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## RESEARCH ETHICS CLEARANCE FAQs

\* This document is intended as a 'living' document that can be added to or changed as queries or issues arise. If your question does not appear below, please contact Lamize Viljoen at [lamize.viljoen@uct.ac.za](mailto:lamize.viljoen@uct.ac.za) so that we can assist you.

There are three sections – Administrative matters, Substantive matters, and Ethics matters. In each section, the questions are listed alphabetically.

### A ADMINISTRATIVE MATTERS

#### A1. Clearance from more than one REC

*Law students propose to use MBChB students as participants to test their understanding of human rights. Is ethics clearance from Law REC sufficient?*

*Yes, in principle, but it is good practice to liaise with appropriate personnel in FHS especially if the research work is to happen during class time. In addition to ethics clearance, permission to recruit students or staff members as research participants is required. (See below under **Use of UCT students or staff members as participants**)*

#### A2. Clearance granted for more than 12 months?

*No. Clearance is granted for a maximum of 12 months (from date of approval), depending on the degree of risk of harm. Subsequent renewal is required appropriate to the degree of risk of harm, but not less than once per 12 month period. In other words, if the research is especially sensitive or has the potential to harm, the REC may grant clearance for a shorter period and request reports after e.g. three or six months before being willing to grant clearance for a longer period.*

#### A3. Does student academic research require REC approval?

*Yes, if the research involves human participants. Each project must have a supervisor. (See also below under **Research Focus Groups**)*

#### A4. Expedited review – what is?

*When a research proposal appears to offer **no more than minimal risk of harm** to human participants, it may be eligible for review and clearance outside of the regular meeting schedule of the REC on the basis that full committee deliberation may be unnecessary. This kind of review is called 'expedited review'. Researchers who believe their planned research falls into this category should contact Lamize Viljoen at (021) 650-3080 or email: [lamize.viljoen@uct.ac.za](mailto:lamize.viljoen@uct.ac.za) Researchers must provide sufficient information so that a judgement call can be made as to whether expedited review is appropriate.*

#### A5. Exempt from review – eligibility?

*When there are no human participants, or when the review and analysis is of information freely available in the public domain (e.g. newspaper reports, meta-analysis of published work, etc) or*

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*when institutional audits are undertaken (provided anonymity is maintained), then research is exempt from ethics clearance.*

*Researchers who plan to do such research should inform the Chair of REC in writing that such research is being planned and that, in the opinion of the lead researcher/PI, it meets the criteria for exemption. A brief outline of the research should be included with the letter. Papers commissioned for conferences are also exempt unless they involve primary research involving human participants. If necessary, a letter confirming exemption can be issued.*

#### **A6. Ethics review application process is so onerous**

*Not really – if the application is complete and properly explained, there is usually no delay in being able to grant approval. The REC does its best to turn applications around as fast as possible. Only rarely is a proposal rejected. In general, queries or requests for substantive detail arise when an application is incomplete or when the researcher has not demonstrated that he or she has considered the ethical implications of the chosen methodology or procedures or particular population.*

#### **A7. Research focus groups – can ‘blanket’ approval for a group be obtained?**

The Research Focus Group (RFG) convenor can submit a ‘generic’ application that describes the general scope of similar projects, outlining with sufficient detail the envisaged procedures, recruitment strategy, who the participants are, what risks of harm and likelihood of direct benefit to participants are anticipated, etc.

The REC reviews the ‘generic’ application and delegates’ responsibility to the convenor to act as a proxy reviewer of the individual projects. The students present sufficient information to the convenor so that she or he can make an assessment of whether the project falls within the scope of the ‘generic’ project approved by the REC. If so, the project can proceed; if not, the student should approach the REC to ascertain whether a separate application is needed.

