



University of Fort Hare
Together in Excellence

TITLE: University Research Ethics Committee of Senate TERMS OF REFERENCE

AUTHOR(S): Dean of Research: Deputy Vice Chancellor: Academic Affairs

IMPLEMENTATION RESPONSIBILITY: Registrar; Deputy Vice Chancellor: Academic Affairs

STRUCTURE APPROVED BY: Senate

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TO BE READ IN CONJUNCTION WITH THE FOLLOWING Documents:

- University Research Ethics Policy;
- University Research Ethics Committee (UREC) and Inter-Faculty Research Ethics Committee (IFREC) Standard Operating Procedures
- Inter-Faculties Research Ethics Terms of Reference

APPROVED BY:

Name: Prof S. Buhlungu
DESIGNATION: Vice Chancellor/Chair of Senate
UNIVERSITY OF FORT HARE

15 November 2019
Date

1. INTRODUCTION

The overarching objective of the University Research Ethics Committee (UREC) is to promote and ensure a culture of ethically responsible research at the University of the Fort Hare (UFH), including, in the humanities, social, behavioural, economic and educational sciences. UREC is mandated to fulfil its function by the Senate of the University. The purpose of UREC is to protect the dignity, rights, safety, and well-being of all participants (human and animal) in research. UREC does this by ensuring independent, prospective and ongoing ethics review is conducted of all research projects undertaken by members of staff, registered students and affiliates.

UREC oversees compliance with ethical principles, values and practices in research in the University through three research ethics committees: the Inter-Faculty Research Ethics Committee (IFREC) (which is a sub-committee of UREC) as well as the two independent accredited committees: the Health Research Ethics Committee (HREC) and the Animal Research Ethics Committee (AREC) (who provide reports to UREC).

These UREC Terms of Reference are aligned with the University Research Ethics Policy and are operationalised in the UREC Standard Operating Procedures (SOP). They are also aligned with the provisions of the National Health Act (Act 61 of 2003) and Department of Health (DoH) Ethics in Health Research Guidelines (2015), Section 73 of the National Health Act (Act 61 of 2003), which requires every institution (such as the University) to establish or have access to a Research Ethics Committee¹.

2. AUTHORITY

UREC is established as a Committee of the Senate of UFH. It therefore derives its authority from the UFH Senate and functions as a Committee of Senate. Administrative support for the scheduling of meetings and producing minutes for UREC is supported by the Office of the Registrar, as the Secretariat of Senate.

Administration of research ethical clearance applications are handled by the respective research ethics committees: the Health Research Ethics Committee (HREC); Animal Research Ethics Committee (AREC) and the Inter-Faculty Research Ethics Committee (IFREC).

This latter, IFREC, as a sub-committee of UREC, reviews ethics applications of all research that does not fall under HREC and AREC. Administrative support for IFREC is provided by the Office of the Dean of Research in the University's Govan Mbeki Research Development Centre (GMRDC).

UREC is registered with the National Health Research Ethics Council ("NHREC"). The registration number for UFH UREC is REC-270710-028.

3. TERMS OF REFERENCE

3.1 UREC was established with the primary purposes of:

- 3.1.1 promoting respect for human rights in research, as well as ethical values and research integrity in the University; and
- 3.1.2 monitoring that all research proposals and practices are reviewed from an ethical perspective.

3.2 The function of UREC is to:

- 3.2.1 Accept for review, research protocols involving participants submitted to it by researchers from other institutions who are not UFH staff members, students or affiliates, where the research protocols involves or affects the UFH community;
- 3.2.2 Consider research proposals from UFH students and staff (within its area of jurisdiction), on behalf of Senate, referred from IFREC, for ethical compliance and scientific validity in accordance with approved Standard Operating Procedures;
- 3.2.3 Consider appeals submitted to UREC and issue letters of outcome of appeals to applicants;
- 3.2.4 Consider cases of non-compliance or where ethical rules and principles are violated and refer them to the appropriate University structures for action;
- 3.2.5 Give due attention to ethics in research that includes certain individuals or categories of participants who may be vulnerable to undue influence and/or duress (for example, the poor and the marginalised, pregnant women, children, people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a clinic);
- 3.2.6 Provide oversight in monitoring the progress, ethics and safety of research in Humans and Animals, and ensure that ethical standards are maintained by receiving reports from IFREC; HREC and AREC;

