health
Department:
Health
PROVINCE OF KWAZULU-NATAL

KWAZULU-NATAL DEPARTMENT OF HEALTH

UMGUNGUNDLOVU HEALTH ETHICS REVIEW BOARD (UHERB)

REC-051010-026

TERMS OF REFERENCE (TORs)

Contents

1. PURPOSE

The uMgungundlovu Health Ethics Review Board hereafter referred to as "UHERB" (is mandated to fulfil its function by the KwaZulu-Natal Department of Health (KZNDOH). UHERB was established in accordance to Section 73 of the National Health Act (NHA) and according to the DoH 2015 Guidelines.

The essential purpose of UHERB, as a recognised ethics committee (REC), accredited by the National Health Ethics Council (NHREC), is to protect the dignity, rights, safety, and well-being of all human participants in health-related research undertaken in public health institutions in the province.

UHERB will also examine the scientific rigor of health related research being undertaken in public health institutions in the Department.

UHERB will be review research application involving human participants, and studies which are low and medium risk only. Proposals will be subject expedited ethics review and full ethics review, whilst certain proposals will be granted exemption from review (Refer to S.O.P)

2. SCOPE OF UHERB

UHERB will conduct independent, prospective and ongoing ethics review of all health research projects undertaken by members of staff of the KwaZulu-Natal Department of Health (KZN DoH) which are not for academic purposes except for those emanating from training centres or academic institutions affiliated to the KZN DOH. The Chair of UHERB, in consultation with the committee may assist the DOH in adjudicating complaints of research ethics transgressions and/or research misconduct by staff or other researchers whose protocols have been approved by UHERB. Any health sciences related research, which requires participant protection and is conducted by a researcher without prior ethics approval will also be regarded as an ethics transgression.

3. RELATIONSHIP TO NON-AFFILIATED RESEARCHERS

Researchers with no affiliation to the Department of Health will not be able to approach UHERB to ethically review and approve their health-related research proposals except those applications that require ethical approval from a REC that is accredited by the NHREC for purposes of applying to the KwaZulu-Natal Provincial Health Research and Ethics Committee (PHREC).

4. ACCOUNTABILITY AND RESPONSIBILITY

The UHERB committee will report to the Chairperson: Provincial Health Research and Ethics Committee, who will in turn report to the Head of Department (HOD) KwaZulu-Natal Department of Health. The institutions shall access UHERB information on ethical clearance, and documents required on the research ethics process on the UHERB webpage of the KwaZulu-Natal Department of Health website.

5. INSTITUTIONAL REQUIREMENTS

The UHERB shall follow the norms and standards set by the NHREC to facilitate best research practice, and will be registered with the National Health Research Ethics Council (NHREC).

6. COMPOSITION OF THE UHERB COMMITTEE

The composition of UHERB will be in accordance with the provisions of the (Department Of Health Ethics In Health Research: Principles, Structures and Processes 2015). These include:

I. Members of UHERB should collectively have the qualifications, experience and expertise to review and evaluate the scientific, medical, legal, psychosocial and ethical aspects of research proposals.

II. Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa and the KwaZulu-Natal DOH;

III. Have at least 9 members, with a simple majority constituting a quorum;

IV. Include members of both genders;

V. Include at least one lay person who have no affiliation to the DOH, is not currently involved in medical, scientific or legal work and is preferably from the community in which the research is to take place;

VI. Include at least one member with knowledge of, and current experience in, areas of research that are likely to be regularly considered by UHERB;

VII. 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;

VIII. Include at least one member who has professional training in both qualitative and quantitative research methodologies;

IX. Include at least one member who is legally trained.

X. Ensure that the membership is equipped to address all relevant considerations arising from the categories of research likely to be submitted to it.

XI. 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.

XII. Have a chairperson

XIII. Elect a deputy (or persons) from the members of the committee

7. MEMBERSHIP OF THE UHERB COMMITTEE SHALL

- Appointment to the Committee will be by nomination by the chairperson of the Provincial Health Research Ethics Committee (PHREC) and co-option by the UHERB's chairperson.
- The Chair of UHERB is appointed by the Chair of PHREC for a renewable term of 4 years.
- The Chair of UHERB reports to the Chairperson of the Provincial Health Research Ethics

Committee.

- Any unanticipated problems involving risks to participants or others or any serious or continuing non-compliance with this document or the requirements or determinations of UHERB and any suspensions of UHERB approval will be reported to the Chairperson of the Provincial Health Research Ethics Committee.
- Members not attending two consecutive meetings without a valid written reason, and without submitting their reviews, risk termination of their membership of UHERB
- UHERB members will serve for a term of 4 years, which could be renewed.
- UHERB members will be required to have continuous personal development in research ethics.
- UHERB may co-opt expert members and other representatives as voting members as required by particular protocols. Voting status is to be confirmed by UHERB in advance on a case-by-case basis.
- On invitation or request, UHERB meetings may be attended by *bona fide* students, researchers and other interested parties as non-voting observers, subject to the signing of confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair.
- A researcher may be requested to attend a convened UHERB or subcommittee meeting to provide information on any aspect of the study but may not participate in the vote or decision making of the Committee.
- UHERB may consult with and/or invite non-members with expertise in special areas to convened UHERB or subcommittee meetings.
- UHERB reserves the right to develop policy documents to provide for any complexity in research-related ethical issues as they develop.

- UHERB will perform its functions according to these UHERB Terms of Reference and Standard Operating Procedures (SOPs) and will maintain written records of its activities and minutes of its meetings and will comply with National Guidelines and applicable regulatory requirements.
- This document will be reviewed and updated every 4 years or as required.
- UHERB members will not be compensated for their work done as part of UHERB. However, they will be compensated by the Department (Under the budget of Health Service Planning, M&E) for their travel expenses to and from meetings.

Changes in UHERB membership will be reported to the SA National Health Research Ethics Council (NHREC).

8. UHERB MEETINGS

Meetings will be held once a month on the first Thursday of every month for 11 months of the year from February to December. Members will be notified annually of the scheduled dates no later than the fourth week of January. The minutes of meetings and the agenda will be circulated to members at least 7 days prior to the meeting. The Chairperson may call a special meeting at any time. A schedule of meetings will be placed on the UHERB web page by the 4th week of January each year. The chairperson of the UHERB may call a special meeting if and when the need arises (Refer to S.O.P).

9. CONFLICT OF INTEREST

UHERB members shall declare any prior interest and/or involvement in any matter being discussed by UHERB to avoid conflict of interest in UHERB decision-making, including reviewing of protocols. In convened UHERB meetings, the Chair shall determine whether the member be recused for items of discussion, or be allowed to remain and address questions when asked to do so, but not vote or participate in final decision-making on the matter in question. (Refer to SOP).

10. CONFIDENTIALITY

"Confidential Information" shall mean certain proprietary, personal, clinical or protocol- specific information, which the UHERB member acknowledges to be confidential. Such information includes all protocols relating to research with human participants and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software. All UHERB members and support staff shall sign a standard confidentiality agreement on appointment to UHERB (see Appendix C).

11. QUORUM

The Committee will make its decisions at scheduled or extraordinary meetings with or without a quorum. The quorum of the committee will be made up of a simple majority. Decisions taken at a quorate meeting will be effective immediately. However, decisions taken at an inquorate meeting will be rectified and acted upon at the next quorate meeting.

12. VOTING

Decisions will be determined by consensus (general agreement).

Where general agreement does not exist, consensus will be undermined and the decision will be arrived at by vote.

Minutes taken at UHERB meetings will be of sufficient detail to show attendance at the meetings; actions taken by UHERB; if applicable, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of disputed issues and their resolution.

Members who declare conflict of interest on a matter will not be allowed to vote on the matter.

13. COMPLIANCE

The UMgungundlovu Health Ethics Review Board functions in compliance with

- National Health Act (NHA) of the Republic of South Africa
- The SA Department of Health Ethics in Health Research: Principles, Structures And Processes (2015) And South African Good Clinical Practice Guidelines (2006).
- Declaration of Helsinki (Current version)
- The Belmont Report

Changes in UHERB Terms of Reference, Standard Operating Procedures and membership will be reported to the SA National Health Research Ethics Council (NHREC).

14. SELECTED REFERENCES:

1. Council for International Organizations of Medical Sciences (CIOMS) (2002). *International ethical guidelines for biomedical research involving human subjects.* Geneva: Author.
2. Department of Health (2015). *Ethics in health research: Principles, structures and processes.* Pretoria: Author.
3. Department of Health (2006). *Guidelines for Good Practice in the conduct of clinical trials with human participants in South Africa*. (*South African Good Clinical Practice Guidelines).* Pretoria: Author.
4. Department of Health, Education, and Welfare (1979). *Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. Report of the National Commission for the protection of human subjects of biomedical and behavioral research*. Washington: Author.
5. Medical Research Council: (2000). *Guidelines on ethics for medical research:*

General principles. Cape Town: Author.

6. Medical research Council: (2003). *Guidelines on ethics for medical research: HIV preventive vaccine research.* Cape Town: Author.
7. Nuffield Council on Bioethics (2002). *The ethics of research related to healthcare in developing countries.* London: Author.
8. Nuffield Council on Bioethics (2005). *The ethics of research related to healthcare in developing countries. Follow-up discussion paper.* London: Author.
9. UK Research Integrity Office (2008). *Procedure for the investigation of misconduct in research.* London: Author.
10. UNAIDS (2000). *Ethical considerations in HIV preventive vaccine research*. Geneva: Author UNAIDS (2007). *Ethical considerations in biomedical HIV prevention trials: UNAIDS/WHO Guidance document*. Geneva: Author.
11. UNAIDS (2007). *Good participatory practice guidelines for biomedical HIV prevention trials.* Geneva: UNAIDS/AVAC. US Federal Regulations: 45 CFR 46. Available from http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
12. World Health Organisation (2000). *Operational guidelines for ethics committees that review biomedical research.* Geneva: Author.
13. World Medical Association: (2008). *World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects*. Geneva: Author.