It is important that the students learn what is expected by the ethics clearance process, including the drafting of information and consent documents, scripts for recruitment, etc. (See above p 8 under **Clearance procedures**)

#### **A8. What is the REC’s role?**

*The REC is tasked with facilitating the highest ethical standards in research conducted under the auspices of the Law Faculty. The members are required to have research ethics training and expertise in a variety of research methodologies.*

*The REC’s first role is as a research ethics reviewing committee that reviews proposals and grants ethics clearance for research that proposes to use human participants as sources of data. The objective is not to delay or prevent research but rather to facilitate high quality research, to ensure adequate protection of participants and researchers, as well as of the institution. Engaging with this form of peer review process is part of the enterprise to make us better researchers and to facilitate and sustain excellence in research endeavours.*

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*The REC also has an educative role in the Faculty regarding research ethics training and consultations. Researchers are encouraged to consult with a member of the REC before submitting a proposal, especially when in doubt about particular aspects. The application process seeks to prompt researchers to consider all the necessary aspects for ethical research when drawing up a research proposal.*

#### **A9. Where do I get the REC application forms?**

*They are available at [http://www.law.uct.ac.za/usr/law/downloads/researchethics\\_app.doc](http://www.law.uct.ac.za/usr/law/downloads/researchethics_app.doc) and may be submitted electronically with a follow-up hardcopy that reflects the necessary signatures.*

#### **A10. Why is ethics clearance necessary?**

*Ethics clearance is necessary for legal and moral reasons. The Constitution protects bodily and psychological integrity. The National Health Act requires that all research involving human participants undergoes ethics review. This requirement is frequently viewed with suspicion, especially by social science researchers who do qualitative research and believe that this type of research should not require ethics clearance. Consequently, ethics clearance is regarded as unwarranted interference.*

*For more on this topic, see Wassenaar & Mamotte 'Ethical issues and ethics reviews in social science research' (2008) Social Science & Medicine 1-11 and Mamotte & Wassenaar 'Ethics review in a developing country: a survey of South African social scientists' experiences' (2000) Journal of Empirical Research on Human Research Ethics 69-78. See also Terre Blanche, Durrheim & Painter (eds) (2006) Research in Practice: applied methods for the social sciences 2<sup>nd</sup> rev ed. UCT Press (in Law Library); Schrag Ethical imperialism: institutional review boards and the social sciences, 1965-2009 Baltimore : Johns Hopkins University Press, 2010 (in Main Library)*

## **B SUBSTANTIVE MATTERS**

#### **B1. Access to government departments or NGOs**

*In addition to ethics clearance, access must be negotiated with the department or NGO concerned for **permission to access documentation or personnel**. Documents that are in the public domain do not require such permission. The department or NGO is entitled to review and approve (or not) the proposed research. To that end, the researcher must supply a clear and explicit explanation of the nature, purpose and intent of the research, including the aims, objectives, methodology, destiny of the findings, etc. In short, the research proposal should be submitted. **This process is separate from the ethics clearance process.** Usually, it is advantageous to have ethics clearance before submitting the proposal to the department or NGO.*

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## **B2. Can REC ethics approval be shared with colleagues working on similar projects?**

*No. Approval is specific to particular researchers. In the case of the RFG (above), a special arrangement is made and the convenor takes responsibility for the integrity of the research administration.*

## **B3. Can student research involve collecting personal data from other students?**

*If the informed consent process is satisfactory, confidentiality is adequately protected and REC approval is granted (if necessary), then this can happen. But such research should be discouraged when data are collected from peers or from students in the class of a researcher because of the potential for difficulties inherent in revealing personal information to peers and undue pressure.*

## **B4. Covert research**

*Covert research, i.e. research that is conducted without participants' knowledge or informed consent, should be avoided as far as possible because it breaches the rights and interests of human research participants in a blatant and fundamental manner. Nevertheless, in exceptional circumstances, it is possible that gathering particular data is so important and potentially valuable that this consideration outweighs the interests of the participants. In such cases, it is possible that covert methodology may be approved.*

*The research proposal must justify and explain fully why the design including deception or covert research is desirable. The explanation must put the REC in the position to evaluate whether the design is justifiable. For example, it may be thought that obtaining informed consent is practically difficult or nearly impossible. The justification would have to demonstrate that the benefit from the research outweighs the nature and risk of harm to participants caused by the deception. The justification would also have to describe how participants would be harmed if they were to give informed consent; what the risk of harm would be; what risk of harm might exist for the researcher if informed consent is requested. The proposal must also describe how the participants will be debriefed after the period of research and how the researcher will deal with the possibly negative reaction from participants who feel aggrieved at having been deceived.*

## **B5. Ethnographic research**

*Many researchers complain that the format of the application form precludes adequate description of planned ethnographic research insofar as the form seems to demand a hypothesis.*

*On the understanding that the primary data-gathering tool for ethnographers is the relationships forged with the people whose 'life world' is being studied, the description of the research would describe the design and the methods by which their life world is anticipated to be explored and analysed. Thus, it may be that the researcher will observe, tape-record, take notes, take pictures, ask various sorts of questions (many unknown at the start of the research, etc.*

