

HSRC Guidelines on Research with OVC

Minors (including orphans and vulnerable children (OVC)) and parental substitutes in the informed consent process for research participation

INTRODUCTION

Important and necessary research is being conducted throughout the country by HSRC and other institutions using minors as participants. Minors are required, in principle, to be assisted by their parent/guardian in the informed consent process. However, many of the minors under consideration do not have parents and very few have a court-appointed guardian. This poses a problem for researchers who wish enrol such minors as participants in research projects because, currently, there is no clear guidance regarding legally acceptable substitute persons who might perform the parental role in the informed consent process.

That the relevant provisions governing research with minors in the National Health Act (not yet in effect) require even more stringent procedures adds to the confusion. Once these provisions are come into effect, it may be well nigh impossible to enrol minor participants in research using current patterns of informed consent processes. Nevertheless, in the interests of fostering consistency under the current conditions for research as well as compliance with the spirit of the legal provisions that protect minors' interests, some pragmatic guidance on how to go forward in the immediate future is helpful.

Some of the most important work is that which seeks to understand and improve psycho-social, economic and educational conditions for orphans and vulnerable children. That is, the (future) well-being of such children is sought to be enhanced. This research generally involves no more than minimal risk of harm. Currently, protocols tend to state that parents or guardians will assist in the informed consent process. On the face of it, this complies with the legal and ethical requirements. However, the reality is that this statement is meaningless and futile: by definition, an orphan does not have a parent and in the South African contexts under study, the likelihood of a court-appointed guardian is extremely small. Everyone knows that the requirement cannot be met but what is the alternative? The net effect is that researchers try to do the best they can in the circumstances by asking whoever brings the minor to the clinic or whoever might be at home to give permission for the minor to participate in the research. While this practical approach is understandable, it is also problematical because it inevitably leads to inconsistencies regarding who is acceptable as a proxy for the parent in the informed consent process. These inconsistencies (even the perception that they might exist) make the quality and integrity of the research vulnerable to criticism on the ground that informed consent processes might be unethical.

PRAGMATIC GUIDELINE

The proposed guideline (below) takes its lead from the Constitution, the Children's Act (partially in effect), the Children's Amendment Act (not yet in

effect), the National Health Act (partially in effect), the Criminal Law (Sexual Offences) Amendment Act (in effect); the Department of Health Ethics in Research Guidelines (2004) available at www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html. (NB the spelling error re 'ethnics' is as per the site); the South African Good Clinical Practice Guidelines (2006) available at www.doh.gov.za/docs/gactsheets/guidelines/clinical/2006/index.html. [It should be noted that despite the impending implementation of the very restrictive s 71 of National Health Act, the Department of Health chose to publish both the Ethics in Research guidelines (2004) and SA Good Clinical Practice Guidelines (2006) which make contrary provision for consent.

The guideline is premised on three conditions which must all be satisfied:

1. The proposed research must hold out no more than **minimal risk of harm** (defined as 'the probability and magnitude of harm or discomfort anticipated in the research will not be greater than those ordinarily encountered or to be expected in daily life, including in routine medical, dental or psychological examinations and in social or education settings'); **and**
2. It must not be possible to do the research with adult participants; **and**
3. The research must propose to investigate a problem of relevance to minors.

For minors <18 years but >12 years

(The parental substitutes should be used in descending order, as listed.)

1. The minor decides whether to participate and thus consents (ie expresses her will) **AFTER**
2. The **parent** gives assistance so the minor makes an **informed choice** and gives permission/not. Parental permission and minor's decision must be consistent, ie if the minor decides not to participate the parent may not override this decision.
3. **If no parent, then guardian** is substitute: either court-appointed OR as indicated by the parent in a Will (per s27 Children's Act);
4. **If no guardian, then foster parent (per order of Children's Court)** is substitute (NB social workers should request that this authority to give permission should expressly be included in the court order; note also that new measures per Children's Amendment Act not yet in effect);
5. **If no foster parent (as per 4. above), then care-giver (per Children's Act:** defined as '...any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care centre where a child has been placed;

e) the person at the head of a shelter; f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and g) the child at the head of a child-headed household') is substitute;

6. **If minor is caregiver and no supervisory adult** (per s 137 Children's Act – not yet in effect), then trusted adult nominated by minor, including but not limited to social worker, community worker or teacher.

In particular circumstances, eg for reasons of extraordinary sensitivity eg discussion about sexual activities, substance abuse etc, it might be desirable for minors (especially older minors ie 16 years and older) to **consent independently ie without parental assistance**. However, researchers must **be mindful of the reporting obligations** – see below.

