

Building stakeholder skills to manage legal complexities in child and adolescent research

*A directory of the legal rights of minor research participants
including children & adolescents*

*HIV AIDS VACCINES ETHICS GROUP in collaboration with
DESMOND TUTU HIV CENTRE and PERINATAL HIV RESEARCH UNIT*



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Disclaimer

This resource aims to provide users with information to better understand the process of HIV vaccine research and development and related ethical, legal and human rights and community involvement issues. It is not provided as medical or professional advice or intended to be used to diagnose, treat, cure or prevent any disease. Persons who have, or suspect that they have, a health related problem should consult a suitable health care provider.

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HAVEG would appreciate any comments to improve subsequent editions. These can be sent to Catherine Slack at slackca@ukzn.ac.za or Jacintha Toohey at TooheyJ@ukzn.ac.za or posted to:

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About the organizations

In 1999 the South African AIDS Vaccine Initiative (SAAVI see www.saavi.org.za) was established as a lead program of the Medical Research Council (MRC), to coordinate HIV vaccine trials nationally. SAAVI aims to help develop locally appropriate HIV vaccines for Southern Africa, in a way that promotes the rights and welfare of trial participants. SAAVI awarded a research grant to the HIV/AIDS Vaccines Ethics Group (HAVEG), based at the University of KwaZulu-Natal, Pietermaritzburg to study the ethical issues relating to South African HIV vaccine trials.

HAVEG

The HIV/AIDS Vaccines Ethic Group (HAVEG see <http://www.saavi.org.za/haveg.htm>) is staffed by experts in various fields, including virology, behavioural sciences, ethics (general, professional, research), and law/ human rights. It has several core focus areas that it addresses through various research, training and consensus-building activities, including:

- To strengthen the ethical legal framework, especially for child participation
- To strengthen consent processes
- To explore fair benefit arrangements.

PHRU

The Perinatal HIV research unit (PHRU see <http://www.hivsa.com>) was established in the early 1990's as an academic unit of the University of the Witwatersrand, based at Chris Hani Baragwanath Hospital in Soweto. Initially the research agenda of the group focused on preventing the transmission of HIV from mother to child using antiretroviral drugs. The research agenda, and total staff component of the PHRC has grown over the past few years and currently approximately 400 staff members are employed in various research projects addressing various aspects of prevention and treatment of HIV in both adults and children. As part of the prevention effort at the PHRC, the HIV AIDS Vaccine Division (HAVD) was established in 2001 with the aim of testing as many suitable candidate HIV vaccines in Phase I and II trials as safely and as quickly as possible in order to identify the best candidate vaccine/s to take forward into large-scale Phase III efficacy trials. The HAVD group has completed a number of Phase I studies and plan to embark as many more Phase I and II candidate vaccines over the next few years. The group has also started to prepare for large-scale Phase III studies in Soweto and in rural Limpopo province, with the ultimate aim of finding a safe and effective HIV vaccine for South Africa.

Desmond Tutu HIV Centre

The Desmond Tutu HIV Centre (DTHC see <http://www.iidmm.uct.ac.za/bekkerwood/index.htm>) is located within the Institute of Infectious Disease and Molecular Medicine at the University of Cape Town, under the directorship of Professors Robin Wood and Linda-Gail Bekker. The DTHC has adopted a strong community

development stance. The centre is also involved in several initiatives including the provision of antiretroviral therapy to patients in the public sector, clinical research such as the developing and testing of vaccine candidates, the preparation of communities for HIV vaccine trials, adherence strategies and adherence research, and the training of health care professionals. The DTHC has identified adolescents as a research imperative and leads studies on adolescent prevention strategies, particularly those involving adolescents in HIV vaccine trials.

Background

South African researchers frequently face ethical-legal complexities when planning and conducting research with minors, for a number of reasons some of which are discussed below. Firstly, the legal framework for such research is in a *state of flux* with the introduction of a number of new laws that impact on the participation of minors in research, such as the National Health Act No. 61 of 2003 and the Children's Act No 38 of 2005. Secondly, some aspects of the legal framework are *inconsistent* e.g. the National Health Act allows only parents or guardians to consent for the participation of minors in research, whereas the Children's Act permits other care-givers to make important health-related decisions for children such as providing consent for medical treatment. Thirdly, the framework is limited by its *lack of tools* which can be used to determine if legal standards have been met; for example, although the National Health Act requires therapeutic research with minors to be in their "best interests" there is no criteria set in the Act, draft Regulations or any other policy document which can be used to establish "best interests". Fourthly, some aspects of the new law for research with minors will be fairly burdensome for researchers. For example, the National Health Act requires researchers to obtain consent from the Minister of Health for all non-therapeutic health research with minors.

Researchers also routinely face a number of challenges with planning and implementing research with minors. These include challenges relating to special child protection laws. For example, researchers report experiencing dilemmas with *mandatory reporting requirements* - minor participants may disclose various forms of ill-treatment, but researchers feel that they lack the skills to identify when reports of ill-treatment fall within the scope of legal requirements for intervention and interaction with the relevant authorities. There are also a range of *informed consent* challenges. For some research with minors, researchers may wish to seek independent consent, and may not be able to establish when this is acceptable. Also, parental consent may be desirable but parents/ guardians may be deceased. In such cases, questions arise as to who can consent for research participation, and how children can have a legal guardian appointed. There are also complex *privacy* challenges whereby parents may consent to enrollment, however, the minor research participant may enjoy privacy for certain elements of the research, such as information regarding sexual risk behaviour or HIV status.

In summary, researchers are conducting much-needed clinical and socio-behavioural studies with children and adolescents in the context of a somewhat contradictory, transitory framework with few tools to guide them. This session aims to introduce researchers (and other stakeholders like ethics committees) to a comprehensive legal resource to guide protocol development and review.

The Legal Directory

This resource entitled *A Directory of the Legal Rights of Child and Adolescent Research Participants* has been developed as a collaboration between the HIV/AIDS Vaccines Ethics Group (UKZN), the Desmond Tutu HIV Centre (UCT) and the PeriNatal HIV Research Unit (Wits).

It is a compendium of all research and non-research related laws that could affect research with minors.

It is framed around a range of contemporary problematic questions in child research and provides legal direction on child rights and researcher responsibilities. It also includes advice for RECs reviewing protocols involving legal minors.

Who is the Legal Directory for?

It aims to assist the 3 primary stakeholders in research, namely researchers, research ethics committees setting standards for child research, and community advisory board members involved in the promotion of participants rights.

How does one use the Legal Directory?

The Legal Directory consists of 5 parts:

- A brief introduction to the law around children, setting out the legal concepts of a child, a minor, and a guardian, and what these terms mean
- Section 1: Consent, dealing with legal requirements around obtaining consent for the participation of minors in research
- Section 2: Privacy, dealing with the legal rights of minor research participants to confidentiality within the research relationship
- Section 3: Special Obligations to children, dealing with special protections in our law for minors; and
- Section 4: Procedural requirements dealing with the procedural issues in place to protect minor research participants from unlawful research.

Sections 1-4 contain the bulk of the information relating to the law around minor participation in research. Each section consists of:

- A brief introduction setting out the law
- A table containing the various legal principles, the sources for these principles found in our law, the implications these principles have for the participation of minors in research, and the actions researchers and RECs should take in this respect; and
- A discussion of Frequently Asked Questions (FAQs) relating to the area of the law.

What sources were consulted for this Legal Directory?

Legislation:

1. Age of Majority Act No 57 of 1972
2. Basic Conditions of Employment Act No 75 of 1997
3. Births and Deaths Registration Act No 51 of 1992
4. Child Care Act No 74 of 1983
5. Child Justice Bill 49 (2002)
6. Children's Act No 38 of 2005
7. Chiropractors, Homeopaths and Allied Health Service Professionals Amendment Act No 40 of 1995
8. Chiropractors, Homeopaths and Allied Health Service Professionals Amendment Act No 91 of 1997
9. Chiropractors, Homeopaths and Allied Health Service Professionals Amendment Act No 6 of 2000
10. Chiropractors, Homeopaths and Allied Health Service Professionals Amendment Act No 50 of 2000
11. Choice of Termination of Pregnancy Act No 92 of 1996
12. Constitution of the Republic of South Africa Act No 108 of 1996
13. Correctional Services Act No 111 of 1998
14. Criminal Law (Sexual Offences) Amendment Act No 50 of 2003
15. Criminal Procedure Act No 51 of 1977

16. Criminal Procedure Second Amendment Act, No 62 of 2001
17. Domestic Violence Act No 116 of 1998
18. Genetically Modified Organisms Act No. 15 of 1997
19. Guardianship Act No 192 of 1993
20. Health Professions Amendment Bill 10 (2006)
21. Health Professions Act No56 of 1974
22. Human Tissues Act No 65 of 1983
23. Maintenance Act No 99 of 1998
24. Marriage Act No 25 of 1961
25. Medical, Dental and Supplementary Health Services Professions Amendment Act No 89 of 1997
26. Medical Scheme Act No 131 of 1998
27. Medical Schemes Amendment Bill 37(2002)
28. Medicines and Related Substances Act No. 101 of 1965
29. Medicines and Related Substances Act No 59 of 2002
30. Medicines and Related Substances Amendment Bill 2002
31. Medicines and Related Substances Control Amendment Act No 90 of 97
32. Mental Health Act No17 of 2002

33. National Health Act No 61 of 2003
34. Natural Fathers of Children Born out of Wedlock Act No 86 of 1997
35. Nursing Act No 33 of 2005
36. Nursing Amendment Act No 5 1995
37. Nursing Amendment Act 1 No 9 1997
38. Prevention and treatment of drug dependency Act No 20 1992
39. Prevention of Family Violence Act No 113 of 1996
40. Prevention of Unfair Discrimination and Promotion of Equality Act No 4 of 2000
41. School Education Act No 6 of 1995
42. Sexual Offences Act No 23 1957
43. South African Medical Research Council Act No 58 of 1991
44. South African Schools Act No 84 of 1996
45. Traditional Health Practitioners Act No 35 of 2004
46. Wills Act No 7 of 1953

Regulations

1. General Regulations made in terms of the Medicines and Related Substances Act, 10 April 2003, No.24727, R 510. Regulation 34(1) –(2)
2. Regulations on the National Health Research Ethics Council No 134 (2007)

3. Regulations on the National Health Research Committee No136 (2007)
4. 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
5. Regulations Relating to Research on Human Subjects, 27 February 2007

Case Law

1. *Burnstein and Others v Bester and Others NNO* (1996) (2) SA 751 (CC)
2. *Directorate for Serious Economic Offences v Hyundai*. (2001). (1) SA 545 (CC).