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*From the point of view of the REC, the description should include a discussion on how the individual interests of the persons under study would be protected. This discussion should be sufficiently detailed to allow the REC to understand what is intended and how ethical obligations will be met. Are systemic harms likely to arise from the findings of the project? How will data be analysed? Is there a theoretical model? Will the community know the research is occurring? I.e., will the researcher 'infiltrate' the community or be there with permission and full co-operation of at least the leadership of the community? Will individuals give permission for tape-recording or photography? Will the researcher explain the destiny of the photographs? If publication is intended, how will the privacy interest of the individual be protected? What measures to protect confidentiality will be in place? Will the findings be made known to the community?*

*Regarding risks of harm and likelihood of possible direct benefit for individual participants, it may be difficult to anticipate these in detail. However, if the purpose of the study is to understand relationships that involve potentially embarrassing or illegal activities, especially in relation to children, the researcher has an obligation to anticipate how these might be dealt with in the event of their occurrence. For example, there is a legal obligation to report child and sexual abuse. Consequently, no matter what the methodology, the researcher must have a plan as to how this obligation will be met or dealt with in the course of the research. Note also that harm can include wrongs; i.e. a person may not be harmed by the research but may nevertheless be wronged. Wrongs should be avoided and harms must be minimised.*

#### **B6. Is ethics clearance required if the research only involves counting students at lunch time on Jammie steps?**

*If the research involves only observation of public behaviour where the data are recorded so that no identification of the members of the public is possible (directly or via identifiers), then ethics clearance is not required.*

#### **B7. Preliminary work or pilot study**

*Must preliminary work undergo ethics review prior to being undertaken? In general terms, preliminary work during which a literature review, tentative research plans and contacts with possible participants are made, does not require ethics review. For example, certain disciplines might speak to informants in the preparation phase of putting a proposal together and then use these data to inform the structure of the research project. If in doubt, please consult with a member of the REC. A pilot study, on the other hand, may need more careful consideration and review if it could be seen as an independent piece of work that may or not lead to a more extensive research project.*

#### **B8. Publication of research findings**

*The findings of a research project, including any limitations, should be reported and subjected to peer review and public scrutiny i.e. in a journal article or like publication. It is important, therefore, to **ascertain before research is started that there are no obstacles to publication**. For example, where permission to conduct the research is required from a state organ, the permission should include reasonable publication of the findings. If the data or findings are*

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*subject to an embargo, this should be made known in the proposal and some effort should be made to try to minimise the embargo.*

*In reporting findings, adherence to the principles of honest, clarity, comprehensiveness and accountability is required.*

#### **B9. Use of UCT students or staff members as participants**

*In addition to ethics clearance for the specific project, **permission to access** UCT student or staff information is required. For students, permission must be sought from the Executive Director: Student Affairs to access students and from the Executive Director: Human Resource for staff members. Thus, ethics clearance and permission for access are separate but interdependent processes.*

#### **B10. What constitutes ‘research’?**

*A systematic investigation designed to develop or to contribute to generalizable knowledge and conducted by means of surveys, interviews, focus groups, ethnographic observations, record reviews, etc.*

#### **B11. What is risk of harm?**

*Harm can be physical, social or psychological, amongst others. Harm may flow from leaks in confidentiality, stress to participants, stigmatisation.*

## **C ETHICAL MATTERS**

### **C1. Conflict of interest**

In accordance with the UCT Conflicts of Interest: Principles, Policy and Rules document (at <http://www.uct.ac.za/downloads/uct.ac.za/about/policies/conflictsofinterest.pdf>) the following fundamental principles and requirements serve as guidelines in dealing with conflict of interest issues.

Committee members have a fiduciary responsibility to serve the interests of the university and of the public generally. All decisions are to be made solely on the basis of a desire to promote the best interests of the university and the public.

Complete integrity of approach and of fairness in procedures is essential. The principles should not just be observed but should be seen to be observed. In many instances, perceptions play an important role in creating the impression of the existence of a dubious conflict of interest. The university’s integrity is to be protected at all times.

Transparency in the form of meticulous disclosure, adherence to prescribed procedures and precise recording of proceedings as well as the reason(s) for arriving at decisions is vital. In defining what constitutes a conflict of interest and in evaluating its significance in particular contexts, a balance should be sought between potentially contradictory considerations.

