



How well does South Africa's National Health Act regulate research involving children?

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Currently there are no laws in South Africa regulating the rights of research participants. The National Health Act is the first attempt by the legislature to use the law to protect research participants, including children. This article describes the strengths and limitations of the provisions, implications for researchers and research ethics committees, and makes recommendations.

Strengths of the Section include that it enables the Minister of Health to issue regulations detailing protections for research participants, it supplements existing law on consent, it introduces the concept of the 'best interests' of the child and it creates procedural safeguards.

Limitations of the Section include that it does not set an independent age for consent to research, it focuses on informed consent and not other protections, it is inconsistent with existing or draft legislation and ethical guidelines, and it

retains the contested distinction between 'therapeutic' and 'non-therapeutic' research. Poor drafting and inconsistencies also impede interpretation.

The implications for researchers are that it facilitates so-called 'non-therapeutic' research on children. However, procedural burdens for obtaining consent are created. Research Ethics Committees (RECs) will have to work with the 'therapeutic' and 'non-therapeutic' distinction as well as new concepts such as 'best interests' of the child, and ensure that consent procedures comply with the Act.

We conclude that while the Act is an important development in the law, it is flawed in places. We recommend that amendments be made and that capacity development be provided to stakeholders.

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Health research involving child participants is essential to develop appropriate interventions promoting their welfare. Preventive research is of increasing importance, including the development of childhood vaccines against HIV.¹ Currently in South Africa there are no laws regulating the rights of research participants in research. Research ethics committees (RECs) generally rely on ethical guidelines and to some extent constitutional and common law. The National Health Act² (hereafter referred to as 'the Bill'), which has been passed and is soon to be implemented, is the first attempt by the legislature to use the law to regulate the rights of research participants, including children.

The South African National Health Act, Section 71

Section 71 of the Act comprises three parts. Section 71(1) contains general provisions regulating consent of all research

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participants. It states that research or experimentation on a living person may only be conducted in accordance with regulations issued by the Minister of Health, with the written consent of the person and provided that s/he has been advised of the objectives of the research and any possible negative or positive health consequences.

Sections 71(2) and (3) contain additional provisions for research involving minors. The sections state the following.

Section 71(2): Where research or experimentation is to be conducted on a minor for therapeutic purposes, the research or experimentation may only be conducted: (i) if it is in the best interests of the minor; (ii) in such manner and on such conditions as may be prescribed; (iii) with the consent of the parent or guardian of the child; and (iv) if the minor is capable of understanding, with the consent of the minor.

Section 71(3)(a): Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted: (i) in such manner and on such conditions as may be prescribed; (ii) with the consent of the Minister; (iii) with the consent of the parent or guardian of the minor; and (iv) if the minor is capable of understanding, with the consent of the minor.

Section 71(3)(b): The Minister may not give consent in circumstances where: (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult; (ii) the reasons for the consent to the research or experimentation are not likely to improve scientific understanding of the minor's condition, disease or disorder



significantly to such an extent that it will result in significant benefit to the minor or other minors; (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy; and (iv) the research or experimentation poses a significant risk to the health of the minor, or there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

Strengths of Section 71 of the National Health Act

Section 71 may appropriately strengthen protections for research participants in the following ways.

1. It establishes a platform for developing a wide range of legal norms for human subjects research. Section 71(1) empowers the Minister of Health to issue regulations containing procedural and substantive safeguards for research participants. For example, detailed provisions for ensuring voluntary and informed consent could be developed in the regulations, including the extent to which researchers should inform participants of risks and benefits, and procedures for assessing understanding, and recording participant decisions.

2. It supplements and strengthens the existing general legal principles relating to informed consent. Currently, for example, common law personality rights, such as the right to physical integrity, protect a person from being medically treated without consent.³ However, there are no statutory laws or precedents dealing explicitly with consent to medical research.⁴ Section 71(1) requires written consent for research and also gives guidance regarding who should consent for child participation.