Policy Documents

1. Good Clinical Practice Guidelines, 2000
2. Guidelines for Good Practice In the Conduct of Clinical Trials in Human Participants in South Africa (2000)
3. Health Sector Strategic Framework 1999 - 2004
4. HIV and AIDS and STI Strategic Plan for South Africa 2007 - 2011
5. Interim National Protocol for the Management of Children Awaiting Trial (2001)
6. National Policy on Testing for HIV (1990)
7. Patient's Rights Charter (2002)
8. Strategic Priorities for the National Health System 2004-2009

Additional Resources

- Jaspan, H, Bekker, L.G, Grant, C., Slack, C., Strode, E., & Berwick, J. (2005). Protecting South Africa's children from HIV: Giving them our best shot. *South African Journal of Science*, 101, 216-217
- McClure CA., Gray G, Rybczyk GK, Wright PF: Challenges to conducting HIV preventative vaccine trials with adolescents. *JAIDS* 2004, 36:726-733.
- Slack, C., Strode, A., Grant, K., & Milford, C. (2005). Implications of the ethical-legal framework for adolescent HIV vaccine trials: Report of a consultative forum. *South African Medical Journal*, 95 (9), 682-690.
- Slack, C., & Kruger, M. (2005). The South African Medical Research Council's Guidelines on Ethics for Medical Research: Implications for HIV-preventive vaccine trials with children. *South African Medical Journal*, 95 (4), 269-271.
- Smit, J., Middelkoop, K., Myer, L., Lindegger, G., Swartz, L., Seedat, S., Tucker, T., Wood, R., Bekker, L.G. & Stein, D. (2005). Socio-behaviour challenges to phase III HIV vaccine trials in Sub-Saharan Africa. *African Health Sciences* 5(3), 198 – 206.
- Strode, A., Slack, C., Grant, K., & Mushariwa, M. (2005). Ethical and legal challenges in enrolling adolescents in medical research in South Africa: Implications for HIV vaccine trials. *South African Journal of Science*, 101, 224-228.
- Strode, A., Slack, C., Wassenaar, D., Singh, J. (In press). One step forward, two steps back: Requiring ministerial approval for all “non-therapeutic” health research with minors. *South African Medical Journal*.
- Strode, A., Slack, C., & Mushariwa, M. (2005). An evaluation of South Africa's ethical-legal framework and its ability to promote the welfare of trial participants involved in HIV vaccine research. *South African Medical Journal*, 95 (8), 598-601.
- Strode, A., Grant, C., Slack, C., Mushariwa, M. (2005). How well does South Africa's National Health Act regulate research involving children? *South African Medical Journal*, 95 (4), 265-266.

BACKGROUND

Children and legal minors have special protection in South African law. This means that a number of laws exist which ensure that children are protected from their youth and inexperience. The terms “child” and “minor” have distinct meanings in South African law. Currently, everyone is a child until the age of 18. At the age of 21 most adults become legal majors.

This means that currently when a person turns 18, they are no longer a child and they lose all special legal protections that exist for children (such as the protections in the Child Care Act No 74 of 1983 to ensure that they receive adequate care). However they only become full legal majors and thus capable of carrying out all legally binding acts unassisted, at the age of 21. This anomaly between ‘children’ and ‘minors’ will be removed in the future, as the new Children’s Act No 38 of 2005 provides that legal majority should be attained at 18 (s 17).

Throughout this directory we have used both terms as they are found in the law. References to minors should be read as references to children below the age of 21 years, and references to children should be read as references to persons below the age of 18 years, until such time as the Children’s Act 38 of 2005 comes into operation. It is important for Researchers and RECs to be mindful of the distinction when reading various sections of the directory.

Who is a child?

A child is a person who is under the age of 18 years, in terms of section 1 of the Child Care Act No. 74 of 1983 and section 1 of the future Children’s Act, No. 38 of 2005.

Who is a minor?

A minor is a person below the age of 21 years. At 21 years of age, a person becomes a legal major in terms of section 1 of the Age of Majority Act No. 57 of 1972. From this point forward a person has full legal capacity and can make all legally binding decisions.

What is a guardian?

One of the primary protections for children and minors is the institution of guardianship to ensure that an adult assists or acts on behalf of a young person when key decisions have to be made. Guardianship refers to the duties and responsibilities that an adult, usually the parent, has in relation to a child. The responsibilities of a guardian include:

- Caring for the minor
- Administering the minor’s property

- Assisting the minor to perform juristic acts, such as entering into contracts

Every person under the age of 21 years should have a legal guardian. Ordinarily, both parents of a child born in wedlock are the natural guardians of a child. If the child is born out of wedlock, the mother is the natural guardian of the child, although an unmarried father can also apply to court to be the child's guardian. If the parents are dead or unavailable to care for the child another person may be appointed as the child's guardian. This could include a person appointed in terms of a will, an adoptive parent or a person appointed as guardian by the High Court. Sometimes a child without a parent or guardian is placed in the custody of a person or institution (such as a foster parent, or a children's home) without a guardian being appointed. In this case, the High Court itself can act as the guardian of a child.

SECTION 1: CONSENT FOR THE PARTICIPATION OF A MINOR IN RESEARCH

Consent for minor participation in research is a complex question, given that our current law does not deal specifically with the issue. This means that for the most part, legal authors have had to take note of general children's legislation, and legislation regarding consent for medical interventions, to try to apply these principles to the research situation. This has led to various debates and disagreements regarding consent for a minor's participation in research.

In the future, the situation will be far clearer, since the National Health Act No 61 of 2003 deals specifically with consent for a minor's participation in research. However, the future situation will not be altogether without complexity, since there are ongoing discrepancies between the provisions of the National Health Act and that of future childcare legislation on the approach taken towards decision making for children in general. It is hoped that once the Children's Act No 38 of 2005 comes into operation, it will guide the interpretation of the research provisions for children in the National Health Act.

Overview of the general legal principles on consent to legally binding acts

In order for consent to be valid in our law, there are a number of requirements it must fulfill. One of these requirements is that in order for consent to be valid, it must be provided by a person who has the capacity to consent.

Generally, our law recognizes that a minor does not have full legal capacity. Until such time as a person reaches a certain age, they are not fully capable of consenting to legally binding acts. In these situations, a parent or legal guardian assists the minor, by providing consent on his or her behalf.

Having said that, there are exceptional circumstances where the law specifically gives people below the age of 21 years the capacity to carry out acts. The case of consent to medical treatment is one of those circumstances, as set out in more detail below. Furthermore, there are times when the law recognizes that a person below the age of 21 years can be declared, or viewed as, a major. For example, a young person may apply for emancipation on the basis of their independent circumstances, and they may be granted emancipation by the fact that they have entered into a valid marriage recognised by law. In these (fairly unusual) circumstances, the person is capable of consenting to legally binding acts without the assistance of a parent or guardian, despite being below the general age required.

Another important requirement for consent is that the consent must be lawful. The act being consented to must be one that our law recognizes as an act that does not offend the morals or our community. Consent for an unlawful act (such as murder) is not recognised as valid consent by our law. By the same token, consent on behalf of a child or minor for an unlawful act would not be valid consent.

A child's right to consent to medical interventions

Currently, the Child Care Act No 74 of 1983 gives children of 14 years of age the right to consent independently to medical treatment, and children of 18 years the right to consent independently to a medical operation.

In future, the Children's Act No 38 of 2005 will continue to provide children of a certain age and capacity the right to consent independently to medical interventions. This Act provides that children of 12 years and below should be entitled to consent independently to all medical interventions, provided that they have sufficient understanding. Additionally, the Act provides that children of 12 years, or children below 12 years of age with sufficient understanding should be entitled to consent independently to an HIV test.

A child's right to consent to research

Given that there is no statute in our current law dealing with consent to research, there has been considerable debate amongst legal authors regarding whether a minor should be able to consent independently to participate in research. Some legal authors have argued that 'therapeutic research' is similar to medical treatment (or a medical operation, if the research deals with an operation). On the basis of the provisions regarding independent consent to medical interventions in the Child Care Act, it has therefore been argued that a child of 14 years of age should be able to consent independently to therapeutic research involving medical treatment, and similarly that a child of 18 years of age would be able to consent independently to therapeutic research involving an operation.

Given the experimental nature of research, other legal authors argue that the two cannot be likened. Additionally, the provisions in the Child Care Act have not helped to clarify the situation with regard to consent for non-therapeutic research.

Since the Child Care Act is the only existing source of clarity on consent for minors with regard to medical matters, and this Act does not apply to minors above the age of 18 years, others argue that persons above 18 years of age (including minors, despite the fact that they only attain majority at 21 years) are able to consent independently for all medical matters, including all forms of research.

The situation will be clearer in the future, as the National Health Act sets out that all minors must have the consent of a parent or a guardian to participate in research. Minors are currently persons below the age of 21 years, but in terms of the future Children's Act will be all persons below the age of 18 years.

