

# Consent to research by mentally ill children and adolescents: The implications of Chapter 9 of the National Health Act

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Chapter 9 of the National Health Act came into effect in March 2012. In this article, the Act's statutory requirements relating to the informed consent to participation in clinical research by mentally ill children and adolescents in South Africa are examined. The necessity of doing clinical research in mentally ill children and adolescents is canvassed briefly and the requirements that chapter 9 sets out for lawful child and adolescent consent to research participation are presented. Furthermore, the limitations of the newly enacted legislation is deliberated upon and selective improvements are proposed.

Because of the likely erosion of the minor's privacy, the requirement that a parent or legal guardian must consent to children's and adolescents' participation in research has the potential to obstruct much-needed mental health research. This requirement is likely to be found unconstitutional. In certain circumstances, ethics committees tasked with the review of research should be allowed to dispense with parental consent, and adolescents recognised as having the necessary capacity to consent independently to research participation. Furthermore, the Act's classification of research into therapeutic and non-therapeutic categories is considered problematic. It is recommended that research permissible in minors be stated in terms of well-defined risk standards.

Finally, the requirement set in subsection 71(3) for ministerial consent in the case of non-therapeutic research in children and adolescents is found to be overly protectionist, as it precludes the capacity of ethics committees to judge the ethics of the proposed research.

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Children and adolescents experience a variety of psychiatric disturbances, including post-traumatic stress disorders, phobias, obsessive-compulsive disorders, depression, various developmental disorders, eating disorders, and psychotic disorders, as well as intellectual disability.<sup>[1]</sup> In a previous contribution, I commented that mentally ill adults are regarded as vulnerable to exploitation in research because there is the potential for their illness to compromise their judgment, reducing their ability to give fully informed consent to research participation.<sup>[2]</sup> Mentally ill children and adolescents are still more vulnerable due to their physical and developmental immaturity.

Codes of research ethics, such as the Declaration of Helsinki,<sup>[3]</sup> alert researchers to the potential for abuse in these research populations. For example, principle 9 of the Declaration of Helsinki emphasises that vulnerable populations need special protection, and principle 17 requires that health research in vulnerable populations be responsive to their health needs.

Glantz<sup>[4]</sup> gives some reasons why mentally ill children and adolescents should be regarded as vulnerable in a research setting. Firstly, because of their psychiatric disorder and youth, they may not be competent

to volunteer to participate in a research project, and therefore will be participating either involuntarily or non-voluntarily. Secondly, the person providing proxy consent on their behalf may have various motives and, therefore, may not primarily be concerned with acting in the best interests of the child or adolescent (for example, parents and family who are overwhelmed by the physical and psychological burden of the child's or adolescent's illness). Thirdly, institutionalised mentally ill children and adolescents are removed from the 'ideal' protective parent. Finally, history indicates that mentally ill children and adolescents have been abused and exploited as research participants.<sup>[5,6]</sup>

Despite these potential pitfalls it is imperative that clinical research is conducted on children and adolescents in order to identify the pathogenesis of their mental illness, to develop effective treatment as well as preventive interventions, and, ultimately, to reduce the effect of mental illness on these children, their families, and the broader community.<sup>[7]</sup> It can even be asserted that there is an ethical duty on responsible healthcare professionals to conduct ethically sound research in mentally ill persons – children and adults – so as to alleviate their burden of disease (as part of the ethical duty of care or the ethical principle of beneficence).

This article examines the statutory requirements relating to the consent of mentally ill children and adolescents to participation in clinical research in South Africa, in light of chapter 9 of the National Health Act which came into operation on 1 March 2012.<sup>[8]</sup> It begins by summarising the legal context regarding consent in which the newly operational provisions of the National Health Act function. This section is followed by a critical examination of the changes in the legal requirements for children's and adolescents' lawful consent to participation in mental health research in terms of subsections 71(2) and 71(3) of the National Health Act.<sup>[2]</sup> Finally, the article suggests some tentative solutions to the problems arising from the provisions of the Act.

