



## One step forward, two steps back – requiring ministerial approval for all ‘non-therapeutic’ health research involving minors

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The new National Health Act has clarified that children may take part in ‘non-therapeutic’ research (NTR) and the age at which they may provide independent consent to such research, viz. at legal majority. However, the Act will require consent from the Minister of Health for all research classed as NTR and involving minors regardless of the level of risk. This requirement is overly broad. It will require that low-risk research without direct benefits, which might be adequately reviewed by an accredited research ethics committee (REC), must also be reviewed by the Minister. As it currently stands this requirement serves no plausible ethical purpose, will cause delays and discourage essential research on the needs of children, and may inspire researchers and RECs alike to ‘foil the system’. We argue that in the long term there should be

comprehensive law reform for child research. However, in the short term, amendments should be made to the Act to narrow the scope of this provision. The amendment should require ministerial consent for research that is currently not approvable by an REC in terms of national ethical guidelines, namely, research that does not hold out direct benefit but presents more than a minor increase over minimal risk. If our law reform recommendations are rejected, we favour the delegation of this task to RECs because, if they receive appropriate training, they should be competent to conduct it. We accept the disadvantages, namely that the same body will review protocols twice from slightly different perspectives and that certain categories of research will remain unapprovable.

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The recently implemented National Health Act<sup>1</sup> (hereafter called ‘the Act’) creates a legal framework for human subjects research including research involving children. Most of the Act came into operation on 2 May 2005. However, section 71, which deals with research involving human subjects, will only come into operation in the future. Section 71(3) sets out the conditions for ‘non-therapeutic research’ (NTR) which includes an obligation to obtain consent from the Minister of Health (hereafter called ‘the Minister’). The Minister has to determine if NTR involving minors meets scientific, ethical and public policy justifications. Any NTR with minors that does not receive ministerial consent will be unlawful. This article describes the ethical-legal problems relating to so-called non-therapeutic child research. It critically examines section 71(3) of the Act and outlines various options for law reform.

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### NTR involving children – necessary but a vexing ethical-legal problem

The Department of Health’s *Health Research Policy in South Africa*<sup>2</sup> identifies research into preventable diseases as a key objective. Much of this research will be conducted with healthy volunteers (like vaccine research) or hold little direct benefit for volunteers (like most phase I drug studies). However this research is part of South Africa’s overall public health strategy. In addition, the Medicines Control Council increasingly requires child data before it will license products for this age category.<sup>3</sup>

The law and guidelines, however, have struggled to define when children can participate in NTR. Currently, there are no legal guidelines on child research (until section 71 of the Act becomes operational). Legal scholars have generally recommended the limited involvement of minors in NTR, namely in low-risk research and with proxy consent.<sup>4,5</sup> Scholars have also tried to establish the age at which children may consent independently to NTR. Some have argued that children of any age may consent to NTR of no risk,<sup>6</sup> while others have argued that persons under 18 should never consent independently to NTR.<sup>5</sup>

Ethical guidance on this issue is not completely harmonised.<sup>7-10</sup> Most guidelines maintain that when the research does not hold out direct benefit, the permissible risk level is a minor increase over the risks of daily life or routine medical and psychological tests.<sup>7,9</sup> Only the Medical Research Council’s general principles do not permit any such increase.<sup>11</sup>



Given this ambiguous guidance, research ethics committees (RECs) have made varied judgements on this issue.

### The National Health Act – an attempt to clarify the participation of minors in NTR?

The Act has clarified some of the ethical-legal ambiguities relating to NTR. It has, firstly, settled the question of whether children can participate in NTR by describing particular circumstances, including that the research does not pose a 'significant risk'. Secondly, the Act has clarified when children can consent independently to NTR by requiring parental/guardianship consent until majority is reached.

### Problems with ministerial consent for all forms of NTR

Although the Act clarifies a number of issues it also creates new problems by requiring ministerial consent for all NTR involving minors regardless of risk level. As prior uncertainties with non-therapeutic child research have largely been clarified by section 71(3), the purpose of this additional procedural requirement is unclear. We assume that parliament wished to provide additional protection for minors in high-risk research without direct benefits, as is provided for in other jurisdictions, e.g. in the US Code of Federal Regulations, an Institutional Review Board (IRB) may not approve non-beneficial child research that involves more than a minor increase over minimal risk. In this case, the research must be approved by the Secretary of the Department of Health and Human Services after expert consultation and public comment.<sup>12</sup>

However our ministerial consent requirement would apply to all forms of NTR with minors. The Act defines health research very broadly, including any research that contributes to knowledge of biological, clinical, psychological or social processes in human beings. The Act does not define NTR. However, in the literature it has been defined as research that seeks generalisable knowledge but does not intend to benefit the individual directly.<sup>13,14</sup> This means that some low-risk research (like certain social science research) would require ministerial consent. We argue that this protection is overly broad. Low or no-risk research does not warrant additional scrutiny or protection in the form of ministerial consent. For example, under this system a study of children's perceptions of traffic hazards would require ministerial approval as it holds no direct benefits for these healthy participants.