Proxy consent given on behalf of a child would still need to be 'lawful' consent in order to be valid – that is, the research proposal for which consent is given would need to be considered acceptable. Ethical guidelines set out detailed considerations (for example, risk standards) regarding acceptable research on children, and these guidelines would be important factors to consider in determining whether consent for child participation in research is lawful. In future, section 71 of the National Health Act provides detailed further guidance on the requirements for acceptable research with children. Fulfilling these requirements is by and large a procedural matter, and is dealt with in Section 4, below.

LAW & IMPLICATIONS:

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
Voluntary Informed consent is required for participation in research	<p>Section 12 of the Constitution of the Republic of South Africa Act No 108 of 1996 gives every person the right to freedom and security of the person, which includes the right only to take part in scientific research with their consent.</p> <p>The Human Tissues Act No 65 of 1983 provides for, amongst other things, the use of human bodies and tissue for the purposes of medical or dental training, research or therapy. S18 of the Act requires informed consent for the removal of tissue, blood or gamete from a living person.</p>	<p>Regulation 2 of the Draft Regulations Relating to Research on Human Subjects, 27 February 2007, requires research participants to be well informed to make informed choices.</p> <p>Regulation 6 lists types of information required for an informed choice.</p> <p>The Draft Regulations Regarding the Use of Human DNA, RNA, cultured cells, stem cells,</p>	Research on all persons (including minors) may only take place where voluntary informed consent has been given for participation.	RECs and researchers must ensure that all research makes provision for informed consent for a minor's participation.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<p>The Department of Health's National Policy on Testing for HIV sets out requirements for obtaining informed consent for the purposes of HIV testing, which includes pre- and post-test counseling. Section 1(1)(c) says that HIV testing may be done for research purposes only with the informed consent of the individual, and in accordance with national legal and ethical provisions regarding research.</p> <p>Section 11 of the National Health Act No 61 of 2003 requires that a health care user have full knowledge, and give written authorization for any health service conducted for experimental or research purposes. S71 of the Act requires research to be preceded by the written consent of the person after he or she has been informed of the objects of the research and any possible positive or negative consequences to his or her health.</p>	<p>blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics, 5 January 2007, provide that human biological material may only be removed from a living person for purposes of research with informed consent. Likewise, the use of donated biological material (such as stem cells or excess embryos) for research purposes requires the informed consent of the donor.</p>		
Minors have limited	The Age of Majority Act No 57 of 1972	Section 17 of the	Current law does not	RECs and researchers will

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
<p>legal capacity until such time as they reach a certain age (currently 21 years) to provide consent for legal acts.</p>	<p>s1 says that a person becomes a legal major at the age of 21 years. From this point onwards a person has full legal capacity and can make legally binding decisions.</p> <p>The Child Care Act No 74 of 1983 defines a child as a person below the age of 18 years. The Act contains provisions to protect children below the age of 18 years, including providing for the consent of a parent or guardian to certain acts.</p>	<p>Children's Act No 38 of 2005 provides that legal majority should be attained at 18 years.</p> <p>Section 71 of the National Health Act No 61 of 2003 provides that a minor does not have the capacity to consent to research independently, and requires the assistance of his or her parent or legal guar</p>	<p>specify at what age minors have the capacity to consent independently to research. However, as detailed below, it is submitted that minors of 18 years and above are able to consent independently to all forms of research.</p> <p>In future, in terms of the National Health Act No 61 of 2003, minors will not have the independent capacity to consent to research until 21 years of age. This will apply until such time as the Children's Act drops the age of majority to 18 years.</p>	<p>need to ensure that informed consent requirements for a minor's participation in research apply to all persons below the age of 18 years.</p> <p>RECs and researchers should keep up to date with changes in the law, since the National Health Act No 61 of 2003 will increase the age for consent by a parent or guardian for research to 21 years, until such time as the Children's Act comes into operation.</p>
<p>In exceptional cases, the law gives minors the capacity to consent independently to a legally binding act</p>	<p>The Child Care Act No 74 of 1983 says that children of 14 years and older can consent independently to medical treatment, and children of 18 years and older can consent independently to a medical operation.</p>	<p>The Children's Act No 38 of 2005 s129 proposes lowering the age of independent consent to medical treatment to 12 years provided the child</p>	<p>Current law allows minors to consent independently to medical treatment at 14 years of age, and to an operation at 18 years of age. Some legal authors</p>	<p>Given the absence of legal provision for a minor's independent consent for research, RECs and researchers would be best advised to</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
(for example, in the case of medical treatment.)		<p>“is of sufficient maturity and has the mental capacity to understand the benefits, risks, social or other implications of the treatment or operation”. S130 of the Act further proposes that all children of 12 years of age, or children below 12 years of age with sufficient capacity, should have the right to consent independently to HIV testing.</p> <p>Section 71(2) and (3) of the National Health Act No 61 of 2003 requires both therapeutic and non-therapeutic research on a minor to be carried out with the written consent of the parent or guardian.</p>	<p>alike therapeutic research to a medical interventions, arguing that minors of 14 years can consent independently to therapeutic research involving treatment, and at 18 years to therapeutic research involving an operation. This is a matter of debate.</p> <p>At the very least, given that the Child Care Act's provisions regarding parental consent for a child's medical interventions only apply to persons below 18 years of age, it can be argued that minors above 18 years of age can consent independently to all medical interventions, including research.</p> <p>These provisions also mean that a minor may, by</p>	<p>insist on the consent of a parent or guardian for research on all minors at least below the age of 18 years (some may even argue 21 years.) Some ethical guidelines tend to advocate a similar approach.</p> <p>RECs and researchers should ensure that informed consent processes also detail the older child's right to provide independent consent for any medical treatment and/or operations within the research project, within the parameters of parental consent for the research as a whole.</p> <p>RECs and researchers should also keep up to date with changes in the law, since once s71 of the</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
			<p>law, consent independently to standard medical treatment (at 14 years of age) and medical operations (at 18 years of age) required within the research project. Once the Children's Act comes into operation, this age limit may drop further.</p>	<p>National Health Act is operationalised through regulations, persons below 21 years of age will not be able to provide independent consent for therapeutic (and non-therapeutic) research, until such time as the Children's Act reduces the age of majority to 18 years.</p>
<p>In other instances, the law recognizes situations where a child him or herself is granted majority status and has full legal capacity, although below the age of 21 years. This is called 'emancipation'.</p>	<p>Section 2 of the Age of Majority Act No 57 of 1972 gives a person of 18 years the right to apply to court for an order declaring him or her to be a major. The court considers various factors (such as financial independence) in granting the application.</p> <p>Section 1 of the Births and Deaths Registration Act No 51 of 1992 grants majority status to a person below 18 years who has contracted a legal marriage. This majority status is retained, even if the marriage ends in divorce or death before the age of 21</p>		<p>An emancipated person would be able to consent independently to participate in medical research.</p>	<p>RECs and researchers may allow an emancipated person to consent independently to research. It would be advisable, however, to require proof of emancipation in the form of a court order or marriage certificate.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	years is attained.			
<p>Where a minor is incapable of providing consent, a parent or guardian gives consent for the child's legal acts.</p>	<p>Child Care Act No 74 of 1983 s39 generally requires the assistance of a parent or guardian to consent for a child's medical treatment and/or an operation, with the age exceptions set out above.</p>	<p>Section 71 of the National Health Act No 61 of 2003 requires the consent of a parent or guardian for a minor's participation in therapeutic and non-therapeutic research.</p> <p>Regulation 4(1) of the Draft Regulations relating to research on human subjects, 27 February 2007, only allows research on children under certain conditions, and with the consent of the parent or guardian.</p> <p>S129 of the Children's Act No 38 of 2005 requires the assistance of a parent or guardian where the child is not capable of consenting to medical interventions. S18 of the Act states that the consent of both parties having</p>	<p>A parent or guardian can give proxy consent for a minor below the age of 18 years to participate in research.</p> <p>When the National Health Act No 61 of 2003 comes into operation, a parent or guardian must give consent for a minor below the age of 21 years to participate in research.</p> <p>As discussed above, the Children's Act will lower the age of majority to 18 years, so that the application of the National Health Act's provisions will change to persons below the age of 18 years.</p>	<p>RECs and researchers must ensure that both therapeutic and non-therapeutic research on minors who are not capable of providing consent, takes place with the consent of the child's parent or guardian.</p> <p>Other procedural issues also need to be dealt with in the case of child participation in research (see Section 4, below).</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		guardianship is required in matters requiring consent for the child.		
In defined circumstances other caregivers, besides parents, can give proxy consent for a child's medical treatment.	The Child Care Act No 74 of 1983 provides for instances where other persons may give consent for medical interventions upon a child. For example, s39 of the Act allows the Minister to provide consent where the parent or guardian is unwilling or unable to do so. S53 transfers certain parental powers to the management of an institution to which a child has been sent, or the custodian of a child. This includes the right to consent to medical treatments or operations, unless the intervention may pose a serious danger to the life of the child.	S71 of the National Health Act No 61 of 2003 specifically requires a parent or guardian to provide consent for a minor's participation in research. 129(2)(a) of the new Children's Act No 38 of 2005 requires consent from the parent or the primary care-giver of the child for medical interventions, in instances where the child is not capable of independent consent. The primary caregiver is defined broadly in s1 of the Act to include not only legal guardians but also those exercising parental responsibilities over the child such as foster	While the present Child Care Act No 74 of 1983 does provide for people other than a parent or legal guardian to provide consent for medical interventions, in defined circumstances, legal authors have generally not argued for the extension of these provisions to include consent for research. So, it is unlikely that a person not falling under the category of 'parent' or 'legal guardian' would be able to provide proxy consent for a minor's participation in research. This position will remain unchanged when the National Health Act No 61 of 2003 and the	RECs and researchers must ensure that adults providing consent for a minor's participation in a research project are in fact parents, or legal guardians. Children without a parent or legal guardian would in all likelihood not be able to take part in research.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		parents and carers at places where a child has been placed.	Children's Act No 38 of 2005 come into operation.	
<p>The law provides for various ways in which a guardian may be appointed for a minor without parents or a guardian, e.g. through</p> <ul style="list-style-type: none"> • Nomination in a will • Adoption • Application to court <p>A court order is required to confirm guardianship.</p>	<p>The Child Care Act No 74 of 1983 s20 says that the effect of an adoption (in terms of an order of court) is that the child is by law recognised as the legitimate child of the adoptive parents.</p> <p>A key principle of the common law is that every person has "testamentary freedom". This enables them to decide freely how to dispose of their property and make other arrangements in their will, such as nominating another person to act as a guardian for minor children.</p> <p>The Guardianship Act No 192 of 1993 provides in section 1 and 2 that a court may make an order appointing a person or persons as the guardian of a minor child.</p>	<p>Section 242(2) (a) of the Children's Act No 38 of 2005 provides that an adoption order confers all parental rights and responsibilities to the adoptive parent. In terms of s242 (3) the child from that time on regarded as the child of the adoptive parents.</p> <p>Section 24 of the Act further allows any interested person to apply to court to become the guardian of a child. The court will consider various factors, such as the best interests of the child and the suitability of existing guardians, before making such an order.</p> <p>Section 27 of the Act</p>	<p>A minor without a parent or legally appointed guardian will not be able to participate in research. However, there are legal processes to appoint a guardian for such a child. If a child has no parent or guardian, the High Court acts as the guardian of the child, but this would be an impractically long process to use simply to obtain consent for research.</p>	<p>Where a minor has no parents, researchers and RECs should require proof of guardianship from caregivers claiming to be guardians of a minor, since transfer of guardianship generally requires a legal process. Alternatively, they may wish to refer caregivers and/or minors to nearby children's organisations or welfare organisations to set guardianship processes in motion.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		allows a parent to appoint a guardian in the event of his or her death. This must be done through a valid will.		
A minor has the right to participate in major decisions involving him or her, even where the parent or guardian provides the consent.	The Constitution of the Republic of South Africa Act No 108 of 1996 provides that a child's best interests are paramount in every matter concerning the child.	<p>S71 of the National Health Act No 61 of 2003 requires that a minor also provide consent for participation in therapeutic and non-therapeutic research, if he or she is capable of understanding.</p> <p>Regulation 4(1) of the Draft Regulations Relating to Research on Human Subjects, 27 February 2007, say that if the minor refuses consent to participate in research, the minor's refusal will prevail over the parental / guardian's consent.</p> <p>Section 10 of the Children's Act No 38 of 2005 says that every child</p>	<p>Our courts have held that the principle of the best interests of the child requires that a child's opinion is an important factor in decision-making. This would include decision-making with regard to research participation.</p> <p>In future, minors will be entitled to take part in decisions regarding their participation in a research project, and to have their views given consideration, even in circumstances where a parent or guardian is legally entitled to provide consent.</p>	RECs and researchers must ensure that research processes and procedures to allow a minor's participation in decisions regarding his or her involvement in research.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		that is of an age, maturity and stage of development to be to participate in any matter concerning that child has the right to participate in an appropriate way, and views expressed by that child must be given due consideration.		