The article has a specific focus: the law on informed consent to participation in clinical research by **mentally ill children and adolescents**. Therefore, the emphasis is on the law as it pertains to **clinical research** and not to standard medical interventions or treatment.

The assessment of a mentally ill child's or adolescent's capacity to consent to research calls primarily for a clinical rather than a juridical judgment, and should be performed in terms of the existing laws and ethical guidelines on a case-by-case basis by the healthcare professional. The article highlights the statutory requirements for legally valid consent, as laid down by the newly operational provisions.<sup>[9-11]</sup>

### General legal context

Informed consent is a primary precondition for legal and ethical clinical research, and is regarded as the 'cardinal principle for judging the propriety of research with human beings.'<sup>[12]</sup> Informed consent is based on the recognition that all persons have unconditional worth, on the basis of the ethical principle of respect for personal autonomy.<sup>[13]</sup> The qualification of unconditional worth implies that those unable, or potentially unable, to make autonomous decisions should be protected, such as the very young, the mentally ill and others.<sup>[14]</sup>

Previously, no specific South African legislation dealt with informed consent in a research setting. Instead, general legal requirements for consent to medical intervention were extrapolated to the research setting.<sup>[15-17]</sup> Chapter 9 changes this, as it requires that participants in clinical research have to consent to research participation: consent to participation is now a statutory imperative. Chapter 9's provisions were enacted to give substance to the directive in section 12(2)(c) of the Constitution, 1996, which states that: '[e]veryone has the right to bodily and psychological integrity, which includes the right ... not to be subjected to medical or scientific experiments without their informed consent.'

Chapter 9 does not specifically address consent to research participation by mentally ill children and adolescents, but the general rules regarding children's consent to research participation are applied in the context of research on mentally ill children and adolescents. Similarly, it should be noted that despite its focus on the mentally ill, the Mental Health Care Act<sup>[18]</sup> does not deal with consent to research interventions. The Act contains no definition

of what 'mental healthcare' encompasses, and does not indicate that 'mental healthcare' may include research; furthermore its repeated emphasis on 'care, treatment and rehabilitation' raises doubts that the phrase 'mental healthcare' as used in the Act should be understood to include mental healthcare **research**. In turn, it also seems that the Regulations<sup>[19]</sup> promulgated in terms of the Mental Health Care Act do not make specific provision for mental healthcare research.<sup>[19]</sup> (I have previously discussed the Draft Regulations Relating to Research on Human Subjects that were published in 2007 but which are currently being re-drafted).<sup>[2]</sup> Consequently, one has to rely on the National Health Act to ascertain the requirements regarding participants' consent to such research.

The rules generally applicable to all research subjects, both children and adults, appear in subsection 71(1) of the National Health Act, which provides that: 'research or experimentation on a living person may only be conducted in the prescribed manner; and with the **written** consent of the person after he or she has been informed of the object of the research or experimentation and **any possible** positive or negative consequences to his or her health' (my emphasis).

As subsection 71(1) of the National Health Act was the focus of a previous contribution,<sup>[2]</sup> only its salient points are highlighted here: consent to participation in research needs to be in writing (the previous common law position prescribed no formalities) and the research participant needs to be informed of the **object** of the research or experimentation as well as '**any possible** positive or negative consequences to his or her health'. Although it seems that proxy consent is excluded from the operation of section 71(1) (the use of 'consent of the person'), it is unlikely that the section will be interpreted by the courts to exclude proxy consent. Lastly, retrospective consent is not permissible – consent must be given in advance of the research intervention.

Next follows a discussion of the two subsections relevant to consent by children and adolescents to participation in research.

### Subsections 71(2) and 71(3) of the National Health Act: Children's and adolescents' consent to participation in research

Subsections 71(2) and 71(3) of the National Health Act specifically pertain to research in children (note that these subsections make no distinction between children and adolescents). The 2 subsections are dealt with separately and, because of their importance to the present discussion, they are quoted in full:

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

on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted –

- (i) in such manner and on such conditions as may be prescribed;
  - (ii) with the consent of the Minister;
  - (iii) with the consent of the parent or guardian of the minor; and
  - (iv) if the minor is capable of understanding, the consent of the minor.
- (b) The Minister may not give consent in circumstances where –
    - (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult;
    - (ii) the research or experimentation is not likely to significantly improve scientific understanding of the minor's condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors;
    - (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy;
    - (iv) the research or experimentation poses a significant risk to the health of the minor; or
    - (v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh that risk.