### Problematic consequences

If the Minister has to consent to all NTR involving children, very large volumes of research will have to be reviewed, including social-behavioural research and student projects.

For example, just one REC at the Human Sciences Research Council reviews on average 36 protocols involving minors every year, many of which hold out no prospect of direct benefit. Given that all universities and science councils are undertaking some child research, it is possible that the Minister may have to review hundreds of protocols per year.

If ministerial consent is not provided, researchers may: (i) elect not to proceed; (ii) make amendments and re-submit; or (iii) ask the High Court to review the minister's decision.

An unintended consequence of this provision may be to discourage researchers from conducting NTR involving minors. Researchers are also likely to question the value of additional scrutiny of low-risk research, which may engender ill will about the bureaucratisation of ethics. Researchers may misclassify research as 'therapeutic' to avoid this process, or their legal obligations.

### Possible solutions

We argue that the current provision needs amendment if, firstly, it is to be meaningful and add value to the review process, and secondly, if it is to be administratively manageable. We suggest three possible solutions. The first two are radical and the remaining one is pragmatic.

#### 1. Replace section 71 with comprehensive legislation regulating child research.

Many shortcomings have been identified with the way in which section 71 regulates research involving minors, e.g. it is based on the controversial notion of classifying research into therapeutic and NTR.<sup>15</sup> Radical law reform may be an opportunity to develop comprehensive legislation for child research (not only health research) and to locate it more appropriately in the Children's Act (Act No. 38 of 2005).<sup>16</sup> This would, however, require political commitment.

#### 2. Make minor amendments to the Act to narrow the scope of ministerial consent to research that cannot be approved by an REC in terms of national ethical guidelines.

In the US system for federally funded research, only research that cannot be approved by an REC must be referred to the Secretary for Health and Human Services. In our ethical-legal framework we have no mechanism to facilitate additional scrutiny and approval of such studies. We suggest that section 73 of the Act be amended to bring it in line with the US system for federally funded research, which has been created to deal with exceptional research rather than all non-beneficial research. This proposed amendment deals directly with the problem by limiting ministerial consent to studies where additional protection is required for under-age participants involved in low-benefit high-risk research. It means that such exceptional research may nevertheless take place in South Africa as the Minister is given the authority to



allow such research in specific circumstances. It reduces the ministerial burden and would be simpler than extensive law reform. However, this will remain an interim solution as other problems with the Act will remain.

### 3. Delegate the Minister's authority to consent to NTR to an appropriate official or body.

Section 92(a)<sup>1</sup> of the Act empowers the Minister to delegate any power given to her in terms of the Act to any person in the employ of the State or any council, board or committee established in terms of this Act. This means that the Minister may lawfully delegate this responsibility. This opens up options, including delegation of this task to the Chief Director of the Health Information Research and Evaluation Unit (HIREU) at the Department, the National Health Research Ethics Council (NHREC), or an REC.

In the absence of law reform, this task could be delegated to the HIREU or the NHREC. However, this means that another committee will have to read and approve large volumes of non-risky research that could have been managed by a competent REC. This adds no ethical value to the existing process, only more burden and longer delays. Also, it is not within the NHREC's mandate to review protocols.<sup>1</sup>

Alternatively this task could be delegated to RECs. RECs are in effect already performing this task so there is therefore no additional workload for them. However it would mean that RECs have to perform two different functions with regard to the same protocol, namely they would have to establish if it was ethical and if it met the public policy criteria described in the Act. Also, RECs will still not be able to approve certain categories of research.

## Conclusions

Section 71 of the Act is a step forward in that it clarifies the circumstances in which non-therapeutic child research is lawful, which could facilitate critical public health research. However, important gains are undermined by an overly broad requirement for ministerial consent for all forms of non-therapeutic child research.

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