

DURBAN UNIVERSITY OF TECHNOLOGY COMPOSITION AND TERMS OF REFERENCE OF THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE	
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Related documents and policies:	
Research Ethics Policy	

RESEARCH ETHICS TERMS OF REFERENCE

Context: This document functions in the framework of the “Research Ethics Terms of Reference”

Date: October 2020

I. PREAMBLE

The Durban University of Technology (DUT) 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, the environment and animals. The DUT-Institutional Research Ethics Committee (DUT-IREC) has the responsibility of evaluating, approving and monitoring research involving humans, animals 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, animals and the environment by adhering to the principles of beneficence, justice and respect for persons, especially vulnerable populations, animals 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 DUT-Institutional Research Ethics Committee (DUT-IREC) of the Durban University of Technology is a sub-committee of Senate.

PURPOSE:

The DUT-IREC exists to support the efforts of the faculties to meet appropriate international standards for ethics in research on human participants, environment and animals. It is tasked specifically to oversee the ethics of research on human participants carried out by anyone in the university, wherever this occurs (staff, graduate, and undergraduate). 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, with respect to methodology and accountability to those researched.

2. REPORTING LINE

The Durban University of Technology Institutional Research Ethics Committee (DUT-IREC) 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.

Faculty Research Ethics Committees (FREC's) are subcommittees of DUT-IREC and review category 2 proposals only (Refer to Section 6 of the DUT Research Ethics Policy). However, the FREC cannot issue ethics clearance numbers as the DUT-IREC is the only accredited committee with the National Health Research Ethics Council which can issue clearance numbers. All category 2 proposals reviewed at FREC is to be sent to

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ENVISION2030

transparency · honesty · integrity · respect · accountability
fairness · professionalism · commitment · compassion · excellence

3/07/2023

THE DUT
2022 TOP 500

DUT-IREC for. For quality check and issuing of Ethical Clearance numbers.

3. TERMS OF REFERENCE

The essential function of the DUT-IREC 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, animals and the environment. Special attention will be paid to research that includes vulnerable participants. The DUT-IREC is also available to review, advise on, and approve or reject research proposals involving human participants, animals 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 DUT-IREC includes:

- Policy development and advice,
- Responsibility for seeing that all research on humans, animals and environment meets 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 DUT-IREC is composed of the following individuals:

- At least 15 members (33% constituting a quorum)
- Two representatives appointed from each Faculty
- One member with a law qualification
- Two lay persons who have no affiliation with DUT and represent the community; and
- Additional members may be co-opted by the DUT-IREC from relevant interest groups, where the DUT-IREC does not have the necessary expertise to evaluate particular research issues (e.g. environmental ethics, intellectual property rights, indigenous knowledge systems, qualitative/quantitative expertise, bio-ethics, professional care/counselling expert, etc.). Co-opted members have full voting rights and must sign the confidentiality agreement; and
- Chairperson appointed by the Deputy Vice Chancellor responsible for Research (DVC: RIE) at DUT
- Administrator

Member	Number of members
Faculty representatives (2 per faculty)	12
Lay persons	2
Law expert	1
Co-opted members	Optional
Administrator (non-voting)	1
TOTAL: Voting members (Quorum)	15 (5)

TOTAL: Non-voting members	Administrator

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

4.1.2 SUBCOMMITTEE: FACULTY RESEARCH ETHICS COMMITTEES (FRECS)

1. The FRECs are responsible for the evaluation and approval of research proposals in the context of their respective faculty. Only research proposals that involve minimal risk research may be granted ethical approval by the FREC.
2. Membership of the FREC:
 - The Faculty representative on DUT-IREC is the Chairperson of the FREC;
 - Four standing members;
 - Further members with full voting rights may be co-opted from relevant interest groups, where the FREC does not have the necessary expertise to evaluate particular research issues (e.g. environmental ethics, intellectual property rights, indigenous knowledge systems, qualitative/quantitative expertise, bio-ethics, professional care/counselling expert, etc.); and
 - Administrator (non-voting).