### Subsection 71(2)

Subsection 71(2) significantly affects the age at which independent consent to participation in clinical research is possible. Previously, an adolescent over the age of 14 years was considered able to consent independently to medical treatment and therapeutic research. Section 39(4) of the Child Care Act<sup>[20]</sup> determined that a minor over the age of 14 could consent independently to medical treatment<sup>[21]</sup> and medical treatment was considered (perhaps wrongly?) to be analogous to research. This determination was supported by ethical guidelines which provide that adolescents may consent unassisted to research (e.g. Guideline 5.3.1.2.1 of Book 1 of the MRC Guidelines on Ethics for Medical Research).<sup>[22]</sup>

Subsection 71(2) prohibits a 'minor' from giving independent consent to research participation. While the Act does not define the term 'minor', the Children's Act<sup>[23]</sup> and the Constitution of 1996 define a minor as anyone under the age of 18 years. (Previously, in terms of section 1 of the repealed Child Care Act, a 'minor' had been defined as someone below the age of 21, whereas a 'child' was anyone below the age of 18.)

In accordance with subsection 71(2), children and adolescents under the age of 18 years now require the consent of a parent or guardian to participate in mental health research. This requirement is in sharp contrast to the Choice on Termination of Pregnancy Act,<sup>[24]</sup> according to which a minor female of any age may consent to the termination of her pregnancy; and to section 129 of the Children's Act which, in fact, **lowers** the age of independent consent to medical **treatment** to 12 years of age (provided the child is of 'sufficient maturity and has the mental capacity to understand the benefits, risks, social or other implications of the treatment or operation').

A second significant aspect is the requirement that, according to subsection 71(2), a minor may participate in 'therapeutic research' only with the consent of the minor's parent or guardian as well as that of the minor. The requirement that a 'parent' or 'guardian' alone may consent to the minor's participation in research, and not another person who has the care of the minor, may present problems. The previous legal position (according to the Child Care Act) allowed a 'custodian' of a child to consent in situations where children were in children's homes, mental healthcare facilities or other places of safety. Although the legislator clearly intends to protect children from abuse, the requirement in subsection 71(2) could mean that, as a consequence, children without parents or guardians are denied access to mental health research which will directly benefit them.

A third aspect of subsection 71(2) which deserves attention is the requirement that, in the case of so-called 'therapeutic' research, minors should 'consent' to participation. Previously, older children and adolescents 'assented' to certain types of mental health research participation, while their parents 'consented'. The interpretation of subsection 71(2) to mean that, in the case of therapeutic research, the consent of the minor is needed but only the **assent** of parents, is not supported.<sup>[25,26]</sup> Such an interpretation is unlikely to be supported by the courts, as the subsection specifically uses the word 'consent' and not 'assent'.

The requirement for parental consent to a minor's participation in therapeutic research will have the consequence of eroding the minor's privacy. In the past, minors were able to consent independently to participation in research which, for example, is aimed at finding more appropriate drugs to treat sexually transmitted diseases. Minors did not have to tell their parents that they were sexually active or suffered from a sexually transmitted disease, in order to gain their consent to participate. Mental health research which is aimed at studying the link between adolescent use of dagga and the subsequent onset of certain mental disorders would become problematic in terms of subsection 71(2), as the requirement of parental consent would necessitate the disclosure of the adolescents' drug-use and violates their privacy. Subsection 71(2), therefore, could impede important research to find treatment options appropriate for use in adolescents. Adolescents may refuse to participate in research because seeking parental consent will mean a violation of their privacy.

