HUMAN SCIENCES RESEARCH COUNCIL
RESEARCH ETHICS COMMITTEE
TERMS OF REFERENCE

1. Introduction

In August 2002, the Board (the governing body) of the Human Sciences Research Council (hereafter referred to as HSRC) established a research ethics committee. The function of this committee is to promote research ethics and research integrity in the organization, including the ethics review of research proposals. The HSRC Research Ethics Committee (hereafter referred to as REC) (international equivalent titles: Institutional Review Board, Independent Ethics Committee) is mandated to fulfil its function by the Board of the HSRC.

The HSRC REC has **US Office of Human Research Protections** Federal Wide Assurance accreditation (FWA 00006347, IRB No. 00003962).

2. Terms of Reference

2.1 The HSRC Research Ethics Committee was established with the primary purposes of:

- reviewing and monitoring research proposals and practices in the HSRC from an ethical perspective;
- promoting respect for human rights in research, as well as ethical values and research integrity, both within the HSRC and within the broader social sciences community in South Africa.

2.2 The essential function of the committee is to review the protocols of all research projects involving human participants, including health-related projects, proposed to be undertaken by members of staff of the HSRC. The purpose of this review is the protection of the dignity, rights, safety and well-being of all human participants of research. Special attention will be paid to research that may include vulnerable participants.

2.3 The committee is available to review, advise on, and approve or reject research protocols involving human participants within the borders of South Africa submitted to it by researchers in any Province in the Republic of South Africa or internationally who are not members of staff of the HSRC.

2.4 The National Health Act (Act 61 of 2003) establishes a National Health Research Ethics Council within the South African National Department of Health and mandates that every institution, health agency and health establishment at which health research is conducted must establish or have access to a research ethics committee (REC) registered with and accredited by the National Health Research Ethics Council. The HSRC's REC is the appropriate body to be accredited with the National Health Research Ethics Council of the South African National Department of Health.

2.5 The HSRC's REC, once accredited in terms of this Act, will be empowered to take disciplinary steps against researchers who violate either national or the HSRC's own ethics guidelines. Any social or health-related research which requires participant protection conducted by an HSRC staff member without prior ethics approval will also be regarded as a research ethics transgression necessitating action by the committee.

2.6 The committee will review and refer complaints of any research ethics transgression and / or research-related misconduct by HSRC staff members and other researchers on projects where protocols have been approved by the committee. Reports of alleged unethical practices by HSRC research staff in the course of field research approved by the REC may be reported by members of the public on a dedicated toll-free HSRC ethics hotline.

2.7 The REC requires notification of adverse events and serious adverse events that occur at research sites as they happen (within 7 working days of occurrence).

2.8 The REC requires notification of protocol deviations or protocol violations with a minimum of delay.

2.9 The REC may conduct monitoring of approved research with or without advance notification to the Principal Investigator, provided that on arrival at the site the monitor furnishes the researchers on duty with proof of identification and REC mandate.

3. Code of Ethics

The overarching ethics guidance for the HSRC will be the (2004) National Department of Health *Ethics In Health Research: Principles, Structures And Processes.* For clinical trials, the National Department of Health (2006) *South African Good Clinical Practice Guidelines* will apply. Where relevant, the SA MRC Guidelines and major international guidance documents such as the CIOMS guideline, the most recent version of the Declaration of Helsinki and the UNSECO guidelines might apply.

3.1 In May 2006 the HSRC adopted a Code of Ethics in which the HSRC Board members and employees commit themselves to a code of ethical behaviour that accords with the HSRC's status, values, principles and obligations. The purpose of the Code is to promote good governance by establishing a set of ethical values and standards that are consistent with the objects and vision of the HSRC, as well as with its constitutional and legal framework, and that are binding on Board members and all employees.

3.2 The ethical values that guide the HSRC's conduct include: professional excellence, non-partisanship and independence, non-discrimination, honesty and integrity, respect, fairness and collaboration.

3.3 The ethical standards are designed to ensure that all research conducted by or on behalf of the HSRC must uphold the highest ethical standards including respect and protection of confidentiality; transparency; scientific and academic professionalism; and accountability and responsibility. The Board adopted, and may revise from time to time, on the advice of the HSRC Research Ethics Committee, a detailed Code of Research Ethics which is binding upon all HSRC employees who undertake research activities.

3.4 It is the responsibility of the relevant HSRC researchers to ensure that persons or organisations who undertake research in collaboration with the HSRC comply with acceptable ethical research standards in such collaborative work.

4. Governing principles

The HSRC REC adheres to the following broad principles:

- Standardised and transparent procedures

- Holds regular meetings
- Avoids conflicts of interest of members
- Provides an appeal procedure
- Reports to the HSRC Board
- Helps and not hinders research.

5. Membership

5.1 Members (including an international ethics advisor) are appointed by the CEO in consultation with the Chairperson of the Board by means of nominations and co-option. This is submitted to the Board for ratification. The external members and HSRC representatives serve for a three-year term of office subject to annual confirmation, and may make themselves available for further three-year periods.

5.2 At least three members of the committee should be external to the HSRC, including:
- A person with broad expertise in human rights, particularly relating to the rights of children, women, the elderly and other vulnerable groups;
- A person with a strong background in ethics;
- A community representative with an informed interest in the social sciences.

5.3 Other REC members are internal to the HSRC, and are selected as follows: One researcher from each research unit (where appropriate) nominated by his/her Executive Director (ED) to be a member, with the possibility of one or more alternates available from each research unit to share the load of attendance at meetings and reviewing. Of the unit representatives, one must be a Chief Research Specialist or above, the other a specialist at any level.

5.4 Chairperson and Vice-chairpersons: The Chairperson and one Vice-chairperson of the committee should preferably be external members and the other Vice-chairperson a member of the HSRC.

5.5 The CEO ensures that representation across the units provides coverage of the disciplines and methodologies of the human and social sciences.

5.6 The committee endeavours to achieve gender and racial proportions among members at least equivalent to the research staff in the HSRC and as required by the Health Act related guidance for accredited RECs

5.7 The committee has powers to co-opt external individuals or HSRC researchers with specialised knowledge if the expertise of the standing committee is considered to be lacking specialized experience for a given task.

5.8 The external members of the REC are remunerated in accordance with Board-approved HSRC policies

6. Appeals

The CEO is not a member of the Research Ethics Committee, since a researcher wishing to contest a decision made by the REC would appeal to the CEO. In such cases, the CEO may refer the case to another organisation's accredited Research Ethics Committee for a second opinion before providing his/her ruling.

7. Standard operating procedure

7.1 The REC meets every month (except December and January) with a quorum of five people including the Chair. Those present must include the members who have previously been assigned by the Chairperson to review any particular submission for that meeting.

7.2 The committee will make available to its members a comprehensive checklist (revised from time to time) to guide the reviewers in their decisions. The checklist will also be available to researchers making submissions.

7.3 Researchers must submit written applications for ethics clearance on a prescribed form, writing to specified length and providing stipulated supporting documents (research protocol, information sheet, informed consent, questionnaire, etc).

7.4 The committee, after considering inputs from the reviewers of a submission, would make one of four decisions by consensus: approval; require minor amendments; require major amendments; rejection.

7.5 Proposals requiring minor amendments may be approved outside the meeting by a subcommittee comprising the Chairperson or Vice-chairperson, with additional reviewers where necessary and noted/ratified at the next meeting. Proposals requiring major amendments are resubmitted to the full committee. Rejected submissions may be re-submitted for fresh review by the full committee.

7.6 At the discretion of the Chairperson, and subject to their observing the confidentiality of the meeting, applicants may attend to clarify points of issue but they are not part of the decision making.

7.7 Committee members whose applications are being discussed must declare their interests in such applications and recuse themselves for that part of a meeting or by invitation of the committee may remain present to provide points of clarification. They are not part of the decision making.

7.8 Although it is mandatory that all research with human participants conducted by HSRC researchers must be ethically approved before data collection commences, the REC has processes in place to expedite the approval of certain types of research:

- The committee grants exemption from ethics review of research that meets the exemption criteria, for example reviews and analyses of data or material that is freely available in the public domain, and conference commissions (except where they involve primary research).
- Where appropriate research, which is an extension of a study already approved by the REC, may qualify for a class approval.
- Provision is also made for fast-tracking the approval of urgent applications by contacting the Chairperson through the REC administrative officer or directly.

7.9 If a protocol is deemed to be a clinical trial the following procedure applies:

(i) Institutional registration is in place to meet the statutory requirement to register clinical trials with the South African National Clinical Trials Registry. (See www.sanctr.gov.za). The HSRC REC Administrative Officer serves as central contact point. Applicants are therefore not required to register but simply to log in, using general username and password.

(ii) Steps in the registration process of a clinical trial are as follows:

a. Finalise contract negotiations and project planning
b. Complete the national trials register application form. Do not register as a new user, simply log in as HSRC user at www.ethicsapp.co.za, the username is hsrc, password rehsrc. A unique application number will be generated by the NHREC (South African National Human Research Ethics Council) system.
c. Apply for ethics clearance with HSRC REC. Submit a print-out of the form completed at www.ethicsapp.co.za and the unique application number as generated, together with all other documents required for HSRC research ethics application.
d. Once clearance has been obtained from the HSRC REC, a unique HSRC reference number will be provided by the HSRC REC administrative officer.
e. Using the NHREC application number, as well as the HSRC ethics reference number, the trial can now be registered on the SANCTR (South African National Clinical Trials Register) site utilising the SANCTR Toolkit - (www.sanctr.gov.za).
f. The National Department of Health will then issue a National Register Number.
g. This number must be forwarded to the HSRC administrative officer for reference.

(iv) The REC Administrative Officer provides the relevant support / passwords after the HSRC REC has granted clearance, to facilitate (e)

7.10 Provided there is no more suitable or eligible REC in South Africa and subject to capacity, certain terms and conditions, the HSRC's REC (which has FWA accreditation) may conduct ethics review of external proposals submitted by researchers not employed by or contracted to the HSRC. In such instances, the ethics review is undertaken according to approved conditions. A predetermined fee is payable.

7.11 The HSRC REC will, where applicable and on request, consider reciprocal recognition of research ethics committees at other institutions such as universities and other science councils, in order to facilitate ethics clearance of projects, for example joint projects or advice on appeals to the CEO.

7.12 An administrative officer is assigned to spend part of his/her time on supporting the work of the REC. The officer

- receives applications and assigns REC numbers to protocols,
- checks that applications are complete and signed,
- compiles and distributes agenda packs, including applications and supporting documents, one week before a meeting,
- is in attendance at the monthly meetings and compiles detailed minutes of the discussions and evaluation of applications,
- provides written feedback to applicants within two weeks of each REC meeting,
- is in frequent contact with the Chairperson regarding the assignment of protocols to members for reviewing, follows-up on revisions to applications, applications for expedited review, applications that qualify for exemption from ethics review, and related matters,
- provides feedback to applicants on the approval process,
- administers requests for renewals and amendments by referring them to the Chairperson,

- assists the Chairperson with the annual REC report,
- administers HSRC REC accreditation with the SA NHREC and US OHRP, and
- keeps records.

7.13 Functions of the Chairperson include approving proposals that do not require substantial review, allocating each proposal to at least two members of the committee besides him/herself for detailed review, granting exemption from review where appropriate and arranging expedited reviews in exceptional circumstances.

7.14 The reviewers assigned to a submission ideally represent a mix of suitable skills, race and gender.

7.15 The overarching ethics guidance for the HSRC will be the (2004) National Department of Health *Ethics In Health Research: Principles, Structures And Processes.* These guidelines will be adapted, in time, for a social science environment.

8. Annual reports

The Chairperson of the committee is responsible for an annual report to the Board of the HSRC, at its May meeting, covering membership, activities during the previous financial year, summary statistics and other relevant matters. A brief version of the report is included in the HSRC's Annual Report.

9. Other matters

9.1 All committee members must receive initial and ongoing training in research ethics and committee work. Training is a standing item on every meeting agenda.

9.2 While the HSRC Board in principle retains its authority to amend or reverse any REC decision in terms of powers granted to the Board, such actions will be exceptional with the default being that the independence of the REC will be respected and maintained.

9.3 Members of the HSRC REC are accorded indemnity by the Board for legal action, for example, consequent upon their decisions.

9.4 With the consent of the Chairperson, observers are permitted to attend REC meetings for training or related purposes, provided that appropriate confidentiality forms are signed.