FREQUENTLY ASKED QUESTIONS:

At what age does childhood end?

At present, while the Child Care Act No 74 of 1983 defines a child as a person below 18 years of age, the law relating to the age of majority say that a person becomes a legal major at the age of 21 years. At this age, a person acquires full legal capacity, and he or she is able to carry out many lawful acts previously 'incapable' of doing. The new Children's Act No 38 of 2005 will resolve the current anomaly between 'childhood' and 'minority / majority'. When the Act comes into operation it will repeal the Age of Majority Act No 57 of 1972. In terms of the new law, a child or minor will be a person below 18 years of age.

Can minors consent independently to research?

The position in current law is unclear, since current law does not deal specifically with consent for a minor's participation in research. Given children's lawful entitlement to consent independently to medical treatment at 14 years (and to an operation at 18 years), there are those who argue that a child of 14 years of age can consent independently to therapeutic research. This position is debatable, and also does not provide an answer for independent consent to non-therapeutic research. Given that the Child Care Act No 74 of 1983 is the only current piece of legislation that deals with parental consent for medical interventions on behalf of a child, and that this law only applies to children below the age of 18 years, it is

submitted that after 18 years of age a minor may provide independent consent to participate in all medical interventions, including therapeutic and non-therapeutic research.

When the National Health Act No 61 of 2003 is operationalised (at the time that the regulations in terms of s71 are finalized and gazetted), minors will not be able to consent independently to research, be it therapeutic or non-therapeutic, and consent of a parent or guardian will be required for minor research participants. Since the National Health Act refers in the research section to 'minors' (persons currently below 21 years of age), this means that only a person of 21 years or older will be able to provide independent consent to research. The Children's Act No 38 of 2005 will lower the age of majority to 18 years, so that the National Health Act provisions will then only apply to persons below 18 years of age. Given this state, it can only be hoped that the Children's Act comes into operation before the National Health Act.

Can minors consent independently to medical interventions within the research?

Yes. Providing informed consent for a minor's participation in research generally entails obtaining full information on, and providing consent to, all aspects of the research (including any medical interventions that take place as part of the research protocol). This means that where a parent or legal guardian provides consent for a minor's participation in research, they should generally be provided with information on, and therefore given general consent for the various medical interventions that may form part of the research – including necessary treatment that may arise from time to time. However, during the actual research, a child of 14 years is able to provide independent consent to medical interventions (for example, treatment for a sexually transmitted infection) as they arise, without the parent's or guardian's consent. This age will lower to 12 years (provided the requisite capacity is there) once the Children's Act No 38 of 2005 is operationalised. This should be explained to both parents / guardians and minors during the informed consent process, so that parents are aware that they are giving a general consent for the various research interventions, but that older minors may consent independently from time to time when the need for interventions consisting of a proven treatment or operation arise.

Are there any circumstances when minors can consent independently to research?

A few. Minors who have been emancipated in terms of the law are legal majors, and are able to give independent consent to research. Also, those who are legally married are considered by the law to be majors, and may consent independently to research. The fact that a minor gives birth to a child, however, does not result in emancipation. Since instances of emancipation are fairly unusual in our law, researchers should require proof of legal majority before the general age.

Can a parent or guardian provide proxy consent for a child's participation in research?

Yes. Our law enables a parent or guardian to provide proxy consent in instances where a minor is not able to provide such consent. This applies to the case of research. However, other legal and ethical principles (and procedural requirements) usually operate in conjunction with the parent's right to consent. These legal principles set out instances where research on minors is considered to be lawful (and ethical), and parents would only be able to provide proxy consent for a minor's participation in lawful research.

What if the parent him or herself is a minor? May they provide proxy consent for their child's participation in research?

No, not unless the parent has been emancipated by law. Where an unmarried minor gives birth to a child, the minor's parent/s (or guardian/s) become the legal guardian/s of their grandchild. So, in this instance, the grandparent would be lawfully capable of providing consent for research participation by his or her grandchild. Section 242 of the new Children's Act No 38 of 2005 confirms this common law position, so that in the future this law will remain unchanged.

Can a parent or guardian provide passive (that is, not explicit) consent for a minor's participation in research?

Our current law does not explicitly deal with consent for participation in research, as set out above. In future, the National Health Act No 61 of 2003 will require written consent for medical research participation. Given this, researchers would be best advised to insist on explicit consent from a parent or guardian for the minor's participation in research even before the National Health Act comes into operation. When the Act is operational, the requirement for written consent will preclude passive consent for research participation.

Do both parents have to provide consent for a minor's participation in research?

Generally not, although this will change once the Children's Act No 38 of 2005 comes into operation. Since our current law does not provide explicitly for consent for minor participation in research, this question is not dealt with. However, the Child Care Act No 74 of 1983, when referring to parental consent for medical interventions, simply refers to 'a' parent or 'a' guardian. This suggests that the consent of one parent or guardian may be sufficient. The National Health Act No 61 of 2003 also refers only to the parent or guardian of the minor. Some ethical guidelines set higher standards, and require the consent of both parents / guardians depending on the balance of risks to direct benefits to the child within the research. Where ethical guidelines set higher standards, researchers and RECS would be advised to adhere to these standards.

In future, the Children's Act No 38 of 2005 will guide the interpretation of other laws relating to children. This Act provides that where there is more than one guardian of a child, both parties should provide consent in matters where the law requires consent for the child. Once the Act comes into operation, researchers and RECS would be advised to insist on the consent of both parents or guardians in instances where proxy consent for a minor's participation in research is required.

Can a person other than a parent or legal guardian (for example, a caregiver exercising parental responsibilities over a minor) provide proxy consent for a minor's participation in research?

Neither current nor future law deals specifically with proxy consent by a caregiver for a minor's participation in research. While our law does provide for proxy consent for medical interventions by persons other than parents / guardians in defined circumstances, these provisions have never been extended to include the situation of research. Researchers would be advised to insist on the consent of a parent or legal guardian, where a minor is incapable of providing consent.

Can a minor take part in decisions regarding consent to research participation? What if the child refuses consent?

Yes. In terms of our current law, the Constitution holds that the best interests of the child are paramount. While this principle is not defined in our law, the courts have expanded on it in various cases involving custody of children. They have generally held that the principle 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. One of the key factors in this analysis has always been the views of the affected child. In one case, it was held that whilst a child's views are not always indicative of their best interests an informed, mature and intelligent opinion can carry substantial weight. Thus it could be argued that in terms of current law, a child's participation (and even assent) should always be a necessary pre-requisite for participation in research, provided they are in a position to express their views.

In terms of future law, a child should be entitled to make his or her wishes known with regard to research participation, with due weight given to his or her opinion based on his or her capacity. Draft regulations at present advise that if a child refuses to participate in research, the child's position should prevail, despite the presence of consent by the parent or guardian.