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In the context of the REC and ethics clearance applications, a conflict of interest or of commitment may arise. A **conflict of interest** involves not only the direct, personal and pecuniary interests of the individual, but also those of members of his or her immediate family circle. A **conflict of commitment** may involve the time and investment expected from a staff member or student in ordinary university business, including teaching and learning, versus the time and investment available for doing the proposed research properly.

How to know whether a conflict of interest exists? It may be useful to ask yourself the following questions about relationships or interests:

- Would I be willing to have the proposed arrangements generally known?
- What would my research participants think about this arrangement?
- What would the public think?
- How would I feel if the relationship was disclosed through the media?
- What would my colleagues think about the arrangement?

When a member of the REC has an interest in research proposals before the REC, he or she must disclose this fact and recuse him or herself from participating in discussion and decision-making about those proposals.

When a researcher (staff member or student) has an interest in the research over and above the ordinary expected research interest, he or she must disclose this and indicate how he or she plans to manage the conflict of interest.

In all cases and in line with the educative and facilitative role of the committee, the REC may invite those persons who have declared a conflict of interest to attend the meeting to answer questions for clarification but such persons will be requested to leave the meeting for the discussion and decision-making relating to the research proposal in which he or she has the conflict of interest.

## **C2. Filming or recording**

Consent documents must explain clearly and explicitly that visual or audio recording is desired. Participants must be requested to give permission for this to happen, i.e. not just be told that it will happen. If publication of research data is likely and it can be reasonably foreseen that pictures or other examples of visual media would be included, then this must also be explained and specific permission for such publication should be sought, having explained the possible harms that might flow from such publication.

## **C3. How does confidentiality differ from anonymity?**

Confidentiality concerns that data that are collected. The privacy interest of the participant must be protected by ensuring that data are kept securely so that persons not involved with the research are not able to find out the participant's identity.

**Anonymity** is part of research design – nobody can identify the source of the particular data, not even the researcher. **Anonymising**, on the other hand, is the process of removing

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identifying detail so that data cannot easily be linked to participation. This process is commonly used in research in order to protect the privacy and confidentiality interests of participants. Furthermore, sometimes it may be necessary to retain the means to link data to participants. In instances of anonymising, care must be taken to keep the key to re-linking separately and securely so that 'unauthorised' persons are not able to gain access.

Certain types of data collection methods require good confidentiality measures, including audio recordings, demographic data including descriptions of a small category (e.g. a white female Dean at UCT), qualitative studies of few participants with highly individual information, and the use of random identity numbers on participants' data with a separate name/number list.

Researchers must protect confidentiality of data gathered during research to protect the integrity of the research, the privacy of the research participants and to protect sensitive information obtained in research, teaching, practice and service. Information obtained in the course of research that may reveal the identity of a participant, is confidential unless the participant agrees to its release. Agreement to release of personal information should be sought only when the participant is properly informed about possible harms that may occur.

Confidential information provided by research participants, employees, clients or others must be treated as confidential even if there is no legal protection or privilege. The obligation to maintain confidentiality extends to members of the research or training teams and collaborating organizations who have access to the information. To ensure that access to confidential information is restricted, the principal researcher is responsible for ensuring that researchers, administrators and other relevant parties adequately trained and instructed to take the steps necessary to protect confidentiality.

When gathering confidential information, long-term uses thereof, including its potential placement in public archives or examination thereof by other researchers or practitioners, must be considered. Some information is permanently embargoed, i.e. it may not be released in public at all; other information is partly embargoed, i.e. the actual data may not be made public but may be indexed or analysed to show trends.

Guarantees of complete confidentiality should not be given lightly. In certain circumstances, statutory obligations to report e.g. child abuse, sexual abuse, etc will override a guarantee of confidentiality. See below.

It cannot be assured that other participants in a focus group will maintain absolute confidentiality. However, confidentiality can be encouraged by requesting focus group participants to sign a pledge of confidentiality as part of the consent process for participation.

Anonymity can be ensured by appropriate design of the project, i.e. data can be collected without identifiers. Research reports can preserve anonymity by properly disguising the identity of participants and their localities.

#### **C4. Informed consent**

Participants must give informed consent prior to participating in research as a matter of ethics. Consent does not have to be in writing but the information given to the prospective participant



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to help him or her decide whether to participate should be in writing. Exceptions might include an invitation to participate in a simple survey that elicits only a small uncomplicated amount of information.