Subsection 71(2) directs that minors may consent to research participation only if they are 'capable of understanding'. This direction is in line with the common law and case law requirement that the person who consents must be legally and factually capable of understanding information and deciding on a course of action.<sup>[15]</sup>

Subsection 71(2) gives researchers no guidance on how to evaluate whether a child or adolescent would be considered under the Act to have the capacity to consent to mental health research participation; we have to rely on general legal and ethical rules. In each case, it must be clinically assessed whether the child or adolescent has the capacity: (i) to understand to what he or she is consenting; (ii) to

choose decisively for or against participation in research; *(iii)* to communicate his or her choice; and *(iv)* to accept the need for an intervention.<sup>[27,28]</sup> Mentally ill children and adolescents may have difficulties in relation to each of the above. For example, any of the developmental disorders – such as attention deficit hyperactivity disorder (ADHD), autism spectrum disorders or intellectual disability – may impair cognitive and decision-making skills. Some mental disorders may influence the child or adolescent's capacity to choose whether to participate, for example, depression (which may prompt the child to take a fatalistic attitude to research participation), or disorders which cause an inability to regulate behaviour or which prompt impulsive acts. Some mental disorders may profoundly impair the child or adolescent's insight into the true nature of the research intervention, such as psychosis.

Subsection 71(2) further directs that the research or experimentation may only be conducted if it is 'in the best interests of the minor', which correlates with the best-interests clause in the Constitution and the Children's Act. Section 9 of the Children's Act reads: 'In all matters concerning the care, protection and well-being of a child, the standard that the child's best interest is of paramount importance, must be applied'. Note the use of 'child' rather than 'children', indicating that the **specific** child's interest should be of utmost importance, as well as the use in subsection 71(2) of 'best interests of **the** minor'. Therefore, it is not sufficient to show that the research is in the interest of mentally ill children and adolescents generally, it must be in the best interest of the **specific** child or adolescent. This provision places an onerous duty on mental health researchers, considering that in mental health research – more so than in other medical research – it is notoriously difficult to show that any research intervention is likely to benefit research participants in general or a specific research participant (for example, take the 50% placebo effect reported in a paediatric antidepressant study).<sup>[29]</sup>

Finally, subsection 71(2) uses the term 'therapeutic' and subsection 71(3) the term 'non-therapeutic'. The use of these terms may be problematic in relation to mental health research in children and adolescents. Apart from the lack of a clear definition of these terms in the Act, it is often difficult to distinguish between the two 'types' of research. It is understood that therapeutic research contains many non-therapeutic elements, such as blood draws, which have no benefit to the individual research participant, and that in the case of placebo-controlled trials the therapeutic mental health-trial research participant in the placebo arm may not benefit at all. At best, therapeutic research has merely the **potential** to benefit the individual mentally ill child or adolescent research participant, given that an **unproven** drug or intervention is being tested. Consequently, it is sometimes difficult to distinguish between 'therapeutic' and 'non-therapeutic' research.

Furthermore, the distinction in the National Health Act between 'therapeutic' and 'non-therapeutic' research fails to take into account different risk standards. Mental health research that is considered therapeutic may have more severe risks attached to it than so-called

non-therapeutic research. Conversely, non-therapeutic research may have very little risk attached to participation, making the added requirement of ministerial permission unnecessary.<sup>[30]</sup> For instance, a subject may merely be required to complete a questionnaire, but the results may yield important information.

It is suggested that, as is the case in local and international ethical guidelines, the legislator should rather have used different categories of risk or defined the research permissible in minors in terms of well-defined risk standards.<sup>[31]</sup>

### Subsection 71(3)

The subsection sets a high threshold that needs to be met when children and adolescents participate in so-called 'non-therapeutic' mental health and other health-related research. The Minister of Health is to consent to their participation, in addition to the consent of the minors themselves and their parents or guardians. The subsection is clearly aimed at protecting minors from harm through unscrupulous research, but the decision could have been left to ethics committees, as was the case in the past. The requirement for ministerial consent will likely lengthen the approval process of protocols.

A second aspect of the section is valid and used generally as a measurement of the ethical appropriateness of research by ethics committees: the Minister may not consent to the minor's participation in non-therapeutic research if the objects of the research may be attained if that research were carried out on adults.

