

<b>DURBAN UNIVERSITY OF            TECHNOLOGY            COMPOSITION AND TERMS OF REFERENCE OF THE INSTITUTIONAL            RESEARCH ETHICS</b>	
<b>Document number:</b>	
<b>Document name:</b>	Composition and Terms of Reference of the Institutional Research Ethics Committee
<b>Co-ordinating Exec Manager / Document owner:</b>	DVC: Research, Innovation and Engagement
<b>Operational manager/s</b>	Executive Deans Academic Heads of Department, Faculty Officers, Registrar
<b>Contact &amp; tel. no. for support:</b>	Director: Research and Postgraduate Support
<b>Status:</b>	Approved
<b>Approved by:</b>	Senate
<b>Date approved:</b>	29 August 2012
<b>Date last amended:</b>	28 August 2013
<b>Date for review/ next review:</b>	2015
<b>Title of manager responsible for policy review :</b>	Director: Research and Postgraduate Support
<b>Title of manager responsible for monitoring implementation of this policy</b>	Executive Deans, Registrar
<b>Related documents and policies:</b>	
Research Ethics Policy	

## **RESEARCH ETHICS TERMS OF REFERENCE**

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

**Date:** July 2013

### **I. 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 subjects, the environment and animals. The Institutional Research Ethics Committee (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 Council of South Africa, which is the accrediting body. All members are required to have initial and ongoing training in research ethics.

#### **LOCATION:**

The Institutional Research Ethics Committee (IREC) of the Durban University of Technology is a sub-committee of Senate.

#### **PURPOSE:**

The IREC exists to support the efforts of the faculties to meet appropriate international standards for ethics in research on human subjects, environment and animals. It is tasked specifically to oversee the ethics of research on human subjects 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 subjects, with respect to methodology and accountability to those researched.

### **2. REPORTING LINE**

The Institutional Research Ethics Committee (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 IREC and can review category 2 proposals only. However, the FREC cannot issue ethics clearance numbers as the IREC is the only accredited committee with the National Health Research Ethics Council which can issue clearance numbers. A schedule for all category 2 proposals reviewed at FREC is to be sent to IREC for noting every term.

### 3. TERMS OF REFERENCE

The essential function of the 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 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 (please see the Standard Operating Procedures document for the detailed terms of reference and information).

#### ACTIVITY:

The work of the 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 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 IREC from relevant interest groups, where the 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 from the voting members
- Administrator

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

**\*\*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 clearance by the FREC.
2. Membership of the FREC:
  - The Faculty representative on IREC is the Chairperson of the FREC; Four standing members;
  - Further members with full voting rights may be co-opted from relevant interest groups; and
  - Administrator (non-voting).

<b>Member</b>	<b>Number of members</b>
Faculty IREC representative (Chairperson)	1
Standing members	4
Co-opted members	Optional
Administrator (non-voting)	1
Chairperson: IREC (ex officio)	1
<b>TOTAL: Voting members</b>	<b>5 plus Co-opted members</b>
<b>TOTAL: Non-voting members</b>	<b>2 (Administrator, Chairperson IREC)</b>

#### 4.2 STANDING

The members of the IREC 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 IREC. The 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 IREC, should the need arise.

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

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

#### 5. ADMINISTRATIVE SUPPORT STRUCTURE

The 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 IREC proceed efficiently.

## **6. MEETINGS, APPLICATION PROCEDURE AND REVIEW PROCESS**

### **6.1 CONFLICT OF INTEREST**

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

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

**Business relationship or Affiliation:** If the IREC 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 IREC.

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

IREC 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 IREC's review of the protocol or related matters.

### **6.2 FREQUENCY OF MEETINGS**

The IREC 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](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 IREC gives a subcommittee consisting of the chairperson and two IREC 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 IREC. 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 IREC 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 IREC 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 IREC**

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

## **12. FEES TO BE CHARGED FOR EXTERNAL PROPOSALS**

The 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 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.