SECTION 2: THE PRIVACY RIGHTS OF RESEARCH PARTICIPANTS WHO ARE LEGAL MINORS

Research involving minors is complicated from the perspective of the right to privacy, due to the fact that the research relationship may involve not only the participants, but also their parents or legal guardians. This is particularly an issue when the protocol involves older children or adolescents as research subjects, as they may have expectations of privacy regarding information that they will disclose to researchers or that researchers may obtain during the research process.

Unfortunately the law does not deal directly with a minor's right to privacy in research. The only direct reference to the right to privacy in research is found in the draft Regulations on Research with Human Subjects, 23 February 2007 (not yet finalized). They state in Regulation 2 that researchers must ensure the protection of the privacy and confidentiality of all research participants. This does not give any guidance on how to apply the general legal principles relating to privacy to research with minors, when a parent or guardian must give consent to research participation. This means that in order to answer questions relating to privacy, we need to apply the general legal principles of privacy to adolescent research.

Overview of the general legal principles on privacy

Everyone has a constitutional, and common law right to privacy. However our courts have held that this right is not absolute, and only extends to those aspects of a person's life that the person him or herself, as well as society, recognises should be kept private. In many instances our laws spell out instances when a person is entitled to privacy. However, where the law is silent, our courts use a test to determine whether something is capable of being protected by the right to privacy:

- A person must have the capacity to form an expectation that the information will be kept private; and
- The expectation itself is regarded as reasonable by the community.

So, the right to privacy is shaped by the limits of legitimate expectation and the community's values. Additionally, there are certain grounds of justification recognised by law when it would not be wrongful to disclose private information. In other words, there are situations where even though information is private it can be disclosed to others in certain circumstances. Grounds of justification include where consent has been given for disclosure, 'necessity' (where the law considers a disclosure to be necessary for various reasons), or where an accepted law provides for a limit to privacy.

A minor's right to privacy regarding health status and treatment

Although the law is silent on a legal minor's right to privacy in research, it does deal with a child's right to privacy relating to their health status (including HIV status) and their treatment. Accordingly, when applying the general principles relating to privacy to a minor research participant, it is important to also recognise these existing legal principles relating to health status and treatment.

The National Health Act No 61 of 2003 only deals with the right to confidentiality of 'users'. 'Users' are described in section 1 of the Act as being those who receive treatment (including receiving blood or blood products) in a health establishment or who use a health service. Notably, health research is defined separately. The Act further provides that if the 'user' is under the age at which they can consent to medical treatment (currently 14), then the 'user' includes the parent, guardian or other person authorised by law to act on their behalf.

We can draw two important conclusions from the Act:

- People taking part in research (as opposed to those accessing a 'health service) do not generally fall within the definition of a 'user'. Therefore, a research participant's right to confidentiality is not covered by the Act, and their right to confidentiality with regard to research will be determined by general legal principles relating to privacy. However, where research participants access an existing, as opposed to experimental, health service (e.g. treatment for a sexually transmitted infection) within the research project, they would fall within the definition of a 'user' and be granted the right to privacy as set out in the Act.
- The Act links consent to confidentiality. This means that it provides that when children need assistance with consenting to a procedure they do not have the right to privacy, since the person consenting on their behalf (parent/guardian/other) is seen as the 'user' and therefore the bearer of the right to privacy. Children only have independent privacy rights when they consent independently to medical treatment.

The Children's Act No 38 of 2005, which will come into operation in the near future deals with privacy in three places:

- Section 13 of the Act provides every child (a person under the age of 18) the right to privacy regarding their "health status". Health status is not defined but it is assumed that this refers to a child's medical condition or diagnosis. This right may be limited where maintaining confidentiality it is not in the best interests of the child (s 13(1)(d)).
- Section 133 says that no person may disclose the fact that a child is HIV positive without consent, except in certain defined circumstances, such as in terms of a court order. Consent to the disclosure may be provided by the child if they are over 12, the child if they are under 12 but understand the benefits, risks and social implications of the disclosure, the child's parent or care-giver, a hospital superintendent, the children's court and a designated child protection organisation.

- Section 134(1) provides children over the age of 12 with the right to access contraceptives and to confidentiality regarding the obtaining of condoms, contraceptives or contraceptive advice in s 134(1).

Finally, although not directly linked to the provisions on privacy in the Act, there are also a number of other express statutory limitations on a child's right to privacy. For example, a general obligation is created in section 150 to identify children in need of care and protection. Such children must be referred to a social worker for investigation of the matter and the initiation of possible further steps to assist the child (s 150(2)). A child will be in need of care and protection if they are, for example, living in a child headed household, are required to perform child labour, are being maltreated or abused, or have been exploited (s 150(1)).

Applying the laws and principles to research with children

Since the law does not deal specifically with the right to confidentiality within research, we submit that based on the law and general principles the following conclusions can be made:

- A minor research participant has the right to confidentiality within the research relationship if he or she is mature enough to form a reasonable expectation of privacy, despite the fact that a parent or guardian may provide consent for the research as a whole. However this expectation must be reasonable. This assessment doesn't need to be done individually with every adolescent. It can be assumed that most adolescents would have expectations of privacy regarding their personal interaction with researchers during the research process and this would be reasonable given that their parents or guardians have consented to their participation.
- A minor research participant has the right to medical confidentiality with regard to those aspects of the research that he or she is lawfully able to consent to, independently of his or her parent or guardian (such as standard (as opposed to experimental) medical treatment within the research).
- The right to confidentiality may be limited in certain circumstances. The boundaries of a child's privacy are based primarily on the need to protect children from harm.

LAW AND IMPLICATIONS:

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
Every person (including a minor) has the right to privacy.	<p>Section 14 of the Constitution of the Republic of South Africa Act No 108 of 1996 gives every person the right to privacy</p> <p>The common law gives everyone the right to <i>dignitas</i> which includes the concept of the right to privacy.</p>	There is no new law or proposed law reform.	Every research participant, including a research participants below the age of 21 years, has the right to privacy.	
In the medical context, our law says that the right to privacy means that every person is entitled to keep their medical information confidential.	Section 14 of the National Health Act No. 61 of 2003 says that any information relating to a person's health status, treatment or stay in a health establishment is confidential.	<p>Section 13, of the Children's Act No 38 of 2005 says that every child has the right to confidentiality regarding their health status.</p> <p>The draft Regulations on Research with Human Subjects, 23 February 2007, state in Regulation 2 that researchers must ensure the protection of the privacy and confidentiality</p>	Every research participant (including a minor) has the right to have their medical information (such as their health status or the health treatment they receive) kept confidential while taking part in a research project.	<p>Researchers and RECs should develop institutional SOPs and policies to ensure the privacy of minor research participants is protected with regard to the storing of information, access to this information and any special measures in respect of minor research participants.</p> <p>Informed consent documents should clearly</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		<p>of participants.</p> <p>Regulation 17 of the Draft 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, state that all genetic medical records and other health information must be treated confidentially and only released with a patient's informed consent.</p>		<p>state how privacy will be protected.</p>
<p>Our law generally links the right to medical confidentiality to the process of consent – that is, the person who consents to a medical intervention is the person who bears the right to confidentiality.</p>	<p>Section 39 of the Child Care Act No 74 of 1983 gives a child of 14 years the right to consent independently to medical treatment.</p> <p>Section 1 of the National Health Act (2003) says that where a user of the health</p>	<p>The Children's Act No 38 of 2005 gives children of 12 years (or those younger than 12 years, who have sufficient understanding) the right to consent independently to an HIV test. Section 133 of the Act gives these same children the right to confidentiality</p>	<p>The laws do not deal specifically with confidentiality within research, and the unusual consent procedures for participation in research (that is, where a parent or guardian consents even on behalf of older children) make direct application of</p>	<p>Researchers and RECs should ensure that the informed consent processes set out a child's right to confidentiality with regard to medical interventions (such as necessary medical treatment) to which he or she consents</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<p>care system is under the age of 14, their parent or legal guardian acts on their behalf and becomes the bearer of the child's right to confidentiality.</p>	<p>regarding their HIV status.</p> <p>Likewise, the Children's Act gives a child of 12 years the right to access contraceptives independently, and the right to confidentiality in this regard (s134).</p>	<p>this principle difficult.</p> <p>However, they would apply to specific medical interventions accessed by a minor while taking part in the research.</p> <p>If a minor is able to consent independently to medical interventions within the research (e.g. currently a person of 14 years would be able to consent independently to medical treatment), he or she would exercise a right to confidentiality with regard to that intervention.</p>	<p>independently, within the research. This right may be exercised by a minor in given circumstances, despite the fact that a parent or guardian consents to the research as a whole.</p> <p>Researchers and RECs should keep up to date with changes in the law, since when the Children's Act comes into operation the age of independent consent will be lowered (see Section 1, above).</p>
<p>In the absence of specific laws interpreting the right to privacy in various contexts, the general principles apply.</p> <p>The general legal principles regarding privacy state that a person has the right to</p>	<p>The general test of privacy has been developed by our courts in various cases, such as <i>Burnstein and Others v Bester and Others NNO</i> (1996) (2) SA 751 (CC) and <i>Directorate for Serious Economic</i></p>	<p>There is no new law or proposed law reform.</p>	<p>Where a minor research participant is capable of forming what society considers to be a reasonable expectation of confidentiality with regard to information revealed during the research process, he or she should</p>	<p>Researchers and RECs should develop SOPs and policies for research with minors that try to establish reasonable boundaries for privacy rights. The boundaries of rights to confidentiality should be detailed in the informed</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
privacy in respect of: <ul style="list-style-type: none"> Information that an individual reasonably expects to be kept private Where the expectation is also regarded by society as reasonable. 	<i>Offences v Hyundai.</i> (2001). (1) SA 545 (CC).		have that right. This is a complex legal analysis that would apply in the case of older research participants with sufficient maturity and understanding. In other instances, a parent or guardian would exercise the right on behalf of the minor.	consent documents.
<p>There are some express limitations on a child's right to privacy.</p> <p>Even where there is no limitation on a right, it can be waived (not used).</p>	<p>Section 16 of the National Health Act No 61 of 2003 says that a user's health records may be used for research purposes if the user's personal particulars are removed.</p> <p>Our law also contains special protections for children who are ill-treated. These protections frequently result in breaches of the right to confidentiality. See Section 3, below.</p>	<p>Section 13 of the Children's Act No 38 of 2005 says that every child is entitled to confidentiality regarding their health status except where this is not in their best interests.</p> <p>Section 133 of the Children's Act also says that no person may disclose a child's HIV status without consent, unless to do so is within the person's powers or duties, it is necessary to do so, or it is required in court</p>	<p>Research involving minors may lawfully limit the right to confidentiality in the specified circumstances.</p> <p>For instance, research on a minor's health records may take place without consent provided that the minor's personal details are removed from the records.</p> <p>Furthermore, where maintaining a minor's right to confidentiality is not 'in the best interests of the child', a disclosure may be lawful. For example, if a</p>	<p>Researchers and RECs should develop SOPs on the process and criteria to be followed in the event that there is a need to consider limiting a minor research participant's right to confidentiality 'in their best interests'.</p> <p>Informed consent documents should specify potential limits to a minor's right to confidentiality, and the processes to be followed in order for a determination to be made in this respect.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		proceedings or by way of a court order.	<p>child is HIV positive and is considered to need the care and support of their family in order to comply with ARV treatment, then it may be considered to be in their best interests to disclose their HIV status to their family.</p> <p>Any person may waive (not exercise a right). A parent in an informed consent document waive their right to information regarding their child's participation in the trial.</p>	