Prospective participants must be able to choose voluntarily, free from undue influence or subtle pressure, whether to participate. In particular, researchers should recognize the possibility of pressure that may derive from researchers' expertise or authority and should take this into account when designing participant information and consent documentation.

Informed choosing can occur only when researchers explain, in language understandable to the potential participants, the nature of the research and what will be expected of them; that they will participate in research; that they are free to choose to participate or to decline to participate; that if they choose to participate, they are free to withdraw from participation at any time without reason or consequent penalty; what nature and risk of harm are likely to occur, e.g. discomfort, emotional upset or trauma; what limitations on confidentiality might exist, e.g. in focus groups, because of statutory reporting obligations or because of social stigma; what benefit participation is likely to bring to the participants; and any other aspect about which a participant ought to enquire.

The objective is to place the potential participant in a position where he or she can make a responsible choice about whether to participate. The standard for disclosure is one of reasonableness and fairness so that foreseeable consequences of participation can be discussed before the participant is enrolled. The prospective participant should be permitted sufficient time to consider his or her choice, including time for consultation with others e.g. where the proposed research is sensitive or complicated.

#### **C5. Mandatory reporting obligations for researchers**

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 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 dilemma for researchers wishing to investigate minors' sexual activities is whether they ignore the strict letter of the law or report as indicated. The clash is obvious: legal protection of the minor may lead to social harm for that minor and the question is whether a researcher, who has but a transient role in the life of the minor, ought to take on the responsibility of a social worker.

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 ethics clearance application must explain fully how the researcher plans to deal with the obligation to report, so that the REC is able to deliberate effectively.

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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.

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

## **C6. Minors in research**

Important and necessary research is being conducted throughout the country using minors as participants. In principle, minors cannot give informed consent because they are legally incapacitated. Consequently, parental or guardian permission is required. Many of the minors under consideration do not have parents and very few have a court-appointed guardian, but socially relevant and important research is proposed, e.g. with street children or children orphaned by AIDS. Other times, research may be possible only if minors are permitted to agree independently to participate i.e. without the direct and specific permission of a parent or 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 come into effect, it may be well-nigh impossible to enrol minor participants in research using current informed consent processes. In the meanwhile however, 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

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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.

### ***C6.1 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.

### ***C6.2 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 whether 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 or not. If the child is reluctant, this must be respected. No child should be forced into participation.

The Informed consent documentation must explain out to parents that their *permission* is sought to approach the child to request participation and 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.

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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.

### **C6.3 Pragmatic guideline**

The guideline<sup>1</sup> 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](http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/index.html) (currently under revision); the South African Good Clinical Practice Guidelines (2006) available at [www.doh.gov.za/docs/gactsheets/guidelines/clinical/2006/index.html](http://www.doh.gov.za/docs/gactsheets/guidelines/clinical/2006/index.html). [It may 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](http://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 under 18 years but over 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.

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<sup>1</sup> This pragmatic guideline was drafted for and accepted by the HSRC REC. It is currently in use with a number of other RECs in South Africa too.

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- 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 may be preferred that minors (especially older minors i.e. 16 years and older) **consent independently, i.e. without parental assistance**. However, researchers may not simply decide this and implement the preference.

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](http://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.** In addition, researchers must be mindful of the reporting obligations – see below.

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### **For minors under 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. Minors must decide whether to participate, i.e. parental permission cannot override the minor's decision not to participate.

### **C7. Raising concerns**

Anyone who has concerns about research being carried out currently or planned or who wishes to raise any queries, should communicate with a member of the research ethics committee. Confidentiality is respected and, where possible, anonymity prevails.

### **C8. What happens if unexpected problems arise during research?**

Ethics clearance is granted on the understanding that any unanticipated problems and risks, changes to the research plan, or any harm (social, psychological, physical or legal) must be reported to the research ethics committee. It may become necessary to amend the research proposal, to stop the research because of ethics violations (i.e. to withdraw clearance) etc. Principal or lead researchers must bear in mind that they remain responsible for the integrity of the research process and may be held responsible for failure to act appropriately.

### **C9. Who must report problems in the course of research?**

The principal or lead researcher (and in the case of student research the supervisor or convenor) must report promptly any non-compliance with university policies, especially those regarding responsible conduct of research.