
Informed Consent Guidelines re Minors (including orphans and vulnerable children (OVC)) and Parental Substitutes

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 to enroll 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.

The relevant provisions in the National Health Act that governing research with minors, which came into effect in March 2012, require even more stringent procedures. However, the necessary regulations associated with s 71 did not come into effect simultaneously. Consequently, there is considerable confusion concerning how to manage proposals to enroll minors in research. If the regulations come into effect without any changes being made to s 71, it may be well nigh impossible to enroll minor participants in research using current patterns of informed consent processes. For more information on the position of the HSRC's Research Ethics Committee (REC) regarding this situation, please refer to the note on the last page of this document.

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.

INFORMED CONSENT IS A PROCESS

That informed consent is a process rather than a once-off encounter is important to grasp. This insight may be well understood in the social science context, depending on the research methodology of the particular study. For example, where the methodology involves ethnography, participant observation, several interviews over an extended period of time etc, both the researcher and the participant will grasp that the informed consent process is on-going. The precise nature of the process depends on the type of methodology. In some instances, however, notably when only a brief encounter between researcher and participant is anticipated, the informed consent process seems to be regarded as a necessary obstacle to be overcome rather than recognising the importance of the process.

The tone of informed consent documentation should be respectful and mindful of the fact that any research participant can decline to participate. Consequently, the invitation to participate should indicate to potential participants that their participation would be appreciated. Many information sheets and consent forms that come before the HSRC Research Ethics Committee are worded appropriately but disconcertingly there are many that are not so worded, necessitating interventions by the REC.

Requesting permission from parents/guardians for minors' participation in research

When a study involves minor participants, parental or guardian permission must be sought before the minor is approached. Importantly, with an older minor (e.g. over the age of 12 years) the parent's permission relates to the minor can choose to participate, rather than whether the minor may participate. Section 10 of the Children's Act provides that

'every child that is of such an age, maturity and stage of development as to be able to participate in any matter concerning that child has the right to participate in an appropriate way and views expressed by the child must be given due consideration.'

Accordingly, where research holds out only minimal risk of harm, the minor should choose whether to participate; his or her parent gives permission for him or her to so choose. With younger minors, it is more subtle: the parent gives permission for the child to be approached and, generally, it is accepted that the child will say yes to participation. However, if the child is reluctant, then this must be respected. No child should be forced into participation.

The Informed consent documentation should therefore spell out to parents that their permission is sought to approach the child to request participation. That it is the child's decision whether to participate. In the minor's assent form, it should be explained that the parent's permission has been obtained to request the minor to choose whether to participate.

In this way, the minor's rights to dignity and autonomy are respected and it cannot be argued that the process is against the best interests of the minor.

PRAGMATIC GUIDELINE

The proposed guideline (below) takes its lead from the Constitution, the Children's Act (wholly in effect from 1 April 2010), 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.

A helpful series of booklets 'The Children's Act explained, especially Booklet 3: The courts and the protection of children, may be found on the website of the Department of Social Development at www.dsd.gov.za/index under Documents/Acts/Children's Act/downloads.

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 (i.e. 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, i.e. 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.
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 (i.e. a child of 16 years and older in a recognized 'child-headed household', then 'responsible person'** (per s 137 Children's Act), assists the minor. The factual absence of such a 'responsible person' should not preclude enquiries whether one can be appointed. The 'responsible person' may be appointed by the Children's Court, a government body, or and NGO. To assist the minor caregiver in this way would definitely be in the best interests of the minors concerned. To ignore the opportunity to assist is arguably unethical.
7. **If minor is caregiver and no supervisory adult** and it is not possible for the structures relating to 'child-headed households' to be activated, then a trusted adult nominated by minor, including but not limited to social worker, community worker or teacher. Some responsible adult should be available. If the minor caregiver is so isolated that there is none, then the minor should **not** be recruited for being too vulnerable. Appropriate interventions can be provided outside of the research context to support him or her.

In particular circumstances, e.g. for reasons of extraordinary sensitivity e.g. discussion about sexual activities, substance abuse etc, it might be desirable for minors (especially older minors i.e. 16 years and older) **to consent independently, i.e. 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 the 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, i.e. independent consent by such minors is not generally permissible. Minor must decide whether to participate, i.e. 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 (e.g. 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.

For specifically designated persons, there are statutory reporting obligations – see below.

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). 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. 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 Act 38/2005 Section 110 (in effect from 1 April 2010)

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. The Criminal Law (Sexual Offences and related matters) Amendment Act 32 of 2007 provides for a National Register for Sex Offenders in terms of s 42(1). This Register for Sex Offenders

Contains particulars of persons convicted of any sexual offence against a child or a person who is mentally disabled or are alleged to have committed a sexual offence against a child or a person who is mentally disabled.

Section 111 of the Children's Act provides for a National Child Protection Register. Part A records abuse or deliberate neglect inflicted on specific children. Part B records persons who are unsuitable to work with children...in order to protect children in general against abuse from these persons. Enquiries relating to Part B of the Register must be made via the office of the Director-General of the Department of Social Development.

It is doubtful whether the National Child Protection Register or the National Register for Sex Offenders can be of much assistance in the research context. The type and duration of the relationship with children or adolescents that occurs in the research context, differ considerably from the type and duration in an institution that cares for or educates children or adolescents; i.e. the research context involves only relatively brief encounters with the participants, whereas the caring or educating context includes more opportunity to win the trust of the child or adolescent. However, the possibility of a person's unsuitability should be kept in mind.

In the research context, thus, the best safeguard against the possibility that researchers or research assistants might turn out to be 'unsuitable to work with children' is to adopt 'best practice'. It is recommended that best practice would be satisfied by ensuring that

1. Recruitment and training of staff for research studies should include discussion of what constitutes improper behaviour towards children and adolescents; and that
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 that
3. 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, e.g. 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 social science research practice.

Notice prepared by the HSRC REC, to clarify its current pragmatic response to the provisions of section 71 of the National Health Act, which came into effect in March 2012

The National Health Act's section 71 governs 'research on or experimentation with human subjects'. This section was made effective from 1 March 2012 by proclamation in the Government Gazette.

The content of this provision has an extremely restrictive impact on research, particularly if the research involves minor participants. No regulations came into effect simultaneously. This presents a problem for compliance because there is no current guidance on how to comply, and the newly proclaimed section 71 is inconsistent with the current SA Department of Health (2004) ethical guidelines and policies.

Until clarity is obtained, the HSRC REC has decided to proceed, in the interim, on the same basis as before the proclamation, i.e. **the ethics review process will, in certain circumstances, deviate from the newly proclaimed provisions of s 71, but will follow the same rigorous and comprehensive ethics review process as it has always done.** The REC will thus continue to approve methodology, recruitment strategies and informed consent requirements and processes in accordance with current ethics guidelines and policies.

The implications of this decision by the REC for researchers are that changes to methodology and informed consent processes may have to be made if and when the provisions of section 71 are made properly implementable.

(Last updated October 2012)