FREQUENTLY ASKED QUESTIONS:

If a parent consents to the enrolment of a minor in research, does the minor still have an independent right to confidentiality (e.g. in relation to private information disclosed during the research)?

A minor may have the right to confidentiality, where this appears reasonable in the circumstances. While this answer seems inadequate, the problem is that our law does not deal specifically with the right to confidentiality with regard to research. Using the general principles in our law, minors have a right to privacy if they can form an expectation of privacy that is regarded as reasonable by society. Generally speaking this would probably mean that older children with sufficient maturity and understanding would be entitled to have information they considered to be private, respected and protected. Even though a parent or guardian may be providing consent to consent to research participation as a whole, a minor may nevertheless

have a right to privacy regarding certain health information within the research. As far as possible, this should be discussed as part of the informed consent process.

Do minors over the age of 14 have the right to confidentiality regarding medical treatment that may be offered as part of the research (e.g. VCT, pregnancy testing, access to terminations of pregnancy and STI treatment)?

Yes. Given that a person of 14 years or older can consent independently to such services independently outside of the research context, it is argued minors above the age of 14 years would have a right to privacy regarding such medical treatment even though it is provided within the broader context of a research relationship. Children of any age also have the legal right to privacy regarding terminations of pregnancy. These rights should be set out in the informed consent process, so that a parent or guardian is also aware of these rights.

Are there any limitations on a child's right to privacy?

Yes. A child's right to privacy is limited by a number of laws. Firstly, section 16 of the National Health Act No 61 of 2003 says that users may give consent for the disclosure of private information (s 14) and that user's records may be used for research purposes if the user's identity is not going to be revealed. This applies to all persons, including minors. Section 13 of the Children's Act No 38 of 2005 says that a child is only entitled to confidentiality regarding their health status where this is in their best interests. There are also other express limitations on a child's right to privacy, such as the mandatory reporting laws discussed in Section 3, below.

Are researchers under an obligation to disclose a child's HIV status?

Researchers are not currently under a legal obligation to disclose a child's HIV status. However, when the Children's Act No 38 of 2005 is implemented, in terms of s13 researchers would have to make such a disclosure if it was in the child's best interests.

SECTION 3: SPECIAL OBLIGATIONS TOWARDS CHILDREN

In this section, we look at the various provisions in our law to ensure that children below the age of 18 years receive adequate care and are protected from exploitation and harm. These provisions often create obligations upon service providers (such as health care workers and social workers) to report instances where children are in need of intervention by the relevant authorities.

Overview of laws that protect children from inadequate support and from harm

Child-care laws contain various provisions to ensure that children receive adequate care such as nutrition, medical care, protection from harm and the care and support of an appropriate caregiver. Where children are in situations that fail to provide them with adequate care, the law makes provision for processes to identify and report such children, in order that they may be assisted to receive the care and support that they need to develop. For example, the Child Care Act No 74 of 1983 requires various persons who care for a child to report any suspicions of ill-treatment or injury that may arise during their care for a child.

Laws to protect people from violence (such as the Prevention of Family Violence Act No 113 of 1993, and the Domestic Violence Act No 116 of 1998) also apply to children. These laws protect children, amongst others, from harm (such as physical or sexual abuse) in various domestic settings. Again, these laws oblige service providers to report suspicions of children who are being ill-treated or harmed.

Finally, all criminal laws (such as the Sexual Offences Act No 23 of 1957) set out acts that are crimes. Certain acts against children (such as sexual intercourse with a person below 16 years of age, and requiring a child to participate in sex work) are considered to be crimes, and service providers would be required to report suspicions of such offences. Additionally, children themselves may participate in crimes (such as shoplifting) – in these instances there is generally no legal obligation on society to report such crimes unless the child is being coerced or compelled to act on behalf of an adult, in such a case it could be considered to be a form of maltreatment and thus an obligation would exist to report the information to the authorities.

Application of the laws to the research setting

Firstly, researchers and RECs need to ensure that research involving children does not result in acts that may be harmful to, or exploitative of children. Of more relevance, however, is the fact that researchers may become aware of situations where children are being ill-treated or abused as a result of the information they receive during a research project. At times, this knowledge may create legal obligations upon researchers to report the circumstances to the relevant authorities. It is important for researchers to be aware of these provisions, so that they may ensure that

- They respond in a lawful and appropriate manner;
- They assist children in need of care and protection; and finally
- They inform children, as well as parents or guardians, of their obligations at the outset, as reporting may result in breaches of confidentiality.

LAW AND IMPLICATIONS:

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
<p>The law protects children from maltreatment, abuse, neglect and degradation; for example:</p> <ul style="list-style-type: none"> • Failure to provide adequate care • Assault • Abandonment • Rape • Abuse 	<p>The Prevention of Family Violence Act No 113 of 1993 protects children from violence within the family.</p> <p>The Domestic Violence Act No 116 of 1998 protects children from various forms of domestic violence (violence taking place within their home) including physical, sexual, emotional, verbal, psychological and economic abuse.</p> <p>The Constitution of the Republic of South Africa Act No 108 of 1996 s28 protects children from maltreatment, abuse, neglect and degradation. It also specifically protects children</p>	<p>The Children's Act No 38 of 2005 s150 sets out circumstances when children are in need of care and protection. This includes where they are abandoned or orphaned, homeless, receiving inadequate care, or are being maltreated, abused, neglected or degraded.</p> <p>The Criminal Law (Sexual Offences) Amendment Bill No 50 of 2003 introduces new offences to protect children from a range of acts relating to sexual abuse and exploitation. There are new offences relating to the sexual exploitation and grooming of children, the</p>	<p>Child research participants are protected from maltreatment, abuse and neglect occurring within the research trial, as well as outside of the trial.</p>	<p>Researchers must ensure that the research interventions do not amount to, or result in maltreatment, abuse and neglect of children. They should also note any reports of maltreatment, neglect or abuse of child research participants outside of the research trial, that come to their attention as a result of the research.</p> <p>Researchers need to keep up to date with changes in the law, so that when the new childcare and sexual offences legislation is passed they are aware of what amounts to offences against children, and</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<p>from exploitative labour practices.</p> <p>The Child Care Act No 74 of 1983 s42 and s50 protects children who have been ill-treated, injured, abandoned or who suffer from a nutritional deficiency disease.</p> <p>The Sexual Offences Act No 23 of 1957 s9 makes it an offence to allow a child to engage in sex work. Section 14 makes 'heterosexual' sex with a child below 16 years of age an offence, and 'homosexual sex' with a person below 19 years of age an offence. However, if the perpetrator is also young (below 21 years) and it's their first offence, it would not be unlawful.</p> <p>Section 52S of the Child Care Act No 74 of 1983 and s43 of the Basic Conditions of</p>	<p>exposure and display of pornography to children and the use of children in pornography. S14 sets the age of consent to sexual activity at 16 for boys and girls and criminalizes consensual sex with a child below the age of 16 years.</p> <p>The Bill also protects children who engage in consensual sex with other children from criminal prosecution by:</p> <ul style="list-style-type: none"> • Requiring the written permission of the National Director of Public Prosecutions for bringing a charge where consensual sex between children takes place • Requiring prosecution to be instituted against both parties in this case • Allowing a defence to the charge if both parties were children at the time 		<p>maltreatment of children.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	Employment Act No 75 of 1997 prohibit the employment of children below 15 years of age, as well as the employment of children in situations that jeopardize their well being.	of the offence and there was not more than a 2 year age gap between them.		
The law creates mechanisms for minors and others (including health service providers) to remedy instances of maltreatment, abuse, neglect and degradation.	Section 4(3) of the Domestic Violence Act allows the complainant to apply for a protection order against domestic violence. If the complainant is a minor, they can apply without the assistance of a parent or guardian. Also, any person with a material interest in the well being of the complainant (such as a counsellor or health service provider) can apply for a protection order on behalf of a minor, without the minor's consent.		A researcher may apply for a protection order, without the consent of a minor research participant, if the minor is being subjected to domestic violence.	<p>Researchers should familiarise themselves with the definition of domestic violence, and take note of domestic violence against minor research participants.</p> <p>Researchers should ensure that the informed consent process discloses the possibility of a protection order being applied for without a minor's consent, if instances of domestic violence are revealed.</p>
At times, the law creates legal obligations upon various persons (including health care	The Prevention of Family Violence Act s4 requires any person caring for a child who suspects that the child is	The Children's Amendment Bill B19 of 2006 s105 obliges people caring for children (including nurses, doctors,	A researcher who learns that a child research participant is being maltreated is under an	Researchers should familiarize themselves with obligations in order to ensure they comply with

