OPINION

Child research in South Africa: How do the new regulations help?

A E Strode, C M Slack

Ann Strode is a lawyer and Catherine Slack a clinical psychologist. They have worked with the HIV/AIDS Vaccines Ethics Group in the School of Applied Human Sciences, University of KwaZulu-Natal, Pietermaritzburg, South Africa, since 2000 to explore and strengthen the ethical-legal framework for the conduct of HIV vaccine trials. Both have a special interest in the participation of children and adolescents in research.

Corresponding author: *A E Strode (strodea@ukzn.ac.za)*

Child research is governed by legal norms in the National Health Act (2003) and the Regulations. There is increasing harmony between the two on many issues, including the conditions under which children should be enrolled in research. The most striking disjuncture in the ethical-legal framework remains the allowable consent strategy for child research, where the law requires mandatory parental or legal guardian consent for all child research, while ethical guidelines afford research stakeholders the discretion to implement exceptions to this approach in specific justifiable circumstances.

S Afr Med J 2015;105(11):899-900. DOI:10.7196/SAMJ.2015.v105i11.9838

Several legal norms regarding South African child health research are contained in section 71 of the National Health Act[1] (hereafter referred to as the NHA), which became operational on 1 March 2012.[2] On 19 September 2014, the Minister of Health published Regulations Relating to Research with Human Participants.[3] These regulations complete the phasing in of the new legal framework for regulating health research as established by the NHA. In the past few months, revised national ethical guidelines have been released.[4] This article describes the relevant sections of the Regulations that deal with minors, and discusses their implications for research ethics committees (RECs) reviewing research involving persons under the age of 18 years.[5]

Research with minors

Section 71 of the NHA[1] sets norms for research involving human subjects who are minors. These include that 'therapeutic research' must be in the best interests of the minor.[1] Also, ministerial consent must be obtained for 'non-therapeutic research' with minors,[1] critiqued elsewhere as overly broad in scope.[6] Furthermore, mandatory parental consent should be obtained. Minors who demonstrate 'understanding' should consent alongside the person providing proxy consent and not merely assent to the study. The latter consent strategy has been criticised elsewhere as overly restrictive because other consent approaches endorsed by ethical guidelines are excluded.[4,7]

The new Regulations Relating to Research with Human Participants[3] helpfully confirm some of the principles that had hitherto only been provided for in the national ethical guidelines, and provide some clarity on the norms in section 71 of the NHA; however, in other instances they do little to resolve competing approaches to consent.

Vulnerability, indispensability and risk standards

The new Regulations address three general issues relating to human subjects research with children. Firstly, minors should be considered a vulnerable population.[3] 'Vulnerable persons' are defined as research participants who are at 'increased risk of research-related harm, or who are limited in their freedom to make choices, or relatively incapable of protecting their own interests'.[3] This is in line with the current approach in the national ethical guidelines.[4] The Regulations require RECs to pay special attention to protocols involving such persons, while, however, emphasising that it would be a form of unfair discrimination to unjustifiably exclude such persons from research, since they are deserving beneficiaries of its outcomes.[3] This approach encourages RECs to balance child protection and research facilitation. Secondly, the participation of minors must be scientifically indispensable to the study design.[3] This confirms the position in the national ethical guidelines.[4] Thirdly, minors can only participate in research when they will be exposed to particular levels of risk, an approach that corresponds well with the risk categories described in national ethical guidelines.

The above suggests that RECs seeking to ascertain the conditions under which minors could be enrolled in research will find fairly good harmonisation between legal and ethical norms on this issue.

'Therapeutic research' with minors

Section 71(2)(a) of the NHA provides that therapeutic research with minors may only be undertaken if the study 'is in the best interests of the minor'.[1] The Regulations provide some direction by defining both the terms 'therapeutic research' and 'best interests'. Therapeutic research is defined as being research 'that holds out the prospect of direct benefit' to the participant,[3] which corresponds to the national ethical guidelines.[4] The 'best interests' of the minor is defined as ensuring that 'significant decisions affecting a minor's life should aim to promote, amongst others, the minor's physical, mental, moral, emotional and social welfare'.[3] This suggests that RECs reviewing research that holds out the prospect of direct benefit to the child/children should consider the degree to which of the abovementioned domains of welfare might be promoted by the study.[4]

'Non-therapeutic research' with minors

Section 71(3)(2)(ii) of the NHA provides that non-therapeutic research with minors can only take place with the consent of the

