic of South Africa, 1996, s 6 and 7, Children's Act No 38 of 2010)
- *Non-discrimination due to heath status*: Section 6 of the Children's Act (No. 38 of 2005) includes a number of general principles that the Act is based on including child's right not to be discriminated against on the basis of their "health status"
- *Mandatory Reporting:* Any person who becomes aware of abuse (both physical and sexual) or neglect of a child is obliged to report this to the relevant authorities (s 54(1)(a), Criminal Law (Sexual Offences and Related Matters) Amendment Act No 32 of 2007, s 110, Children's Act No 38 of 2010). Applied to research, these provisions protect child research participants from exploitative research, and furthermore, place obligations on researchers to identify and report children in need of protection, even where this may interfere with research objectives or burden the research process
- *Detailed provision for informed consent for medical treatment performed on children:* Our children's laws set out detailed provisions for informed consent for children's medical interventions. Applied to research, this means children may have the capacity to consent independently to certain health-related interventions/ procedures within a research protocol. Although these provisions do not refer specifically to research, they are an indication of the law's protection of children in this area, and, in the past, have been argued to apply to the case of 'therapeutic'

research involving minors. Children's law allows children of a certain age to consent independently to medical treatment (including HIV testing) (Strode et al., 2010) and provides for proxy consent by a parent, guardian or care-giver in the case of children who are incapable of consenting independently (, s 129 – 132, Children's Act No 38 of 2005)

- *Provision for anonymity in specified health research:* The Children's Act No 38 of 2010 provides that where research is conducted on children's court case records, Part A of the Register (relating to child abuse and neglect) or the adoption register, no information relating to the identity of the child must be included in the research (s 66, 115 and 248, Children's Act No 38 of 2010). This means that research involving these official records must ensure that a child cannot be identified by the research
- *Privacy regarding health status:* The Children's Act provides that every child has the right to privacy regarding his/her health status. This would apply to both therapeutic and research environments (s 13, Children's Act, No. 38 of 2010).

Mentally Ill or Disabled:

The Mental Health Act No 17 of 2002 in s 8(1) provides for the care, treatment and rehabilitation of persons who are mentally ill. It provides for various rights of mental health care users that are common to all patients (such as the right to human dignity and privacy, the right to confidentiality in s 13, the right to treatment only with informed consent, and the provision in s 9(1) for proxy consent in the case of those who are incapable of consenting) and that would apply to their participation in research. There are no research specific provisions; however, specific additional protection includes the following:

- *Best interests of the mental health care user:* As with children, our law provides that in performing the rights and duties set out in the Act, regard must be had for what is in the best interests of the mental health care user (s 7(2) Mental Health Act No 17 of 2002). Applied to research, research that is not in the 'best interests' of the mental health care user would not be lawful.
- *Protection from exploitation, abuse and degrading treatment:* Mental health care users must be protected from exploitation (s 11(1)(a), Mental Health Act No 17 of 2002), and this would include protection from exploitative research
- *Mandatory Reporting:* Any person who witnesses any form of exploitation, abuse or degrading treatment towards a mental health care user is obliged to report this (s 11(2) Mental Health Act No 17 of 2002). Applied to research, this would create an obligation upon research staff to report exploitation of mental health care users within research
- *Non-Discrimination:* Mental health care users are protected from unfair discrimination on the grounds of mental health status (s 24 Mental Health Act No 17 of 2002). Applied to research, research that unfairly discriminates against a mental health care user, that unfairly excludes them from participation or that places a mental health care user at risk of stigma and discrimination, would be not permissible.

Employees:

The Labour Relations Act No 66 of 1995 and the Employment Equity Act No 55 of 1998 protect the rights of employees. There are no research specific provisions. However the following protections are relevant:

- *Protection against unfair dismissal*: Employees may only be dismissed in certain defined circumstances (s185, Labour Relations Act No 66 of 1995). Applied to research this means that they cannot be penalised in this way for refusing to participate in health research

- *Non- Discrimination:* Employees are protected from unfair discrimination on various grounds (including, amongst others, HIV status) in terms of s 6 of the Employment Equity Act (No. 55 of 1998). Applied to research, research that unfairly discriminates against an employee, or that exposes an employee to stigma and discrimination, should not be permitted
- *Prohibition of medical testing:* Medical testing of an employee is prohibited, unless justified by the medical facts, employment conditions, social policy, the fair distribution of employee benefits or the inherent requirements of the job. This has implications for health research involving employees at their workplace, in that it means that the researchers must be able to show that any medical testing that forms part of the research is justified
- *Prohibition of HIV testing:* HIV testing of an employee is prohibited, unless justified by an order of the Labour Court. This has implications for health research involving employees at their workplace, particularly if the research is conducted without consent. The Labour Court has held in the case o*f Joy Mining Machinery v National Union of Metal Workers of South Africa and Others (* 2002 (23) ILJ 391) that anonymous, unlinked HIV surveillance research involving HIV testing is justifiable.

