

4. ETHICS COMMITTEES

An established research ethics committee must review and approve all research proposals involving human participants. This section details requirements for institutions in establishing an ethics committee, researchers in submitting research proposals and ethics committees in considering, reviewing and monitoring research proposals and projects.

- The primary role of a research ethics committee is to protect the rights and welfare of research participants. The primary responsibility of each member is to decide, independently, whether in his or her opinion the conduct of proposed research will so protect participants.
- Institutions or organisations that undertake research involving human participants should ensure there are adequate resources to establish and maintain an ethics committee in accordance with the prescripts outlined in this document.
- Terms of reference must be set out by the institution or organisation when establishing an ethics committee. Terms of reference must include the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms for reporting and remuneration, if any, for members.
- The institution or organisation must accept legal responsibility for the decisions and advice received from the research ethics committee and indemnify the ethics committee's members.
- Researchers without affiliation to an institution or organisation with a research ethics committee must ensure that their projects are approved by an established ethics committee.

4.1 Composition

The research ethics committee should consist of members who, collectively, have the qualifications and experience to review and evaluate the science, health aspects and ethics of the proposed research. Research ethics committees should be independent, multi-disciplinary, multi-sectoral and pluralistic.

A research ethics committee must:

- Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa;
- Include members of both genders, although not more than 70% should be either male or female;
- Have at least nine members, with 60% constituting a quorum;
- Have a chairperson;
- Include at least two lay persons who have no affiliation to the institution, are not currently involved in medical, scientific or legal work and are preferably from the community in which the research is to take place;
- Include at least one member with knowledge of, and current experience in, areas of research that are likely to be regularly considered by the ethics committee;
- Include at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker or nurse);
- Include at least one member who has professional training in both qualitative and quantitative research methodologies;
- Include at least one member who is legally trained.
- The institution or organisation must ensure that the membership is equipped to address all relevant considerations arising from the categories of research likely to be submitted to it.

The research ethics committee must ensure that it is adequately informed on all aspects of a research protocol, including its scientific and statistical validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document.

4.2 Appointment of Members

The institution or organisation must determine procedures for recruitment and of appointment to the research ethics committee.

Members must be given formal notice of appointment and assurance that the institution or organisation will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of their duties as committee members.

4.3 Procedures

Research ethics committees should establish and record working procedures concerning:

- Frequency of meetings;
- Preparation of agenda and minutes;
- Distribution of papers prior to meetings;
- Presentation of research protocols;
- Presentation of all documents and other materials used to inform potential research participants;
- Quorum and methods of decision-making;
- Requirements for submission of research projects for ethical approval;
- Registration of applications;
- Timely review and notification of decisions;
- Written notification of decisions to researchers;
- The recording in writing of decisions made by the Committee and reasons for decisions;
- Confidentiality of the content of the protocols and of a committee's proceedings
- Reporting of adverse events;
- Reporting of amendments to protocols;
- Access to documents;
- Regular monitoring;
- Complaints procedures;
- Procedures for easy and adequate access to members of ethics committees;
- Fees charged, if any;
- End-of-trials review.

The ethics committee may approve, require amendment to, or reject a research proposal on ethical grounds. The ethics committee must record decisions in writing and should include reasons for rejection. A research ethics committee's feedback should be structured so as to be instructive to the researchers concerned. Researchers should be made aware that their statement of ethical considerations should not be a rote checklist but a real engagement with ethical issues.

In considering a research protocol, a research ethics committee may seek assistance from experts, but the committee must be satisfied that such experts have no conflicts of interest in relation to the research project under consideration.

A research ethics committee must ensure that no member of the committee adjudicates on research in which that member has any conflict of interest in relation to the research project under consideration.

A researcher must disclose to the research ethics committee the amount and sources, or potential sources, of funding for the research and must declare any affiliation or financial interest when proposing and when reporting the research.

A research proposal must include a statement of the ethical considerations involved in the proposed research. An ethics committee must be satisfied that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage.

Researchers' proposals for health research to be conducted in community settings must include a clear plan on how the communities will be consulted or involved in the research process, and how, in general, they are to be kept informed.

Communication between research sponsors and ethics committees should be directed through the Principal Investigator. In some situations, particularly in the private sector, the Principal Investigator may be an employee of the sponsoring company or of a clinical research organisation. All documents and other material used to inform potential research participants should be approved by the ethics committee, including plain-language information sheets, consent forms, questionnaires, advertisements and letters.

Research ethics committees must ensure that their members receive initial and continued education in research ethics and science, and are kept aware of current issues and developments in the broad area of ethics and science

4.4 Advocacy Role and Interpreters

Advocacy: An ethics committee must consider whether persons playing an advocacy role for any participant or group of participants should be invited to the ethics committee meeting to ensure informed decision-making and understanding by these participants.

Interpreters: Where research involves the participation of persons unfamiliar with the language in which the research is to be conducted, a research ethics committee must ensure that:

- The participant information statement has been translated into the participant's language;
- It is the investigator's responsibility to ensure that the participant understands the participant information statement;
- An interpreter is present during discussions with the participants about the project. As a rule the interpreter should be independent, but when the research proposal is of minimal risk, a relevant language-speaking relative or friend of the participant may be acceptable.

4.5 Expedited Reviews for Maximal Public Benefit

A research ethics committee may establish procedures for expedited review of research when this is in the public interest, and in so doing, determine the class or classes of research to which an expedited review procedure is to apply. Expedited review and approval may be considered for research where participants have a disease that may be rapidly fatal.

In general, research with potential to cause physical or psychological harm should not be considered for expedited review. This includes drug trials, research involving invasive procedures and research involving sensitive personal or cultural issues.

4.6 Recording of Decisions

A research ethics committee shall maintain a record of all research protocols received and reviewed including the:

- Name of responsible institution or organisation;
- Project identification number;
- Principal investigator;
- Title of the project;
- Date of ethical approval or non-approval;
- Approval or non-approval of changes to the protocol;
- Approval or non-approval of changes to the information sheets and informed-consent forms;
- Approval or non-approval of changes to advertising materials, letters and notices;
- Complaints from researchers whose protocols were not approved;

- The terms and conditions of approval of any protocol;
- Whether approval was by expedited review;
- Whether the opinion of another ethics committee was considered;
- Action taken by the ethics committee to monitor the conduct of the research.

For multi-centred research proposals, the ethics committee shall also record, from information provided by the investigator:

- Details of other centres involved
- The approval status of the study at each centre;
- Details of any amendments required at other centres.

An ethics committee shall retain on file a copy of each research protocol and application submitted to it for approval. The file shall include information sheets, consent forms and relevant correspondence, all in the form in which they were approved. A list shall be kept of committee members who were present during discussion of the application and when the final decision of the committee was reached.

4.7 Monitoring

A research ethics committee has the responsibility to ensure that the conduct of all research approved by the ethics committee is monitored. The frequency and type of monitoring should reflect the degree of risk to participants in the research project.

A research ethics committee must request at regular periods, at least annually, reports from the principal investigator on matters including:

- Progress to date, or outcome in the case of completed research;
- Information concerning maintenance and security of records;
- Evidence of compliance with the approved protocol;
- Evidence of compliance with any conditions of approval.

Research ethics committees should inform the principal investigator, in writing, of decisions made after the review of progress reports.

A research ethics committee may recommend and adopt any additional appropriate mechanism for monitoring, including the random inspection of research sites, data and signed consent forms, and records of interviews, with the prior consent of research participants.

As a condition of approval of each protocol, a research ethics committee shall require that researchers immediately report anything that might warrant review of ethical approval of the protocol, including:

- Serious or unexpected adverse effects on participants;
- Proposed changes in the protocol;
- Unforeseen events that might affect continued ethical acceptability of the project.

A research ethics committee, as a condition of approval of the research proposal, may require researchers to inform the committee, giving reasons, if the research project is discontinued before the expected date of completion.

4.8 Complaints

- Each research ethics committee should establish complaints procedures.
- Any person has the right to forward a complaint to the National Health Research Ethics Council, if the response of the local Ethics Committee is considered inadequate.
- The National Health Research Ethics Council in collaboration with Ethics Committees should develop a policy to protect whistle-blowers, these are researchers who have identified unethical behaviours on the part of colleagues and divulge such information in good faith. The National Research Ethics Council will develop guidelines for “whistleblowers”.

4.9 Suspension or Discontinuation of Research

Where a research ethics committee is satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the research ethics committee may withdraw approval. The research ethics committee shall also inform the researcher and the institution or organisation of its action, and shall recommend that the research project be discontinued or suspended, or that other appropriate steps be taken.

Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the ethics committee.

4.10 Compliance Reports to the National Health Research Ethics Council (NHREC)

The National Health Research Ethics Council will be responsible for auditing the activities of research ethics committees to ensure their compliance with this document. All research ethics committees must be registered with the National Health Research Ethics Council, and must provide a list of their members, before considering any research protocol.

An institution or organisation and its ethics committee shall open its records to the NHREC on request.

An institution or organisation and its ethics committee shall report annually to the NHREC information relevant to its procedures, including:

- Membership and membership changes;
- The number of meetings held;
- Confirmation of participation by required categories of members;
- The number of protocols presented, the number approved and the number rejected;
- Monitoring and related problems;
- Complaints procedures and number of complaints received and handled.