Member	Number of members
Faculty DUT-IREC representative (Chairperson)	1
Standing members	4
Lay persons	2
Law Expert	1
Co-opted members	Optional
Administrator (non-voting)	1
Chairperson: DUT-IREC (ex officio)	1
TOTAL: Voting members	8 plus Co-opted members
TOTAL: Non-voting members	2 (Administrator, Chairperson DUT-IREC)

4.2 STANDING

The members of the DUT-IREC/FREC 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 chairperson of the FREC will be a member of the DUT-IREC. The DUT-IREC Chairperson will be appointed by the Deputy Vice-Chancellor responsible for Research at DUT (DVC: RIE) and the deputy chairperson will be elected through vote. The chairperson may delegate her/his responsibility to another member of the DUT-IREC/FREC, should the need arise.

The Durban University of Technology provides the members of the DUT-IREC with professional liability insurance when they are acting in good faith while carrying out the professional duties of the DUT-IREC.

4.3 RULES

The following membership rules apply:

- The term of office for voting members of the DUT-IREC/FREC 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

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- deliberations of DUT-IREC/FREC meetings;
- Membership of the DUT-IREC/FREC should as far as possible reflect the diversity of the South African society; and
- Ideally, not more than 70% of the DUT-IREC/FREC should be of one gender only.

5. ADMINISTRATIVE SUPPORT STRUCTURE

The DUT-IREC 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 DUT-IREC proceed efficiently.

The FREC administrative office will be situated within the Faculty Office overseen by the Research Co-Ordinator/FRC Chairperson.

6. MEETINGS, APPLICATION PROCEDURE AND REVIEW PROCESS

6.1 CONFLICT OF INTEREST

DUT-IREC/FREC 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 DUT-IREC/FREC member has a personal relationship with the principal investigator or key personnel of a research protocol under review by the DUT-IREC/FREC.

Relationship to the research study: If the DUT-IREC/FREC member (his/her spouse or immediate family member) is the principal investigator or co-investigator of the research protocol under review by the DUT-IREC/FREC.

Business relationship or Affiliation: If the DUT-IREC/FREC 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 DUT-IREC/FREC.

Financial Interest: If the DUT-IREC/FREC member has a financial interest that could be affected by the outcome of the research protocol under review by the DUT-IREC/FREC. 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.

DUT-IREC/FREC 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 DUT-IREC's/FREC's review of the protocol or related matters.

6.2 FREQUENCY OF MEETINGS

The DUT -IREC/FREC will meet at least once a month, from January/ February to November/December of each calendar year, to discuss and review research protocols/studies. The proposals reviewed will include undergraduate, postgraduate and independent studies both from students and researchers employed at the institution and those outside of the institution seeking ethical approval.

6.3 PROCEDURE

Research Ethics Terms of Reference

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 FREC gives a subcommittee consisting of the chairperson and two FREC 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. Thereafter, the approved proposals with all attachments, together with the reviewers' comments, applicants feedback response to FREC and FREC approval letter must be forwarded to DUT-IREC for quality check, i.e., to check if all ethical issues were addressed satisfactorily prior to issuing Ethical Clearance numbers.

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 DUT-IREC/FREC. 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 is 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 FREC via the FRC-for approval.

9. SERIOUS ADVERSE EVENT REPORTING

The term Serious Adverse Event (SAE) is usually 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 DUT-IREC by the researcher. (Please refer to the SOP document).

I 0. 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.

I 1. AUDITING OF DUT-IREC

The DUT-IREC including the FREC may be audited by the National Health Research Ethics Council.

I 2. FEES TO BE CHARGED FOR EXTERNAL PROPOSALS

The DUT-IREC, with the approval of Senate (SENEX), levy a schedule of fees for review of external proposals. The schedule of fees must be approved by Senate (SENEX) from time to time as required. The fees received may be used for expenses related to the operation of the DUT-IREC, 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.