Prisoners:

The Correctional Services Act, No. 111 of 1998 protects the rights of prisoners. The accompanying regulations (No. 26626 published on the 30 July 2004) deal specifically with research involving prisoners. These provisions are somewhat contradictory. They exclude prisoners from participating in research (which also prevents them from benefiting from certain forms of research). Regulation 7 provides that a prisoner may not, even with his or her consent, be subjected to any medical, scientific experimentation or research. However the regulation provides further that a prisoner may participate in clinical trials with the Commissioner's approval. Despite this contradictory guidance (which seems to suggest that prisoners may only participate in clinical research, not social science research), there are other protections which are relevant:

- *Treatment only with informed consent:* Section 12(4)(a) of the Act provides that prisoners must give their informed consent to all medical examinations and treatment (Correctional Services Act, No. 111 of 1998). Applied to research, this means that prisoners must give their consent to 'therapeutic' research participation.
- *Prisoners' rights must be protected*: Section 4(2)(c) provides that the rights of prisoners as established by the Act may not be violated *(*Correctional Services Act, No. 111 of 1998). Applied to research, any research involving prisoners would only be lawful if it did not infringe any of their rights.

Table 2: Summary of current legal protection for vulnerable groups in health research

Area of law providing protection	Law establishes a risk standard to protect vulnerable participant	Law requires informed consent for research participation
Health law	No	Yes
Anti-discrimination law	No	No
Children's law	No	Law requires informed consent to medical treatment, and this could include consent to 'therapeutic' research

Area of law providing protection	Law establishes a risk standard to protect vulnerable participant	Law requires informed consent for research participation
Employment law	No	No
Correctional services law	Yes, an indirect risk standard exists as the Regulations attempt to protect prisoners by excluding them from research	Law requires informed consent to medical treatment, and this could include consent to 'therapeutic' research

Table 3: Summary of <u>future</u> legal protection for vulnerable groups in health research

Area of law providing protection	Law establishes a risk standard to protect vulnerable research participants	Law requires informed consent to research participation
Health law	Yes, for children in the National Health Act. There are no risk standards for other vulnerable groups	Yes, in the National Health Act
Anti-discrimination law	No	No
Children's law	No	Law requires informed consent to medical treatment, and this could include consent to 'therapeutic' research
Employment law	No	No
Correctional services law	Yes, an indirect risk standard exists as the Regulations attempt to protect prisoners by excluding them from research	Law requires informed consent to medical treatment, and this could include consent to 'therapeutic' research

2.4 Evaluation of the Legal Framework

2.4.1 Strengths of Legal Framework

The legal framework for protection of vulnerable participants shows the following strengths:

1. The South African legal framework recognises and protects many of the same vulnerable groups (such as women, children, the aged and the disabled) as do national ethical guidelines (see next section). The protection in law is (for the most part) **not** specifically related to research participation, however, the fact that the law has created special protection for certain vulnerable groups (such as people with disabilities and children) means that a legal framework is in place for identifying such groups.

2. South African law does contain provisions that would promote the rights of vulnerable groups in research (in particular, there are well developed laws on informed consent). These provisions are **not** currently research-specific, however, they can be applied to the context of research. Additionally, there are provisions that would protect vulnerable groups from:
   - Unfair discrimination related to research
   - Maltreatment, abuse, neglect or degradation during the research process
   - Harmful or exploitative research; and
   - Participation in research without voluntary and informed consent.

2.4.2 Weaknesses of legal framework

The legal framework for protection of vulnerable participants shows the following weaknesses:

1. T**here are no specific provisions in current law for vulnerable groups in research,** even though current law provides general broad protection (such as protection against unfair discrimination) to people considered to be vulnerable. Current law does not define vulnerable research participants.

2. **Future research-specific laws will not provide adequate protection to the full range of groups considered vulnerable.** S71 of the National Health Act (2003) will only address one particular vulnerable group, namely children. Furthermore, provisions related to this group are restrictive, such as the requirement of mandatory parental consent for all health research and consent from the Minister of Health for all 'non-therapeutic' research regardless of risk level. The draft regulations on human subjects (2007) do not recognise participants who are vulnerable due to broader, rights-based factors (such as social marginalisation, or illiteracy).

3. **Neither current, nor future laws, set standards for acceptable levels of research-related risk**. The future National Health Act (2003) only provides a risk standard for children participating in 'non-therapeutic research', and an indirect one for children participating in 'therapeutic research'. Given the important role

that risk standards play in protecting vulnerable participants this is a significant omission.

4. **Current law requires informed consent to research, however, detailed guidance is not provided** on issues such as who can provide proxy consent, when children would have the capacity to consent independently etc (s 12, Constitution of the Republic of South Africa, 1996). **The future NHA (2003) consent provisions are restrictive** as they require written informed consent in all circumstances (s 71, National Health Act, No. 61 of 2003). This failure to create a balanced approach to informed consent is a significant weakness in our legal framework.