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
<p>providers) to report instances of maltreatment, abuse, neglect and degradation against children</p>	<p>being ill-treated or deliberately injured to report this to police officer, commissioner for child welfare or social worker.</p> <p>The Child Care Act s42 (1) requires any person (such as a nurse, medical practitioner and social worker) attending to a child, who suspects the child is being maltreated, to report this to a designated officer. Section 42(2) states that this may result in the removal of the child to a place of safety or hospital. Section 42(5) makes failure to report an offence.</p>	<p>social workers) to report instances of abuse and neglect of children to the relevant authorities.</p> <p>The Criminal Law (Sexual Offences) Amendment Bill No 50 of 2003 s54 requires any person with knowledge of a sexual offence against a child to report this to the police.</p>	<p>obligation to report the practices, despite the confidential nature of the research relationship.</p>	<p>obligations, despite the fact that their actions may result in the child's removal and probable termination of participation in the research trial.</p> <p>Researchers should disclose their obligations to report at the outset of the trial, since such obligations may result in breaches of confidentiality.</p>
<p>Certain acts are defined by our law as crimes, and are punishable offences, even when carried out by minors.</p>	<p>The Sexual Offences Act No 23 of 1957 s 20 makes it an offence for any person (including a child) to live off the earnings of prostitution.</p> <p>The Drugs and Drug</p>	<p>The Criminal Law (Sexual Offences) Amendment Bill No 50 of 2003 criminalises rape, (unlawful sexual penetration without consent), as well as sexual assault and violation.</p>	<p>Generally, researchers are not under a legal obligation to report knowledge of a crime committed by a child. However they may be under ethical obligations</p>	<p>Researchers should disclose their ethical obligations to protect child research participants at the outset of the trial, since children and their parents should be aware if referrals</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<p>Trafficking Act, No 140 of 1992, s4 makes it an offence to use or have in their possession any dependence producing substance. Section 5 also states that it is an offence to deal in drugs. Section 10 places an obligation on the owner; occupier or manager of any place of entertainment to report to the police any suspicion that they have that someone is using or dealing in drugs.</p> <p>The South African Schools Act No. 84 of 1996 says in s3 that every learner between the ages of 7 and 15 must attend school. An obligation is placed on their parents to ensure that this obligation is fulfilled.</p>		<p>to assist children in need of care, for example, children who are abusing substances may need to be referred to appropriate social services.</p> <p>Although researchers do not have to report children who are playing truant from school they nevertheless should ensure that research takes place out of school hours. It would be against public policy for parents to consent to research which will require their children to miss school, if they are under the age of 15.</p>	<p>are going to be made to social services for problems such as drug dependency.</p> <p>RECs should ensure that protocols involving school going children will be conducted in such a way that they do not interfere with their schooling.</p>

FREQUENTLY ASKED QUESTIONS:

During research, if a child discloses details of a sexual offence (for example, rape, sexual assault, under-age sex with a partner above 21 years of age, being required to participate in sex work), what are the researchers legal obligations?

A researcher is obliged to report sexual offences against children. Laws relating to children and to sexual offences require people caring for children to report ill-treatment and abuse of children – this would include sexual offences against children. A researcher (or even a person providing a research intervention, such as a counsellor) would be required to report suspicions (or actual reports) of a sexual offence against a child research participant in his or her care.

Sexual offences include:

- Rape
- Indecent Assault
- 'Heterosexual' sex with a child below the age of 16 years (notwithstanding the consent of the minor)
- 'Homosexual' sex with a child below the age of 19 years (notwithstanding the consent of the minor)
- Being required to take part in sex work

In the case where minors are engaged in 'consensual sex', the law does provide measures to protect children from being charged with a crime. For example, the Sexual Offences Act No 23 of 1957 says that sexual intercourse with a person below the stipulated age limit, where the sexual partner is also a minor (below the age of 21 years), would generally not be considered to be an offence, unless the sexual partner had been charged with this crime previously. The proposed Criminal Law (Sexual Offences) Amendment Bill No 50 of 2003 seeks to increase this protection in cases of consensual sexual activity between children, by protecting children from prosecution where there is no more than 2 years age gap between them, as well as requiring any charges that are brought against children to be brought against both parties, and only with the written consent of the National Director of Public Prosecutions.

What does this mean for research on the sexual activities of minors?

Since consensual sexual activity with minors (and in certain circumstances between minors) may be a criminal offence, it may be very difficult to gain ethical approval and/or obtain consent for research regarding sexual activity in minors below the age of 16 years (or 19 years, in the case of 'homosexual' sexual activity). This position will improve when the new Criminal Law (Sexual Offences) Amendment Bill No 50 of 2003 comes into operation, since consensual sexual activity between minors will, in many circumstances, not be criminalized or prosecuted. Researchers and RECs should look out for information regarding the Bill becoming law, particularly since Parliament has recently shown renewed commitment to finalizing the Bill.

Due to the fact that confidentiality is an integral right of a research participant, it is important that a researcher disclose his or her obligations to report certain acts against a child at the outset, despite the fact that the disclosures may dissuade some children from participating in the research.

During research, if a child discloses that they are being maltreated, neglected or somehow exploited, what are a researcher's legal obligations?

As set out above, a researcher has a legal obligation to report ill-treatment of children. This would include an obligation to report physical abuse against children, neglect of children (such as failure to provide adequate care for the child's needs) as well as exploitation of children (such as child labour).

During research, if a minor discloses that they have, or will commit an offence (e.g. abusing substances, committing theft, committing a sexual offence) what are a researcher's legal obligations?

A researcher is under no general legal obligation to report information regarding criminal offences. However, a researcher may feel that he or she is under an ethical obligation to report certain conduct (e.g. substance abuse), where this would be in the best interests of the child. Additionally, where a child is being exploited and required to commit an offence (e.g. sex work), this would amount to ill-treatment, in which case a researcher would be obliged to report this ill-treatment.

SECTION 4: PROCEDURAL REQUIREMENTS FOR APPROVAL FOR RESEARCH WITH LEGAL MINORS

Our ethical-legal framework, as established by the National Health Act No. 61 of 2003 and the Medicines and Related Substances Act No 101 of 1965, places a number of procedural obligations on health researchers. *All health research* must obtain ethical approval. If the research is classified as a clinical trial there are also a number of additional obligations that must be met such as obtaining the authorization of the Medicines Control Council.

There is only one special procedural obligation that relates to research with minors, found in section 71(3) of the National Health Act. The provision requires obtaining ministerial consent for all non-therapeutic health research with minors, and sets criteria for consideration before ministerial consent may be provided. This particular provision is not in operation yet, but it is envisaged that it will become operational in the near future, once regulations are approved. The relevant regulations are presently in draft form.

LAW AND IMPLICATIONS:

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
All health research must be approved by a Research Ethics Committee (REC).	<p>Section 73(2)(b) of the National Health Act No 61 of 2003 says that RECs must grant approval for health research.</p> <p>Section 1 of the Act defines health research as any research which contributes to knowledge of</p> <ul style="list-style-type: none"> Biological, clinical, psychological or social processes in human beings; 	There is no new law or proposed law reform.	All research on minors that falls within the definition <i>health research</i> must obtain ethical approval.	Researchers and RECs must be aware of the definition of health research and ensure that they are aware of when ethical approval is required for research protocols.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<ul style="list-style-type: none"> • Improved methods for the provision of health care services; • Human pathology, • The cause of disease; • The effects of the environment on the human body; • The development or new application of pharmaceuticals, medicines and related substances; and • The development of new applications of human technology. 			
<p>Health research must be reviewed by a registered, accredited and independent REC.</p>	<p>Section 73(1) of the National Health Act No 61 of 2003 says that every institution, health agency and health establishment at which health research is conducted, must establish or have access to an REC.</p> <p>Section 72(6)(b) of the National Health Act states that the</p>	<p>Regulation 2 of the draft Regulations Relating to Research on Human Subjects, 23 February 2007, state that all health research must be reviewed by an independent, accredited REC.</p>	<p>Research protocols for health research on minors must be reviewed by an approved REC.</p>	<p>Researchers undertaking health research must set up, or have access to, an REC which is registered with the NHREC.</p> <p>The Council has not yet started the process of registering RECs. So, RECs are advised to keep up to date with information on this process. The Department of Health website at</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	National Health Research Ethics Council (NHREC) must register and audit RECs.			www.doh.gov.za may provide assistance.
RECs may only grant ethical approval for health research if the protocol is relevant and meets their ethical standards.	<p>Section 73(2) of the National Health Act No 61 of 2003 requires RECs to review research to ensure that it 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.</p> <p>Section 73(2) also says that RECs must grant approval for research that meets the ethical standards of the REC.</p>		<p>Health research on minors must be relevant and in line with the ethical standards established by the NHREC, entitled <i>Ethics in Health Research: Principles, Structures and Processes</i>, 2005.</p> <p>In particular, the national guidelines require that minors should participate in research only when</p> <ul style="list-style-type: none"> • Their participation is indispensable to the research • Their participation is 	Researchers and RECs should familiarize themselves with the national ethical guidelines to ensure that health research on minors meets the minimum requirements.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
			<p>not contrary to their best interests</p> <ul style="list-style-type: none"> • The research proposes to investigate a problem of relevance to children • Risk standards set out in the guidelines are met; and • Minimum conditions relating to informed consent have been met. 	
<p>Clinical trials must be approved by the Medicines Control Council (MCC)</p>	<p>The Minister of Health in consultation with the MCC has issued the General Regulations made in terms of the Medicines and Related Substances Act, 10 April 2003. Regulation 34(1)–(2) sets a standardized</p>	<p>Regulation 3 of the draft Regulations Relating to Research on Human Subjects, 23 February 2007, says that researchers are obliged to submit their research proposals to an REC and when necessary</p>	<p>Any research on minors that is classified as a clinical trial must obtain the approval of the MCC.</p>	<p>Researchers and RECs should familiarize themselves with the requirements for approval of a clinical trial by the MCC.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	<p>process for all researchers to apply for authorization for a clinical trial. The procedure includes, amongst other things, a declaration by researchers that they will comply with the Good Clinical Practice Guidelines, provide a copy of the informed consent documents to be used during the trial and submit a copy of approval of the protocol by a recognised ethics committee.</p>	<p>to the MCC.</p>	<p>A clinical trial is a research study designed to answer specific questions about vaccines and new therapies or new ways of using known treatments. The trials determine whether the interventions are both safe and effective.</p>	
<p>Clinical trials must be conducted in accordance with the provisions in the Good Clinical Practice Guidelines</p>	<p>The Good Clinical Practice Guidelines, 2000 issued by the Department of Health set maximum risk standards for research with minors, and describe the consent requirements for such research.</p>	<p>The GCP guidelines are currently being reviewed and updated. It is unclear when the new guidelines will be released.</p>	<p>Clinical trials involving minors are required to meet the standards set out in the Good Clinical Practice Guidelines.</p>	<p>Researchers must comply with the Good Clinical Practice Guidelines issued by the Department of Health. Non-compliance is an offence, in terms of Regulation 42 of the Guidelines.</p> <p>Researchers should develop SOPs to assist with the classification of research into the various risk categories set out in the guidelines.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
<p>Clinical trials must be registered with the South African National Clinical Trials Register.</p>	<p>In November 2005 the Department of Health issued a notice that as from the 1st December 2005 all new clinical trials to be conducted in the country must be registered in the South African National Clinical Trials Register. The notice also explained that trials that started recruiting as of 1st July 2005 must also be registered.</p>	<p>The Draft Regulations Relating to Research on Human Subjects, 23 February 2007 state in Regulation 2(i) that all clinical research must be registered with the South African National Clinical Trials Register.</p>	<p>Clinical trials involving minors must be registered with the SANCTR.</p>	<p>Researchers must ensure that they are familiar with the requirements for registration of a clinical trial. For more information in this regard, researchers may consult www.sanctr.gov.za</p>
<p>If the medical product being researched can be classified as a genetically modified organism (GMO), approval for the research must be obtained from the Department of Agriculture.</p>	<p>Section 5 of the Genetically Modified Organisms Act No. 15 of 1997 provides that the Executive Council for Genetically Modified Organisms may require an applicant to apply for a permit to use a genetically modified organism.</p> <p>A GMO is defined in section 1 of the Act as being an organism, the genes or genetic material of which has been</p>	<p>. There is no new law or proposed law reform.</p>	<p>Clinical trials on minors using a genetically modified organism must be approved by the Department of Agriculture.</p>	<p>Researchers must familiarize themselves with the process of obtaining approval from the Department of Agriculture, where research includes a GMO.</p> <p>Researchers should develop institutional SOPs to determine when new medical products will be considered to be GMOs.</p>

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
	modified in a way that does not occur naturally through mating or natural recombination or both.			
Non-therapeutic health research with minors must obtain the consent of the Minister of Health.	There is no current legal obligation to get authorization for non-therapeutic health research with minors, other than meeting existing requirements regarding obtaining ethical approval and authorization of the MCC, in the case of a clinical trial.	Section 71(3) of the National Health Act No. 61 of 2003 states that where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted if various conditions are met, including that the research is in accordance with the regulations, and the consent of the Minister of Health is obtained. The Minister may not give consent if: <ul style="list-style-type: none"> • The objects of the research or experimentation can also be achieved if it is conducted on an adult; • The research or experimentation is not likely to significantly improve scientific 	Ministerial consent will be required for all forms of non-therapeutic health research with minors. Current law defines minors as persons below 21 years of age, but in future this will be lowered to 18 years of age.	Researchers and RECs must keep up to date with the progress of the National Health Act, since once the regulations are finalized this section may come into operation. At that time, all non-therapeutic health research involving minors will require ministerial approval.

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		<p>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;</p> <ul style="list-style-type: none"> • 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; • The research or experimentation poses a significant risk to the health of the minor; or 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. <p>The Draft Regulations relating to Research on Human Subjects, 23 February 2007, do not give further information on</p>		

LEGAL PRINCIPLE	SOURCES OF LAW: CURRENT	SOURCES OF LAW: FUTURE	IMPLICATIONS FOR RESEARCH	ACTIONS
		how ministerial consent will be obtained.		

FREQUENTLY ASKED QUESTIONS:

The following are common FAQs relating to the procedural requirements for approving health research with minors:

Must student health research projects with human subjects obtain ethical approval?

Yes. Any health research with human subjects will be governed by the National Health Act No 61 of 2003.

What is the risk standard for research with children described in the GCP guidelines?

Clinical trials should not be approved unless the research:

- Does not place the child at no greater than minimal risk
- Involves more than minimal risk but provides direct benefit for the child
- Involves greater than minimal risk, with no prospect of direct benefit to the child, but with a high probability of providing 'generalisable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition'; in addition the risks must represent only a minor increase over minimal risk and the intervention or procedure 'presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or education settings'

What is the risk standard for research with children described in the NHREC guidelines?

The NHREC guidelines state that research involving a child should be approved only if the research, including observational research, places the child at:

- No more than minimal risk (that is, the risk commensurate with daily life or routine medical or psychological examinations – referred to as ‘negligible risk’ in some guidelines)
- More than minimal risk but provides possible benefit for the child participant (the degree of risk must be justified by the potential benefit).
- More than minimal risk, with no prospect of direct benefit to the child participant, but with a high probability of providing significantly generalisable knowledge (the degree of risk must be justified by the risk-knowledge ratio). The risks must represent no more than a minor increase over minimal risk.

When is ministerial consent required for health research?

Ministerial consent for health research is required when:

- The research falls into the definition of health research
- The research involves minors, and
- The research is classified as non-therapeutic research.

At present a minor is a person below 21 years of age. Given the evolving capacity of adolescents, Parliament has elected, in the Children’s Act No 38 of 2005, to lower the age of majority from 21 to 18 years of age. Thus in future at the end of childhood young persons will become full legal majors. Once the Act comes into operation, ministerial consent will only be required for non-therapeutic health research on persons below the age of 18 years.

The National Health Act No 61 of 2003 defines health research as “any research which contributes to knowledge of biological, clinical, psychological or social processes in human beings; improved methods for the provision, of health care services; human pathology, the cause of disease, the effects of the environment on the human body, the development or new application of pharmaceuticals, medicines and related substances, and the development of new applications of human technology”. Any research falling within this definition will be considered health research and will fall within the scope of the Act.

The term “non-therapeutic” research is not defined in the National Health Act. The draft Regulations relating to Research on Human Subjects, 23 February 2007 define it as “any research not directed towards the benefit of individual but rather towards improving scientific knowledge or technical application.”

What are the criteria the Minister of Health must take into account when approving non-therapeutic research with minors?

The Act requires four conditions to exist before ministerial consent may be granted for non-therapeutic research with minors.

Children must be indispensable to the research

Research will only be approved by the Minister if it can be shown that the participation of minors is indispensable for the research. This 'scientific necessity' requirement is not new with regard to minors, and it is contained in our national ethical guidelines. However the guidelines limit this principle to 'children' (below 18 years) and not to 'minors' (currently below 21 years) as is provided for in the Act. This means that researchers would have to demonstrate the scientific necessity of involving persons under the age of 21, once the National Health Act comes into operation. This requirement generally means that the research question could not be answered by the involvement of less vulnerable persons like adults.

The research will result in significant improvement in the understanding of the minor's condition or disorder

This again requires the scientific merits of the research to be demonstrated. Furthermore minors must benefit as a class through the generation of new knowledge. 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, or a set of physical, psychological, neurodevelopmental, or social characteristics that has been shown to affect the health, well-being or risk of future health problems for minors.

Consent to the research will not be contrary to public policy

This is a codification of a common law requirement that consent to any act must be in accordance with public policy in order to be lawful. This requires consent to the harm or risk of harm to be in line with prevailing legal norms. In determining whether something is permitted by the legal order, courts examine prevailing legal norms within the area of the law, including those established by the Constitution to assess the acceptability of the consent. For the involvement of minors in research, the courts would probably examine the legal norms underlying child-care and research-related legislation, in order to determine 'public policy' in this regard. They would probably take into account factors such as:

- the Act's permitting of non-therapeutic research with minors;
- the understanding of parental responsibilities in the Children's Act (e.g. although parents have legal responsibilities to care for and protect their children, they do not have unlimited discretion in decision-making affecting children)
- the focus on promoting child well-being and protecting children from discrimination, exploitation and any other physical, emotional or moral harm in all laws relating to children.

Arguably, research would be in accordance with public policy if it presents *acceptable standards of risk* outlined in law and in ethical guidelines. The National Health Act No 61 of 2003 sets a standard of acceptable risk by stating that the research must not pose a significant risk to the health of the minor. Acceptable standards of risk can also be found in national ethical guidelines.

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 Act sets a clear standard of risk for “non-therapeutic” research by stating that the Minister may not approve research that holds the possibility of significant risk, unless the risks are outweighed by the benefits.

What does the term “significant risk” mean, and who does it apply to?

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. Significant risk may represent more than a minor increase over minimal risk. The term only applies to the process of ministerial consent for non-therapeutic health research with minors.