3. Section 71(2) introduces the concept of the 'best interests' of the child when research for a 'therapeutic purpose' is being considered. This principle, although undefined, is well established in South African divorce jurisprudence^{5,6} and is considered of paramount importance in all matters concerning the child as reflected in Section 28(2) of our Constitution. South African courts have generally held that this means a wide range of factors must be considered to promote a child's physical, moral, emotional and spiritual welfare.⁵ Section 6 of the draft South African Children's Bill⁷ sets out factors for a best interests analysis. These include among others, the child's age, needs, gender, background, maturity and stage of development; physical and emotional security; intellectual, emotional, socio-cultural development; and the need to protect the child from physical and psychological harm. A further significant factor is the view or opinion of the child.⁵ These factors may be equally useful to guide decision-making regarding child research participation.

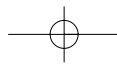
4. Section 71(3)(a)(ii) creates an additional procedural safeguard for children participating in research with 'a non-

therapeutic purpose' by providing that the Minister of Health must consent to the conduct of such research. The Minister of Health's discretion to approve such research is limited by four factors set out in section 71(3)(b)(i) - (iv). These factors include protectionist principles, a risk-benefit analysis, public policy, and a risk standard. The term public policy means that the research should not be contrary to the values that underlie the constitution such as dignity and the promotion of human rights.⁸ The presence of these principles is consistent with the Constitutional Court's⁹ finding that legislation according discretionary powers to public officials should be drafted so as to limit the risk of unconstitutional exercise of those powers.

Limitations of the National Health Act, Section 71

Section 71 of the Act is limited in the following ways:

1. It does not set an age for independent consent to medical research.
2. It focuses on informed consent as the primary protection for trial participants, omitting other protections such as right to dignity, risk-benefit analyses and confidentiality.
3. It may be inconsistent with existing and proposed legislation on consent, e.g.:
 - Section 71(2) requires consent from both the parent/guardian and the child, regardless of age, for therapeutic research. It does not distinguish between minors over and under the age of 14 years.¹⁰ Such distinctions are maintained in other legislation, such as Section 39 of the Child Care Act (and in the draft Children's Bill — the Department of Social Development intends to repeal the existing Child Care Act and replace it with the Children's Bill), which allow a child of 14 years to consent independently to 'medical treatment'. Some scholars argue that by implication, children may be able to give independent consent to take part in research defined as 'therapeutic'.⁴ This section of the Act may, of course, be interpreted as requiring the consent of the minor and the assent of the parents (P Carstens — personal communication, 8 November 2003).
 - Section 71(2) allows for children to consent to research participation only if they are 'capable of understanding'. This is inconsistent with Section 43 of the Children's Bill, which provides that any major decisions involving a child must give due consideration to any views and wishes expressed by the child, bearing in mind the child's age, maturity and stage of development. In other words in terms of the Children's Bill a child's views must be considered even if s/he is not fully capable of understanding the research.
 - Sections 71(2) and (3) state that consent must be provided by 'the parent or guardian' of the minor. According to the current Child Care Act and Criminal Procedure Act, a



person who has been given custody of a child may consent to medical treatment or an operation, instead of the parent or guardian, unless the procedure poses a danger to life.¹¹ According to Section 129(2)(b)(ii) of the proposed Children's Bill, the primary caregiver may consent to any medical treatment or operations where the child is under the age of 12 years, or incapable of understanding the treatment or operation. In the face of inconsistencies between the Act and the Children's Bill it is unclear which will prevail as both provide that in the event of a conflict they will override other law.

- The Act may be inconsistent with existing national ethical guidelines, e.g. the Act's risk standard for 'non-therapeutic' research is that of not 'significant' whereas the Medical Research Council guidelines¹² risk standard for 'non-therapeutic' research is 'negligible' — a risk so small it may be ignored.