2.5 Recommendations for the Legal Framework

Legal protection for vulnerable groups could be enhanced by:

1. *Including broad basic protections for vulnerable groups participating in research within specific legislation relating to particular groups:* such as employment legislation, correctional service and youth offender legislation, mental health legislation, and education laws. A possible example would be for the Department of Labour to develop a Code of Good Practice providing guidance on research in the employment sector. It is recommended that this process of enhancing research protections for vulnerable groups in non-research specific laws be done in an incremental fashion with an initial focus on strengthening the protections for employees and prisoners.

2. *Improving research specific protections for members of vulnerable groups:* A number of changes to the National Health Act could enhance the research protections for vulnerable groups in the future. These should include: (i) reference to a wider range of vulnerable groups as referred to in the national ethical guidelines (ii) Reviewing the provisions on informed consent so as to create a system that both protects vulnerable groups and facilitates research. More specifically, s71 of the NHA (2003) should allow for exceptions to written consent and mandatory parental consent for child research in certain circumstances (iii) The National Health Act (2003) or regulations should set out acceptable standards for research-related risk.

Table 4: Summary of the key weaknesses and recommendations

Weakness	Recommendation	Proposed way forward
There are no current provisions in our law which specifically protect vulnerable groups participating in research	Add basic protections for vulnerable groups within specific legislation such as the Labour Relations Act and the Correctional Services Act	Initially advocate for changes in the field of employment and prisoner law. Develop law reform proposals and submit such proposals to the relevant Cabinet Ministers
Future research specific laws do not adequately protect the full range of vulnerable groups identified in ethical guidelines	Amend the National Health Act	Develop detailed law reform proposals on amendments to the National Health Act for adoption by the NHREC and submission to the Minister of Health
Neither current no future laws set adequate risks standards for vulnerable research participants	Amend the National Health Act	Develop detailed law reform proposals on amendments to the National Health Act for adoption by the NHREC and

Weakness	Recommendation	Proposed way forward
		submission to the Minister of Health
Current law provides limited guidance on informed consent to research participation and the future law is highly restrictive only allowing for written consent to research	Amend the National Health Act	Develop detailed law reform proposals on amendments to the National Health Act for adoption by the NHREC and submission to the Minister of Health

3. ETHICAL PROTECTIONS: VULNERABLE PARTICIPANTS

In terms of the National Health Act No 61 of 2003, the National Health Research Ethics Council (NHREC) has the power to determine norms and standards for research on humans and animals and for the functioning of health research ethics committees (s 72(6)(a) – (c)). In terms of these powers, the NHREC has adopted the Department of Health (2004) *Ethics in Health Research: Principles, Structures and Processes* as national guidance for health research ethics committees in reviewing health research.

RECs throughout South Africa are required to register with the NHREC(s 73, National Health Act, 2003) and to abide by the norms and standards set by the NHREC and the Department of Health, in addition to any research-related principles set out in our law.

In many cases, these RECs also have their own institutional ethical guidelines which they follow in reviewing research protocols. For example, the Medical Research Council (MRC) has a range of ethical guidelines which have been developed over time to guide the ethical review of research undertaken by the MRC. However, these ethical guidelines should comply with the same minimum standards set by national guidelines.

In order to determine **who** is protected as a 'vulnerable participant' (in terms of general characteristics and listed groups), and **what** form of protection was provided, the audit reviewed the following guidelines:

- Department of Health (2004) *Ethics in Health Research: Principles, Structures, Processes*
- Department of Health (2006) *Good Clinical Practice guidelines*
- South African Medical Research Council (MRC) *Guidelines on ethics for health research: General Principles*
- Health Professions Council of South Africa (2008) *General Ethical Guidelines for Health Researchers*
- Health Sciences Research Council (1997) *Code of Research Ethics*.

The following section presents an overview of the nature and extent of protection for vulnerable groups within our current ethical framework.

3.1 Department of Health (2004, 2006) guidelines

3.1.1 Who is considered vulnerable?

The Department of Health (2006) *Guidelines for Good Clinical Practice* define vulnerable participants in terms of a series of attributes (i) Limited economic development (ii) Inadequate protection of human rights (iii) Discrimination on the basis of health status (iv) Limited availability of health care and treatment options (v) limited availability of

individuals in the community to provide informed consent and (vi) Inadequate understanding of scientific research.