In addition, the Minister may not approve research where 'the research or experimentation is **not likely to significantly improve scientific understanding** of the minor's condition, disease or disorder to such an extent that it will result in **significant benefit to the minor or other minors**'. This requirement is of particular concern in the case of research in mentally ill children and adolescents. First, the subsection appears to contradict the definition of 'non-therapeutic' research in that it refers to 'understanding of the minor's condition', implying a 'therapeutic' research intervention. Moreover, researchers in the field of mental health have remarked on the difficulty of accurately predicting the results of a research intervention in children and adolescents. Potential 'significant benefit' is difficult to quantify in many research interventions with children and adolescents, as in the case of adults. A researcher or ethics committee will find it difficult to make this judgement call.

Subsection 71(3) states that the Minister may not allow research which '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'. However, the Act fails to define what 'some risk' and 'significant risk' entail. The terms create confusion as they introduce a different risk standard from that which is used in the ethical guidelines. In the case of children's participation in non-therapeutic research, the MRC Guidelines on ethics for medical research (2004), for example, require that the risk be 'negligible'.



## Conclusions and recommendations

It is an ethical and legal imperative that clinical studies be conducted on children and adolescents in order to identify the pathogenesis of their mental illness, and to develop effective treatment and preventative interventions. These studies must be scientifically viable and ethically sound, and must conform to the legal requirements for valid consent to participation by children and adolescents, as introduced by chapter 9 of the National Health Act.

According to the Act, no one under the age of 18 can consent independently to research participation. If competent to do so, mentally ill children and adolescents give informed consent to participation in research in agreement with their parents or legal guardians. Consent must be in writing. Only research which relates to their mental illness (so-called 'therapeutic' research) is permitted, unless the permission of the Minister of Health is obtained. In each instance the capacity of the mentally ill child or adolescent to give informed consent must be clinically assessed and evaluated on a case-by-case-basis, which supports van Staden's view of a 'functional' approach<sup>[27]</sup> to consent.

The requirement that a parent or legal guardian must consent to the participation of children and adolescents in research, is an obstacle to much-needed mental health research, because the possibility of the minor's right to privacy being eroded is likely to be found unconstitutional if challenged. The Constitution guarantees everyone (including children) the right to privacy in section 14, and the right to physical and psychological integrity in section 12. In view of these guarantees, the recommendation is that, in certain circumstances, ethics committees tasked with reviewing research be allowed to dispense with parental consent and permit adolescents with the necessary capacity to consent independently to such research participation.<sup>[9]</sup> In addition, statutory requirements which impede or obstruct much-needed mental health research may be considered a violation, even if indirectly, of section 27 of the Constitution, which guarantees everyone access to healthcare services. Therefore, they are both unconstitutional and void.

The phrase 'best interests of **the minor**' in subsection 71(2) can be interpreted to mean that the research study must benefit a **specific** child or adolescent. This is too onerous a burden, as mental health researchers may find it difficult to show that a research intervention is likely to benefit research participants or a specific participant.

The Act's classification of research into therapeutic and non-therapeutic categories is also problematic. Research permissible in minors should instead be stated in terms of well-defined risk standards.

Subsection 71(3)'s requirement for ministerial consent in the case of non-therapeutic research in children and adolescents is overly protectionist and precludes the capacity of an ethics committee to pass judgment on the ethics of the proposed research.

Research is urgently needed into several ethical and legal issues surrounding children and adolescents' consent to participation in mental health research. This includes research into the capacity to consent to research participation, in order to determine the extent

to which consent is limited by certain mental disorders, as well as the clinical assessment of the capacity to consent. Also needed is research that will contribute to the development of methodologies and practices, in a South African context, that will help increase the capacity of mentally ill children and adolescents to consent.

It is too early to judge the impact of the new provisions. Despite the potential problem areas indicated, the provisions ought to be interpreted in a way that supports ethically and scientifically valid research, and assists ethics committees and others in the interest of the well-being of mentally ill children and adolescents.

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