UMGUNGUNDLOVU HEALTH ETHICS REVIEW BOARD (UHERB)

COMPOSITION

The composition of UHERB will be in accordance with the provisions of the Department of Health *Ethics in health research: Principles, structures and processes* (2004) and *South African Good Clinical Practice Guidelines* (2006). These include:

- 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.

- Appointment to the Committee will be by nomination and co-option. The total number of Committee members must be no less than 10.

- The Chair of UHERB is elected by the committee for a renewable term of three years.

- The Chair of UHERB reports to the District manager of Umgungundlovu Health District.

- 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 District Manager of Umgungundlovu Health District

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

2.1 Membership of the UHERB committee shall:

- Be representative of the communities it serves and, increasingly, reflect the demographic profile of the population of South Africa and the Umgungundlovu Health District;

- Have at least 10 members, with a simple majority constituting a quorum;

- Include members of both genders, although not more than 70% should be either male or female;

- Include at least two lay persons who have no affiliation to the DOH, 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 UHERB;

- 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.

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

- 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.

- Have a chairperson

- Elect a vice-chairperson (or persons) from the members of the 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 3 years, renewable.

- 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 a confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair.

2.2 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.

2.3 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).

2.4 Quorum

The Committee will make its decisions at scheduled or extraordinary meetings at which a quorum of members is present. Meetings will only be conducted when a quorum is present.

2.5 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.

2.6 Compliance

The Umgungundlovu Health Ethics Review Board functions in compliance with

- National Health Act of the Republic of South Africa
- The SA Department of Health *Ethics in health research: Principles, structures and processes* (2004) and *South African good clinical practice guidelines* (2006).
- Declaration of Helsinki (Current version)
- The Belmont Report