The Department of Health (2004) *Ethics in Health Research: Principles, Structures and Processes* do not specifically define vulnerable groups in the main body of the guideline, however, they assert that adequate protection must be provided for people who are especially vulnerable as a result of poverty or who might currently be underserved (preamble) and that researchers must be aware of the vulnerability of participants in terms of access to health services and education levels (p.4). In Appendix A on selected issues relating to HIV and AIDS research they define vulnerable communities as those with limited economic development, inadequate protection of human rights, discrimination on the basis of HIV antibody status, limited availability of health care and treatment options, inadequate cultural experience or understanding of scientific research, and limited availability of individuals in the community to provide informed consent (p.48). In Appendix D (glossary) on page 60 they state that vulnerable individuals are those whose willingness to volunteer may be unduly influenced by (i) the expectation (whether justified or not) of benefits associated with participation; and (ii) the expectation of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

DOH guidelines (2004; 2006) list various vulnerable research participants. The boundaries between listed groups appear to overlap, and include the following: minors, children and adolescents; pregnant and nursing women; persons with intellectual or mental impairment; people with mental illness or handicaps; disabled persons; persons in dependant relationships; members of communities unfamiliar with medical concepts; people for whom English is not a first language, persons participating in research as groups (referred to as collectivities); persons with restricted freedom such as prisoners; people with substance abuse disorders[1]; members of hierarchical structures (e.g. members of the armed forces; medical , pharmacy, dental and nursing students; subordinate hospital and laboratory personnel; employees of the pharmaceutical industry; persons kept in detention); persons in dependent relationships or comparable situations (e.g. older persons and their caregivers; persons with chronic conditions or disabilities and their caregivers; wards of State and their guardians; patients and health care professionals; students and teachers; prisoners and prison authorities); persons with life-threatening illnesses, persons in nursing homes; patients with incurable diseases and those highly dependent on medical care; patients in emergency situations, traumatised patients and comatose patients; unemployed or impoverished persons, homeless persons; ethnic minority groups; nomads and refugees.

3.1.2 How are vulnerable participants protected?

The DOH (2004) and DOH (2006) guidelines provide various and fairly detailed forms of protection for participants considered vulnerable. The broad protection provided by the guidelines includes the following:

- Providing that research be done on vulnerable participants only where strictly necessary (i.e. cannot be conducted with other populations) (DOH, 2004; DOH, 2006)

[1] Reference to persons with drug disorders is referred to in the DOH (2006) guidelines, not DOH (2004)

- Requiring that the research is responsive to the health needs and priorities of the community (DOH, 2006) and providing that the research is relevant to and aimed at meeting the health needs of the participants themselves (DOH, 2004)
- Requiring selection, recruitment, exclusion and inclusion of research participants to be based on sound scientific and ethical principles rather than on unfair discrimination on the basis of race, age, sex, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief or language (DOH, 2004)
- Requiring researchers to assess the social context that creates conditions for increased vulnerability (DOH, 2006) and requiring researchers to take into account contextual factors (such as global disparities in terms of access to health care) in multi-centre studies (DOH, 2004)
- Requiring researchers to take steps to overcome vulnerability factors and to describe these in the protocol (DOH, 2006) and to show how they will seek to redress vulnerability (DOH, 2004)
- Requiring RECs to consider if sufficient measures are in place to protect the interests of vulnerable populations (DOH, 2006) and requiring RECs to be especially vigilant when considering research proposals involving vulnerable participants (DOH, 2004)
- Requiring that research findings are released in an ethical manner so as not to raise expectations in vulnerable communities (DOH, 2006)
- Requiring that the potential benefits of the research outweigh the potential risks and harms to vulnerable individuals and communities (DOH, 2004)
- Providing strict risk-benefit standards for research on vulnerable participants such as children, adolescents, women (including pregnant women and foetuses), patients requiring emergency care, persons highly dependent on medical care, people with mental disabilities or substance abuse related disorders, prisoners and vulnerable communities (DOH, 2004) .
- Providing that research on some vulnerable participants (e.g. children, persons highly dependent on medical care) not be contrary to their best interests (DOH, 2004)
- Providing for additional requirements in the case of research on specific vulnerable individuals such as pregnant women and foetuses, as well as prisoners, in order to ensure the safety and necessity of the research, to ensure non-bias, and to limit the types of research which may take place (DOH, 2004)
- Requiring that the research takes place with informed consent, with particular attention to the context, language and procedures used to obtain consent (DOH, 2006, DOH, 2004)
- Requiring researchers to take special measures to ensure that vulnerable participants give voluntary, and informed consent (DOH, 2004) and furthermore providing detailed procedures for obtaining informed consent for research on specified research participants (e.g. children, adolescents, pregnant women, foetuses, people with mental illnesses and substance abuse disorders and patients highly dependent on medical care) (DOH, 2004). The procedures differ, but deal with issues such as:
    - Ensuring that a legally authorised person provides consent (e.g. a parent / legal guardian in the case of a young child; both parents in the case of a foetus; a legally authorised representative in the case of an unconscious person)

- Ensuring that a person who lacks capacity to consent must assent to participation, and may refuse participation (e.g. an adolescent must assent and may refuse participation in a trial)
- Ensuring that research that takes place without consent (e.g. emergency care research) only where strictly necessary, and that measures are put in place to allow for lawful consent, as well as withdrawal of consent as soon as reasonably practicable.

3.2 Medical Research Council (2001, 2003) guidelines

3.2.1 Who is considered vulnerable?

The South African Medical Research Council (MRC) has developed their own ethical guidelines which apply to research conducted by, or on behalf of, their research institutions; so called Book 1 (MRC, 2001). Guidelines for HIV preventive vaccine trials - Book 5 – (MRC, 2003) were developed in conjunction with the interim NHREC and have been endorsed by this Council therefore these guidelines would apply nationally to researchers conducting HIV vaccine trials.

MRC (2001) and MRC (2003) identify the following characteristics of vulnerable groups:

- Limited economic development (MRC, 2001)
- Persons from resource-poor communities or those dependent on welfare programmes, who may be vulnerable to undue influence through offers of what others may consider modest material inducements (MRC, 2003)
- Persons who are junior or subordinate members of hierarchical structures, including members of the armed forces, students, employees and prisoners. Such persons are in dependent relationships and may be vulnerable to undue influence or coercion in that they may fear retaliation if they refuse co-operation with authorities (MRC, 2003)
- Persons who engage in illegal activities, such as commercial sex workers, or intravenous drug users. Such persons are vulnerable to undue influence and threats presented by possible breaches of confidentiality and action by legal forces. Persons engaging in socially stigmatized activities may be vulnerable to similar pressures (MRC, 2003)
- Women living in cultures where their autonomy as individuals is not sufficiently recognised. They might be vulnerable to coercion from male partners, family, community members or traditional leaders (MRC, 2003)
- Inadequate protection of human rights (MRC, 2001)
- Inadequate ability to protect HIV related human rights or prevent HIV related discrimination (MRC, 2003)
- Discrimination on the basis of health status (MRC, 2001)
- Stigma or discrimination on the basis of HIV status (MRC, 2003)
- Inadequate understanding of scientific research (MRC, 2001)
- Limited availability and sustainability of health care and treatment options (MRC, 2001)
- Limited community structures (MRC, 2003)
- Limited availability of individuals in the community to provide informed consent (e.g. due to gender, class or other factors) (MRC, 2001)

- Gender or class factors that limit ability to give informed consent (MRC, 2003)

MRC (2001) identifies the capacity to give voluntary and informed consent of these 'special groups' as being a key consideration. MRC (2003) asserts that some communities may have an increased level of vulnerability to harm or exploitation.

MRC (2001) also list specific 'special groups': (i) Pregnant women (ii) Children; (iii) Prisoners (v) People with mental impairment (vi) The elderly (vii) Students (viii) Persons in dependent relationships (e.g. employees and employers, wards of State and guardians; patients and health care professionals), and (ix) Vulnerable communities.

3.2.2 How are vulnerable participants protected?

MRC (2001, 2003) provide detailed protection for 'special groups' and 'vulnerable communities' in a similar manner to that of the Department of Health guidelines. A difference is that the MRC guidelines distinguish between 'therapeutic' and 'non-therapeutic' research, and base some protections (such as risk standards) on the nature of the research being undertaken.

Protective provisions include:

- Requiring research on special and vulnerable groups to be necessary and relevant. That is, that the research should: relate to the illness from which participants suffer (MRC, 2003); be responsive to the health needs and priorities of the community (MRC, 2001); and cannot be conducted in less vulnerable communities (MRC, 2001; MRC, 2003)
- Requiring that the protocol specify if participants are vulnerable (MRC, 2001) and requiring researchers to identify aspects of the social context that create conditions for exploitation or increased vulnerability to harm (MRC, 2003)
- Requiring that the protocol specify measures for overcoming vulnerability factors (MRC, 2003)
- Requiring that research not be conducted on vulnerable groups when protective measures cannot be implemented (MRC, 2003)
- Prohibiting the outright exclusion of some vulnerable groups (i.e. pregnant women) unless such exclusion is scientifically supportable (MRC, 2001)
- Requiring research on special and vulnerable groups to meet strict risk-benefit standards, particularly in the case where proxy consent is given for non-therapeutic research (MRC, 2001)
- Recommending specific measures to offset vulnerability such as capacity building, early involvement of participating communities, and the development of advocacy processes (MRC, 2003)
- Recommending that strategies to offset vulnerability be evaluated (MRC, 2003)
- Requiring that the protocol demonstrate some benefit to the special group or community (MRC, 2001) and how feedback on the outcome of the research will be transmitted (MRC, 2001)
- Recommending meaningful and ongoing informed consent procedures, such as special efforts to ensure adequate understanding of technical concepts (MRC, 2003)
- Providing detailed procedures for ensuring lawful, voluntary and informed consent for therapeutic and non-therapeutic research on specified research participants with limited capacity to consent, including the mentally ill or mentally handicapped, the elderly, pregnant women, unconscious patients, the dying, minors, prisoners,

students and persons in dependent relationships (MRC, 2001). The procedures differ, but deal with issues such as:

- Taking steps to ensure that a person with limited capacity is providing truly voluntary and informed consent (e.g. ensuring there is no coercion based on the participant's dependence, or undue inducement to participate; ensuring the person is given full information regarding the trial and their right to participate / refuse participation in a manner that they understand)
- Ensuring that a legally authorised person provides consent (e.g. a curator / spouse in the case of therapeutic research on a mentally ill person)
- Ensuring that a person who lacks capacity to consent must assent to participation (e.g. a mentally ill person with the ability to comprehend the issues involved should provide assent; a minor with the ability to comprehend the issues involved must provide assent to therapeutic and non-therapeutic research)
- Ensuring that proxy consent for non-therapeutic research only takes place in specified circumstances (e.g. non-therapeutic research on the mentally ill may only take place if the research meets strict risk-benefit standards, amongst other things).

Table 4: Summary of ethical recommendations for vulnerable groups across ethical guidelines

Provision in ethical guideline	DOH 2004	DOH 2006	MRC 2001	MRC 2005
The research cannot be carried out in a less vulnerable group	X	X	X	X
The research is responsive to the needs of the community	X	X	X	
Make special efforts with consent/ pay attention to the content, language & procedures	X	X	X	X
Assess the social context that creates conditions for increased vulnerability		X		X
Take steps to overcome vulnerability factors/ demonstrate how vulnerability will be addressed	X	X		X
Specify vulnerability factors in the protocol		X	X	X
Specify steps to overcome vulnerability in the protocol		X		X
Don't conduct research if protections can't be ensured				X
Evaluate strategies to offset vulnerability				X
Ensure the potential benefits outweigh potential risks	X			X
Take special care in identifying risks			X	
Release research findings in an ethical manner so as not to raise expectations/ protocol should demonstrate how results will be feedback		X	X	
Ensure some benefit to the community is demonstrated in the protocol		X	X	
Post-research investigations to ensure compliance with additional measures	X			
REC to consider if sufficient measures are in place to protect group/REC to be especially vigilant	X	X		

3.3 Health Professions Council of South Africa (2008) General Ethical Guidelines for Health Researchers

3.3.1 Who is considered vulnerable?

The HPCSA (2008) guidelines define vulnerable participants in "according to the UNAIDS definition" – "vulnerable communities refers to those communities that have some or all of the following characteristics: (i) limited economic development (ii) inadequate protection of human rights and discrimination on the basis of health status (iii) Inadequate community/ cultural experience with scientific research (iv) limited availability of health care and treatment options (v) limited ability of individuals in the community to provide informed consent (vi) Being a junior or subordinate member of a hierarchical group (vii) limited literacy levels.

3.3.2 How are vulnerable participants protected?

These guidelines contain the following recommendations specific to vulnerable groups:

- There needs to be appropriate justification for doing research in vulnerable communities. "Vulnerable communities should not be targeted for research just because of administrative and logistical ease of availability" (p.3)
- The research should be **responsive** to the particular vulnerabilities of such vulnerable communities (p. 3). The guidelines note that research in South Africa should be responsive to the health needs of communities, taking into account "the health needs of vulnerable groups such as women, older persons, children and people with disabilities" amongst other factors
- *Impartiality*: Researchers must be aware of the laws concerning unfair discrimination against research participants. Researchers must not discriminate in the selection of participants by including or excluding them on the grounds of "any condition of vulnerability, except where the exclusion or inclusion of particular groups is critical to the research purpose and scientific design" (p. 6)
- Added protection to safeguard vulnerabilities and avoid undue inducements such as "enhanced or added consent procedures would be necessary where appropriate" (p.3)
- Researchers need to consider the possible adverse impacts of their research on vulnerable groups and are urged to observe the highest possible standards to protect the rights of research participants. Researcher's attention is also drawn to the principle of autonomy, including the recognition that research should include special protections for those with diminished or impaired autonomy, that is, dependant and/or vulnerable participants' need to be afforded safeguards against harm or abuse.

3.4 HUMAN SCIENCES RESEARCH COUNCIL (1997)

3.4.1 Who is considered vulnerable?

The Human Sciences Research Council (HSRC) has developed their own ethical guidelines which they apply to research conducted by or on behalf of their research institutions (HSRC, 1997).

The HSRC Code does not actually define vulnerability and it gives only 3 examples of vulnerable participants, namely children, the aged and the disabled.

3.4.2 How are vulnerable participants protected?

Beyond placing a duty on researchers to take special care to protect the rights and interests of vulnerable participants, and providing some limited protection for the participation of children in research, the HSRC Code provides very limited specific recommendations on how to deal with vulnerable participants (HSRC, 1997)

Protective provisions include ensuring that a legally authorised person provides consent for child research (e.g. the parent or guardian).

3.5 Evaluation of the Ethical Framework

3.5.1 Strengths of the ethical framework:

1. The current ethical framework sets out comprehensive protections for vulnerable participants, including requirements that such research be well justified and responsive; that researchers consider those factors that render groups vulnerable; spell out measures that will offset such factors; and consider special consent procedures.

2. Selected groups are given particular attention such as women, children, foetuses, prisoners, patients dependent on medical care, and those with mental disability. That is, most ethical guidelines identify similar participants as vulnerable. Therefore, there is some harmonisation across guidelines in this regard.

3. Current ethical guidance is particularly helpful given the lack of direction in law to guide researchers. For example, in the absence of legal guidance, the ethical provisions setting out the circumstances and the manner in which children may participate in research are currently used as the norms for regulating the participation of children in health research.

4. Most ethical guidelines make an effort to provide an overall definition of vulnerability, with many of them relying heavily on the UNAIDS (2000) definition.

3.5.2 Gaps in the ethical framework:

1. Guideline developers in some instances do not make clear what characteristic of the particular group renders them vulnerable to increased research harms or compromised consent, and on some occasions so-called vulnerable groups are merely listed. Additionally, in many instances, guideline developers do not describe remedies that correspond with particular vulnerabilities.

2. In terms of one requirement that minimizes vulnerability – namely stringent risk standards for research - there is poor harmonization across DOH and MRC guidelines. The approach in the MRC guidelines where “whole protocols” are classed as ‘therapeutic’ and ‘non-therapeutic’ research does not correspond to the DOH approach where research is (more appropriately) conceptualised as comprising a mix of procedures that may/ may not hold out the prospect of direct benefit to participants.

3. The DOH (2004) guidelines do not have an explicit definition of vulnerability in the body of the guidelines. The DOH (2004) guidelines recognise that power and resource inequalities may exacerbate the vulnerability of participants. However, these guidelines provide limited guidance to researchers on how to deal with such vulnerabilities. The guidelines require researchers to 'take into account' this potential vulnerability and to show how they will 'redress' it, but provide no real direction to researchers and RECs on how to proceed.

3.6 Recommendations for the Ethical Framework

The Audit makes the following recommendations for strengthening the ethical framework:

1. It is recommended that guidelines-developers set out the particular features relating to 'vulnerable groups' that may compromise consent or increase research risks, and suggest corresponding remedies to offset these.

2. Future revisions of MRC (2001, 2003) ethical guidelines should consider harmonisation of standards for research risk with those contained in DOH (2004, 2006) guidelines.

3. Future revisions of DOH (2004) should consider the MRC (2003) concrete examples for redressing disparities and inequalities such as community participation, capacity building, and development of health care infrastructure.

4 SUMMARY OF ETHICAL-LEGAL PROTECTIONS

The Vulnerable Subjects Working Group of the National Health Research Ethics Council (NHREC) commissioned an audit of the South African ethical-legal framework with regard to protections for vulnerable groups in research. The Audit aimed to identify the nature and extent of protection for vulnerable research participants in relevant South African legislation, policies and ethical guidelines, and identify strengths and weaknesses of the legal-ethical framework protecting vulnerable research participants. The Audit examined various existing laws and regulations to determine any provisions relating to the protection of vulnerable groups in research and existing ethical guidelines.

In terms of the **legal framework:** the Audit generally found *limited specific legal protection for vulnerable research participants*. South Africa's current legal framework does not contain a research-specific law dealing expressly with research as a whole. S71 of the National Health Act (2003) does contain research-specific legal provisions, however, these are not yet in operation. Furthermore they deal mainly with one vulnerable group, namely minors, and contain some restrictive provisions.

Current laws and regulations that may be applied to vulnerable research participants are scattered through-out various branches of the law and include (i) Laws that specifically provide for and protect the rights and welfare of vulnerable persons (such as children, the mentally ill, prisoners), which would apply to those persons as research participants; (ii) Constitutional and equality laws which protect individuals, with a particular emphasis on the protection of vulnerable members of society. For example, section 9 of the Constitution

(Constitution of the Republic of South Africa, 1996) protects women from unfair discrimination and would extend to protecting women from being unfairly excluded from research on the basis of their sex or gender; (iii) Health laws and our common law which deal with informed consent; and (iv) Health-related laws governing research and other health matters. This suggests that the law already *recognises the vulnerability of many groups* and provides legal protection to them. Although they are not research-specific, many of the provisions do indirectly protect research participants.

Recommendations to enhance legal protections for vulnerable groups are made including: (i) *Adding basic protections for vulnerable groups within specific legislation relating to that group:* such as employment legislation, correctional service and juvenile offender legislation, mental health legislation, and education legislation. (ii) *Having specific provisions in research-specific law for vulnerable groups.* Amendments to the National Health Act No 61 of 2003 should provide protection for a wider range of vulnerable groups (apart from children) in a more flexible manner (iii) *Improving consent provisions in law:* The legislative approach to informed consent needs to be reviewed so as to create a system that both protects vulnerable groups and facilitates research. More specifically, s71 of the NHA (2003) should allow for exceptions to written consent and mandatory parental consent for child research in certain circumstances (iv) *Strengthening risk standards in law:* S 71 of the National Health Act (2003) or draft regulations should set out acceptable standards for research-related risk (v) *Including a right to benefit from the results of health research in law:* For example, in amendments to the National Health Act (2003). This right is contained within Article 15 of the International Covenant on Economic, Social and Cultural Rights which provides everyone with the right to "enjoy the benefits of scientific progress and its applications".[2]