By PRIOR negotiation and arrangement with the communities concerned, the PI can request and **make the justification** for REC approval of a waiver of the parental (or substitute) permission requirement (per DoH 2004 Ethics in Research Guidelines available at www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.htm. NB the spelling error re 'ethnics' is as per the site). The negotiation with the community concerned should include canvassing opinion of a representative body of parents eg via schools. **Factual evidence of such negotiation and willingness on the part of the community must form part of the PI's justification in the protocol.**

For minors <12 years

Parental (or **substitute in descending order as outlined above**) permission must be sought ie independent consent by such minors is not generally permissible. Minor must decide whether to participate ie parental permission cannot override the minor's decision not to participate.

REPORTING OBLIGATIONS

There is no general obligation to report either the commission of or the intention to commit a crime. However, if a researcher becomes privy to information that indicates that direct harm to another person may occur as a result of the intention to commit harm (eg a research participant says 'I'm going to kill her...'), then there may be an obligation, especially when the third person is known to the researcher.

The dilemma for researchers who wish to investigate minors' sexual activities is that the legal age at which minors can consent to sexual activity remains at 16 years (per Sexual Offences Act). (The media reported this week that there is a lobby that wishes the age to be shifted upwards to 18 years!) In effect, *any person* who engages in sexual activities with a minor <16 years commits a crime and may be prosecuted. The Act states that adults must be prosecuted but minors receive different treatment.

Where two minors <16 years engage in consensual sexual penetration, including oral sex and 'fingering', they must both be charged with statutory rape. The national DPP decides whether to prosecute. Eg the insert below is reported today 8 August 2008 on *Legalbriefs*

Criminal: Teenage girls may face statutory rape charges

Two 13-year-olds from Bloemfontein may be the first girls in SA to be tried under the new Children's Act. According to a report in *Volksblad*, **the girls are likely to be charged with statutory rape because they had sexual intercourse with boys aged 15 and 16**. Three of the children live in a children's home in the city. Previously, only males could be charged with statutory rape. The Director of Public Prosecution will decide soon whether all four parties will be charged.

[Full report in Volksblad](#)

Non-penetrative forms of sexual activity also are crimes and are open to charges of statutory sexual assault; the provincial DPP decides whether to prosecute.

Researchers must think very carefully about their methodology, goals and the consequences regarding the reporting obligations (set out below) in light of this legal context. The protocol must explain fully how the researcher plans to deal with the obligation to report, so that the REC is able to deliberate effectively.

1. Sexual Offences Act (proper name Criminal Law (Sexual Offences) Amendment Act 32/2007; in effect from 16 December 2007 except for chapters 5 & 6) includes a broader concept of rape, sexual assault, sexual grooming, sexual exploitation, use of children in pornography including photographs.

Who should report? Anyone.

2. Children's Amendment Act 41/2007 (not in effect yet) Section 110

Who should report?

"Any correctional official, dentist, homeopath, immigration official, labour inspector, legal practitioner, medical practitioner, midwife, minister of religion, **nurse**, occupational therapist, physiotherapist, **psychologist**, religious leader, **social service professional**, **social worker**, speech therapist, **teacher**, traditional health practitioner, traditional leader or **member of staff or volunteer worker at a partial care facility, drop-in centre or child and youth care centre** who on reasonable grounds concludes that a child has been abused in a manner causing physical injury, sexually abused or deliberately neglected, must report that conclusion...to a designated child protection organisation, the provincial department of social development or a police official."

3. Domestic Violence Act 116/1998

Who should report?

Anyone, including a researcher, can apply for a protection order for or on behalf of a minor research participant who is being subjected to domestic violence; the minor does not have to consent thereto.

CRIMINAL RECORD CHECK

There is not (currently) a South African equivalent to the UK requirement of Criminal Record check for persons who work with children. Both the Sexual Offences Act and the Children's Act make provision for a register of **convicted** pedophile offenders but in neither case is the register functional yet. Even if it were, it is doubtful that it would apply to or be of much assistance in a situation like a clinical trial or social science research. The type and duration of the relationship with children or adolescents that might occur in the context of a clinical or other health care research trial, differ considerably from the type in an institution that cares for or educates children or adolescents; ie the trial context involves only relatively brief encounters with the participants whereas the caring or educating context includes the opportunity to win the trust of the child or adolescent.

It seems thus that 'best practice' should be aimed at. It is recommended that best practice would be satisfied by ensuring that

1. the recruitment and training of staff for research studies should include discussion of what constitutes improper behaviour towards children and adolescents; and
2. a declaration is made by the employee in the employment contract that s/he has no conviction for an offence involving or relating to children or adolescents and that s/he has never been charged with sexual assault or in terms of the Domestic Violence Act; and
3. the personal details (including the ID number) of the person are recorded. When the protocol is submitted to the REC for ethics approval, it should include a disclaimer that the employees for the study have not been convicted of an offence involving or relating to children or adolescents. This latter measure provides some protection for the institution and the REC too.
4. In the practical context, think about possible negative perceptions that might arise in the context of the participants and their community and how to avoid them, eg a female 'chaperone' might be required to be present if a male researcher would interview a female adolescent or child, etc. This latter example is of course a basic universal precaution for most physicians in practice but may not be part of research practice.