- 3.2.7 Ensure that all researchers are aware that ethical clearance for a project will expire after a year unless a satisfactory progress report (on the approved template) is submitted via the supervisor or Head of Department/School/Faculty in the case of non-degree projects. This progress report must be submitted on a ten-monthly basis from the date of the approval letter;
- 3.2.8 Review proposed protocol amendments and recertify ethics approval for research in cases where substantive changes are made to the project (e.g. methodology and sample size);
- 3.2.9 Ensure that a programme of ongoing ethics training is in place for members of UREC and IFREC;
- 3.2.10 Develops, reviews and revises policies and procedures related to all aspects of University research ethics;
- 3.2.11 Undertakes any task on research ethics assigned to it by Senate; and
- 3.2.12 Has the authority, to appoint, from time to time, a standing or ad hoc subcommittee to investigate or finalise certain matters under its jurisdiction, in compliance with applicable norms, rules and regulations.

Although IFREC, as a sub-committee of UREC will work through a transparent process and ensure quicker turnaround times for ethics approvals and the issuing of certificates, certificates will be issued by UREC, signed by the Chairperson of UREC.

Ethics approval must be obtained before a study commences. UREC will not consider projects for approval if it is apparent that the research has already been conducted (in which case 3.2.4 above may apply).

4. MEETING PROCEDURES

- 4.1 The University Committees Section in the Office of the Registrar schedules meeting dates, and provides administrative support to UREC as a Committee of Senate
- 4.2 UREC will make its decisions at scheduled meetings once each quarter, as an Ordinary meeting, and as a Special meeting, if required, as per Senate rules.
- 4.3 The University standard meeting procedures applies for all Committees of Senate
- 4.4 The quorum is a simple majority

5. COMPOSITION

The composition of the UREC is in accordance with DoH 2015 Guidelines as far as is relevant to the social sciences and humanities.

Members of UREC will collectively have the qualifications, experience and expertise to evaluate the scientific, legal, psychosocial and ethical aspects of research proposals and appeals received from IFREC.

The Deputy Vice Chancellor (Academic Affairs) is appointed by Senate as Chairperson of UREC. The Chairperson of UREC reports to Senate.

The following applies to the composition of UREC:

1. Members of UREC are appointed for a period of three (3) years;
2. Members of UREC can be re-appointed for a second and subsequent third (3rd) three (3)-year term consecutively;
3. The UREC must have one layperson who is from the communities in which the University is located or conducts its research and who are not currently involved in medical, scientific or legal work;
4. UREC should increasingly, reflect the demographic profile of the population of the Republic of South Africa;
5. Both males and female members are required as members, with no sex holding more than 70% representation; and
6. The total number of members must be no less than 10, including the Chairperson.

Membership of UREC

1. Deputy Vice Chancellor (Academic) (Chair)
2. Chairperson of IFREC / Dean of Research
3. Chairperson of HREC
4. Chairperson of AREC
5. Faculty Deans / Deputy Deans (Research) (or nominee) (6)
6. At least one (1) layperson from the community where the University is located or conducts its research
7. Two senior academics/researchers nominated by Senate with knowledge of, and current experience in, areas of research that are likely to be regularly reviewed by IFREC and ratified by UREC.

8. One (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people. (For example, a medical practitioner, psychologist, social worker or nurse)
9. At least one (1) member who has professional training in qualitative and quantitative research methodologies
10. One (1) member who is legally trained

ⁱThe UREC functions in compliance with, but not limited to, the following documents and guidelines:

- The SA Department of Health (2015) Ethics in health research: Principles, processes and structures.
- The SA Department of Health (2015) Ethics in health research: Principles, structures and processes and (2006) South African good clinical practice guidelines.
- Declaration of Helsinki (Current version)
- The Belmont Report, the US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US
- US Department of Health and Human Services (HHS) 21 CFR 50; 21 CFR 56
- CIOMS 2018
- ICH-GCP- 2018 E6 Sections 1-4
- The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite).