DURBAN UNIVERSITY OF TECHNOLOGY COMPOSITION AND TERMS OF REFERENCE OF THE HEALTH RESEARCH ETHICS COMMITTEE	
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Co-coordinating Exec Manager / Document owner:	DVC: Research, Innovation and Engagement
Operational Manager/s:	Executive Deans Academic Heads of Department, Faculty Officers Registrar
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Related documents and policies: Health Research Ethics Committee Policy	

HEALTH RESEARCH ETHICS COMMITTEE TERMS OF REFERENCE

Context: This document functions in the framework of the "Health Research Ethics Committee Terms of Reference"

Date:

1. PREAMBLE

The Durban University of Technology has identified the need to ensure that there is increased awareness and compliance with well-defined and properly supported codes, protocols and standards to govern the ethics of research on human participants and the environment. The Health Research Ethics Committee has the responsibility of evaluating, approving and monitoring research involving humans, and the environment. It does so by following accepted research ethical guidelines as laid out by the Department of Health of South Africa and the Declaration of Helsinki. It aims to protect the rights and welfare of research participants, and the environment by adhering to the principles of beneficence, justice and respect for persons, especially vulnerable populations, and the environment. In so doing, it must ensure that the research methodology and relevant literature is based on sound principles derived from appropriate studies with the aim to provide an answer to the research question posed.

The committee membership is in accordance with the National Health Research Ethics Council of South Africa, which is the accrediting body. All members are required to have initial and ongoing training in research ethics.

LOCATION:

The Health Research Ethics Committee of the Durban University of Technology is a sub-committee of Senate.

PURPOSE:

The Health Research Ethics Committee exists to support the efforts of the faculties to meet appropriate international standards for ethics in research on human participants, and the environment. It is tasked specifically to oversee the ethics of research on human participants /biological models carried out by anyone in the university, wherever this occurs (staff, postgraduate and undergraduate students). Its aim is to assist all researchers in the university to do their research confident in the knowledge that they are meeting best practices in researching human participants/ biological models, with respect to methodology and accountability to those researched.

2. REPORTING LINE

The Health Research Ethics Committee is an autonomous committee registered with the NHREC and submits its annual report to Senate on the number of proposals received, approved and rejected for ethical clearance.

3. TERMS OF REFERENCE

The essential function of the Health Research Ethics Committee is to review all proposals requiring ethical clearance (categories 2 and 3- refer to guidelines) proposed by independent researchers and students/staff members of the University, and to monitor the implementation of the proposed research. The purpose of ethics review and monitoring is the protection of the dignity, rights, safety, well-being and advancement of all

human research participants and the environment. Special attention will be paid to research that includes vulnerable participants. The Health Research Ethics Committee is also available to review, advise on, and approve or reject research proposals involving human participants and the environment submitted to it by researchers who are not members of the University (Refer to the Standard Operating Procedures document for the detailed terms of reference and information).

ACTIVITY:

The work of the Health Research Ethics Committee includes:

- Policy development and advice,
- Responsibility for seeing that all research on humans and the environment meet national and international requirements with respect to research ethics, and
- Responsibility for building awareness of ethical issues in the university and faculties through education, provision of information and identification of appropriate training programmes.

4. MEMBERSHIP

4.1 COMPOSITION

The membership of the Health Research Ethics Committee is composed of the following individuals:

- At least 9 members with quorum being a simple majority (50% + 1)
- One member with a law qualification
- At least one layperson who has no affiliation with DUT and represent the community; and
- Chairperson appointed by the Deputy Vice Chancellor responsible for Research (DVC: RIE) at DUT from the voting members. The Deputy Chairperson of Health Research Ethics Committee (HREC) shall be elected through voting from amongst members of the Health Research Ethics Committee (HREC); the Chairperson may delegate this responsibility to another member of the Health Research Ethics Committee (HREC), should the need arise. Should there be no volunteers for the position of Deputy Chairperson from the Committee, the DVC: Research, Innovation and Engagement will appoint a Deputy Chairperson from staff at the DUT or an external individual.
- Administrator

Member type	Number of members
Faculty representatives	7
Laypersons	1
Law expert	1
Co-opted members	Optional
Administrator (non-voting)	1
TOTAL: Voting members (Quorum)	9
TOTAL: Non-voting members	**Administrator**

****Co-opted members may vote on matters during meetings but will not form part of the quorum.**

4.2 STANDING

The members of the Health Research Ethics Committee must collectively have the ethical and scientific background and expertise to competently review, approve and monitor all research proposals submitted to it, in order to ensure the ongoing protection of human research participants, and the environment.

The Durban University of Technology provides the members of the Health Research Ethics Committee with professional liability insurance when they are acting in good faith while carrying out the professional duties of the Health Research Ethics Committee.

4.3 RULES

The following membership rules apply:

- The term of office for voting members is three years, and, on the expiry of his/her term, an individual member may indicate his/her availability for a further term of office.
- All the members will be required to sign a confidentiality agreement at the onset of their term of office and/or at the onset of each meeting.
- This agreement is meant to protect the confidential nature of all the documents, discussions and deliberations of committee meetings;
- Membership of the Health Research Ethics Committee should as far as possible reflect the diversity of the South African society; and
- Ideally, not more than 70% of the Health Research Ethics Committee should be of one gender only.

5. ADMINISTRATIVE SUPPORT STRUCTURE

The Health Research Ethics Committee administrative office will be situated within the Directorate for Research and Postgraduate Support. The administrator will be appointed by the University to ensure that all processes related to the functioning of the committee proceed efficiently.

6. MEETINGS, APPLICATION PROCEDURE AND REVIEW PROCESS

6.1 CONFLICT OF INTEREST

Health Research Ethics Committee members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest –including the following:

Personal Relationship: If the Health Research Ethics Committee member has a personal relationship with the principal investigator or key personnel of a research protocol under review by the Health Research Ethics Committee.

Relationship to the research study: If the Health Research Ethics Committee member (his/her spouse or immediate family member) is the principal investigator or co-investigator, supervisor or co-supervisor of the research protocol under review by the Health Research Ethics Committee.

Business relationship or Affiliation: If the Health Research Ethics Committee member serves as a trustee, director, officer, owner or partner of an entity that could be affected by the outcome of the research protocol under review by the Health Research Ethics Committee.

Financial Interest: Where the Health Research Ethics Committee member has a financial interest that could

be affected by the outcome of the research protocol under review by the committee. Included in the definition of financial interest are equity interests e.g. stock, stock options or other ownership interests, payment or expectation of payment derived from intellectual property rights (e.g. patent royalties); and payments received from an entity for consulting or other services.

Health Research Ethics Committee members are required to disclose only those interests that may be affected by the research, which is the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the Health Research Ethics Committee's review of the protocol or related matters.

6.2 FREQUENCY OF MEETINGS

The Health Research Ethics Committee will meet at least once a month, from February to November of each calendar year, to discuss and review research protocols/studies. The proposals reviewed will include 4 Year Bachelor's Degree/Honours, Master's (partial and full), Doctoral and independent studies both from students and researchers employed at the institution and those outside of the institution seeking ethical approval.

6.3 PROCEDURE

All documentation for submission is available on the Research and Postgraduate website http://www.dut.ac.za/research/institutional_research_ethics.

7. GUIDELINES FOR EXPEDITED REVIEW

7.1 BACKGROUND

In order to expedite the ethical review process, the Health Research Ethics Committee gives a subcommittee consisting of the chairperson and two Health Research Ethics Committee members the authority to approve certain study-related documentation in the period between committee meetings. The committee will consider all such approvals for ratification at the next meeting.

7.2 PROCEDURE

7.2.1 CRITERIA FOR PROPOSALS THAT QUALIFY FOR EXPEDITED REVIEW

Research proposals that meet one or more of the following criteria may qualify for expedited review by the subcommittee:

- Research proposals that have previously been "conditionally approved" by the Health Research Ethics Committee. This includes the following: Minor amendments to the participant information leaflet and consent documents; and proposal amendments that involve no additional risk to the research participants.
- A new research proposal, inclusive of all the required documentation, may be considered suitable for expedited ethical review only if it involves "minimal risk" research. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

The expedited review process may not be used for research proposals where the identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability, or be

damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing or health (physical, emotional and mental), unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.

8. ETHICAL CLEARANCE OF UNDERGRADUATE PROJECTS

When ethical clearance is required, the research proposal must be submitted to the Health Research Ethics Committee via the FRC for approval.

9. SERIOUS ADVERSE EVENT REPORTING

The term Serious Adverse Event (SAE) is used within the context of clinical or drug trials. However, a SAE can occur in non-pharmaceutical research as well. Any serious event that can negatively affect research participants or data integrity should be reported to the Health Research Ethics Committee by the researcher. (Please refer to the SOP document).

10. RESEARCH MISCONDUCT

Research misconduct refers to any of the following:

- Fabrication and/or falsification of data and research results; Plagiarism in proposing, performing, reviewing or reporting research;
- Deviation from or failure to adhere to the approved research proposal without prior approval from the REC;
- Researcher misrepresentation and/or falsification of credentials; Deception in the carrying out of research;
- Piracy of research materials;
- Failure to obtain the required informed consent; or
- Breach of confidentiality.

Incidents of research misconduct will be managed in accordance with the University's disciplinary procedures contained in the DUT Staff Code.

11. AUDITING OF

The Health Research Ethics Committee may be audited by the National Health Research Ethics Council.

12. FEES TO BE CHARGED FOR EXTERNAL PROPOSALS

The Health Research Ethics Committee (HREC), with the approval of the relevant DVC, will levy a schedule of fees for review of external proposals. The schedule of fees must be approved by the relevant DVC from time to time as required. The fees received may be used for expenses related to the operation of the Health Research Ethics Committee (HREC), for continuous professional development or specific ethics training. All staff and students registered at DUT will be exempt from paying fees. Students from other academic institutions will pay a nominal fee.