4. The Act retains the controversial distinction between therapeutic and non-therapeutic research that has been abandoned by many ethical guidelines, e.g. the Council of the International Organisations of Medical Sciences (CIOMS) and national law.¹³ This classification is problematic as most research involves some interventions that are not intended to confer direct health-related benefit (e.g. randomisation to placebo). Furthermore, the Act does not define these terms.

5. The Act does not describe the process for obtaining the consent of the Minister for non-therapeutic research. Presumably this will be detailed in regulations. It has been submitted that the Minister may delegate this power to any person acting in terms of the Act.¹⁰

6. Poor drafting and inconsistencies impede interpretation of the section. For example: (i) Section 71(2) requires that a child's 'best interests' be considered when approving therapeutic research, yet no such obligation is created for non-therapeutic research; (ii) while a risk standard is described for non-therapeutic research (Section 71(3)(a)(iv)), no risk standard is described for therapeutic research; (iii) Section 71(3)(b)(ii) implies that non-therapeutic research involves minors with an existing medical condition, making it difficult to classify research with healthy minors that may not confer direct health-related benefit (such as phase I trials); and (iv) the terms 'minor' and 'child' are used interchangeably, when in fact existing law considers minors to be persons below the age of 21 years, and children to be below the age of 18 years.^{14,15}

Implications for researchers

Section 71 will have various implications for researchers, including the following:

1. It provides a specific legal basis for the participation of minors in research including so-called non-therapeutic research, unlike certain current ethical guidelines that restrict

non-therapeutic research on minors to observational research of negligible risk.¹²

2. Research that is classified as either therapeutic or non-therapeutic research will require additional procedures.

- In the case of research classified as therapeutic, researchers may not be able to obtain independent consent from children 14 years and older, but will also need parental consent or assent. This means researchers will be faced with the logistical and practical problems of securing consent where parents or legal guardians are deceased or absent (for example, child-headed households).
- In the case of non-therapeutic research, researchers are obliged to obtain authorisation from the Minister before proceeding. This may be a cumbersome and bureaucratic process.
- In obtaining consent from children, researchers will have to identify children's ability to understand the consent process. Assessing understanding is a complex issue.¹⁶

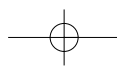
Implications for RECs

Sections 71(2) and (3) will create various obligations for RECs assessing and approving research protocols involving children, including the following.

1. RECs will have to categorise research protocols involving minors as therapeutic or non-therapeutic despite some conceptual problems and lack of definition. They will have to be aware of the temptation of researchers to classify their research as therapeutic as the standard for such research is more relaxed.
2. RECs will need to ensure that consent procedures in all protocols include mechanisms to involve parents and guardians.
3. RECs will also have to ensure that protocols stipulate how it will be determined whether children have sufficient understanding to consent jointly with their parents or guardians to the research.
4. Finally, RECs will need to develop an understanding of the new concepts such as the 'best interests' of the child, and public policy considerations.

Conclusions and recommendations

The Act is an important attempt to develop legal norms and standards regarding the participation of children in research. It fills a legal vacuum that has bedevilled children's law. However in many respects the Act fails to meet its objectives, in part because of poor drafting and a failure to link with existing legal principles and processes. Its ability to protect children and guide researchers and RECs may depend largely on the content of the regulations to be enacted in terms of the Act.





ORIGINAL ARTICLES

It is recommended that: (i) Section 71 of the National Health Act should be amended to be more consistent with the prevailing legislation; (ii) poor drafting and inconsistencies in the Section should be corrected; (iii) the ideal placement of the provisions should be reconsidered to determine whether they are best placed within health or children's legislation; (iv) regulations should provide details for substantive and procedural safeguards to protect the rights of trial participants such as definitions for 'therapeutic' and 'non-therapeutic' research, factors to consider in determining the best interests of the child, the extent of information to be provided to trial participants, how to assess a child's understanding of research, and how to ensure that consent is voluntary and informed; and (v) capacity development should be provided to key stakeholders (RECs, researchers and community advisory boards) on the implications of the Act, including how to use unfamiliar concepts such as the 'best interests of the child' standard.

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