Minister of Health.[1,6] The Regulations provide some direction by, firstly, defining non-therapeutic research as 'research that does not hold out the prospect of direct benefit to the participant but holds out the prospect of generalizable knowledge'.[3] This definition is consistent with the approach taken in the national ethical guidelines[4] and helps RECs to consistently determine which child protocols fall into this category. Secondly, the Regulations help operationalise two of the criteria for ministerial consent. The 'research should improve understanding of the minor's "condition"' and 'it must not pose more than a "significant risk"'. A 'condition' is defined quite broadly as including 'physical and psycho-social characteristics understood to affect health', which accommodates protocols with healthy but at-risk children, while significant risk is defined as being a 'substantial risk of serious harm'. This definition clearly indicates that the risk posed cannot be equated with minimal risk, a term used in the ethical guidelines. Thirdly, the Regulations address some of the procedural complexities of this new requirement by providing:

1. That a delegated authority may provide consent on behalf of the Minister, and
2. Clarity on the procedure to be followed to obtain ministerial consent. Form A has been attached to the Regulations and must be completed by all applicants for ministerial consent. It elaborates the criteria for such consent, by reframing them in standard research ethics terminology. It should be noted that subsequent to the publication of the Regulations, the Minister of Health delegated his power to grant ministerial consent to selected RECs (personal communication, Prof. D R Wassenaar, November 2014). This suggests that registered RECs will perform an additional review of child research that holds out no prospect of direct benefit based on the information contained in Form A. This will be done on behalf of the Minister but at the same time as the routine ethics review.

Other gaps and concerns

Section 71(2)(c) of the NHA[1] restricts consent for child research to parents or guardians, whereas national ethical guidelines allow a broader range of consent approaches in certain defensible circumstances.[4-7] The regulations do little to resolve the tension between the law and ethical guidelines in this regard, stating only that research with human participants should be undertaken with 'appropriate consent processes'. This leaves RECs with an unresolved dilemma between obligations to approve research that they find to be ethical, as set out in section 73 of the NHA, and ensuring that research complies with the legal standards set out in section 71.

Conclusions

On the one hand, the publication of the Regulations is welcome because it ends a long period of flux, beginning in 2005 with the partial introduction of the NHA, and has facilitated greater harmonisation regarding many issues between section 71 of the NHA and the national ethical guidelines. On the other hand, the publication of the Regulations means that the disjuncture regarding allowable consent strategies is in its sharpest focus yet, leaving RECs in a difficult situation.

While the legal and ethical framework appears to cohere far better around the background conditions for child research, it continues to clash over allowable consent strategies for child research. The main consequence may be that RECs will need to justify and document much more carefully the consent approach they approve for child research. Overall, this tension is akin to the dilemma presented by overly rigid legal reporting requirements for underage consensual sex v. a more nuanced ethical approach.[3,8]

Acknowledgements and disclaimer. This article is based on a presentation made by AS at the 3rd Annual ARESA Research Ethics Seminar. It is a joint effort by both authors. The work described was supported by award number 1RO1 A1094586 from the US National Institutes of Health (NIH) entitled CHAMPS (Choices for Adolescent Methods of Prevention in South Africa). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH, or represent the views of any committee or council with which the authors are affiliated.

1. South African Government. National Health Act 61 of 2003. http://www.gov.za/sites/www.gov.za/files/a61-03.pdf (accessed 20 February 2015).
2. Proclamation No. 11 in Government Gazette No. 35081 of 27 February 2012. http://www.greengazette.co.za/documents/national-gazette-35081-of-27-february-2012-vol-560_20120227-GGN-35081.pdf (accessed 1 October 2015).
3. South African Government. Regulations Relating to Research with Human Participants. Government Gazette No. R 719 of 19 September 2014. http://research.ukzn.ac.za/Libraries/Research_Document/National_Regulations_Relating_to_Research_With_Human_Participants_R719_of_2014.sflb.ashx (accessed 25 February 2015).
4. Department of Health, South Africa. Ethics in Health Research: Principles, Structures and Processes (2015 at 59). http://www.nhrec.org.za/docs/Documents/EthicsHealthResearchFinalAused.pdf (accessed 1 September 2015).
5. ARESA (2014). Vol 4, number 2. http://sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Bioethics1/ARESA/newsletter/ARESA%202014%20December%20Newsletter_final.pdf (accessed 1 January 2015).
6. Strode A, Slack C, Wassenaar D, Singh J. One step forward, two steps back: Requiring ministerial approval for all 'non-therapeutic' health research with minors. S Afr Med J 2007;97(3):200-202.
7. Strode A, Richter M, Wallace M, Toohey J, Technau K. Failing the vulnerable: Three new consent norms which will undermine health research with children. South Afr J HIV Med 2014;15(2):46-49. [http://dx.doi.org/10.4102/hivmed.v15i2.18]
8. Strode A, Slack C. Sex, lies and disclosures: Researchers and the reporting of under-age sex. South Afr J HIV Med 2009;10(2):8-10.

Accepted 13 June 2015.