The general findings for the **ethical framework** are that the current ethical framework sets out comprehensive protections for vulnerable participants (DOH, 2004; DOH, 2006; MRC, 2001; MRC, 2003), including requirements that: such research be well justified and responsive; that researchers consider those factors that render groups vulnerable, spell out measures that will offset such factors; and they consider special consent procedures. Selected groups such as women, children, foetuses, prisoners, patients dependent on medical care, and those with mental disability, are given particular attention. That is, ethical guidelines identify similar participants as being vulnerable. Therefore, there is some harmonisation across guidelines in this regard. Current ethical guidance is especially useful given the lack of direction in law to guide the situation of research specifically. For example, in the absence of legal guidance, the ethical provisions setting out the circumstances under which child participants may be engaged in research are currently used as the norms for regulating the participation of children in health research. Most ethical guidelines make an effort to provide an overall definition of vulnerability, with many of them relying extensively on the UNAIDS (2000) definition. Gaps in the ethical framework include that guideline developers in some instances do not clarify the characteristic of the group that renders them vulnerable to increased research harms or compromised consent, and on some occasions so-called vulnerable groups are merely listed. Additionally, in many instances, guideline developers do not recommend strategies to offset particular vulnerabilities. Recommendations for the ethical framework include that guidelines-developers set out the particular features relating to 'special groups' that may compromise consent or increase research risks, and suggest corresponding remedies to offset these.

[2] http://www.unhchr.ch/html/menu3/b/a_cescr.htm [Accessed: 29 August 2008].

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Appendix A: List of all legislation reviewed as part of this audit

- Basic Conditions of Employment Act No 75 of 1997
- Births and Deaths Registration Act No 51 of 1992
- Child Care Act No 74 of 1983
- Child Justice Bill 49 (2002)
- Children's Act No 38 of 2005 and the Children's Amendment Act of 2008
- Choice of Termination of Pregnancy Act No 92 of 1996
- Constitution of the Republic of South Africa, 1996
- Correctional Services Act No 111 of 1998
- Criminal Law (Sexual Offences) Amendment Act No 50 of 2003
- Criminal Procedure Act No 51 of 1977
- Criminal Procedure Second Amendment Act, No 62 of 2001
- Domestic Violence Act No 116 of 1998
- Human Tissues Act No 65 of 1983
- Maintenance Act No 99 of 1998
- Marriage Act No 25 of 1961
- Medical Scheme Act No 131 of 1998
- Medical Schemes Amendment Bill 37(2002)
- Medicines and Related Substances Act No. 101 of 1965
- Medicines and Related Substances Act No 59 of 2002
- Medicines and Related Substances Amendment Bill 2002
- Medicines and Related Substances Control Amendment Act No 90 of 97 and the 2008 Amendment Act
- Mental Health Act No17 of 2002

- National Health Act No 61 of 2003
- Nursing Act No 33 of 2005
- Nursing Amendment Act No 5 1995
- Nursing Amendment Act 1 No 9 1997
- Prevention and treatment of drug dependency Act No 20 1992
- Prevention of Family Violence Act No 113 of 1996
- Prevention of Unfair Discrimination and Promotion of Equality Act No 4 of 2000
- School Education Act No 6 of 1995
- South African Medical Research Council Act No 58 of 1991
- South African Schools Act No 84 of 1996
- Traditional Health Practitioners Act No 35 of 2004

Appendix B: List of all subordinate legislation reviewed as part of this audit

- General Regulations made in terms of the Medicines and Related Substances Act, 10 April 2003, No. 24727, R 510. Regulation 34(1) –(2)
- Regulations on the National Health Research Ethics Council No 134 (2007)
- Regulations on the National Health Research Committee No136 (2007)
- Regulations Regarding the Use of Human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics, 5 January 2007
- Regulations Relating to Research on Human Subjects, 27 February 2007

Appendix C: List of ethical guidelines reviewed as part of this audit

- Department of Health (2004) *Ethics in Health Research: Principles, Structures, Processes*
- Department of Health (2006) *Good Clinical Practice guidelines*
- South African Medical Research Council (2001) *Guidelines on ethics for health research: General Principles*
- South African Medical Research Council (2003) *Guidelines on ethics for health research: HIV preventive vaccine trials*
- Health Professions Council of South Africa (2008) General Ethical Guidelines for Health Researchers
- Health Sciences Research Council (1997) Code of Research Ethics.

Appendix D: List of all policies reviewed as part of this audit

- Health Sector Strategic Framework 1999 - 2004
- HIV and AIDS and STI Strategic Plan for South Africa 2007 - 2011
- Interim National Protocol for the Management of Children Awaiting Trial (2001)
- National Policy on Testing for HIV (1990) (Check to see if this policy has been updated)
- Patient's Rights Charter (2002)
- Strategic Priorities for the National Health System 2004-2009
- Any relevant policies issued by the Department of Correctional Services
- Any relevant policies issued by the Department of Education
- Any relevant policies issued by the Department of Health