



University of Fort Hare
Together in Excellence

UNIVERSITY OF FORT HARE

HEALTH RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

1. INTRODUCTION

The University of Fort Hare (UFH) Health Research Ethics Committee's Terms of Reference (ToR) is aligned with the UFH Research Ethics Policy as well as with the National Health Act 61/2003 and the Department of Health's 'Ethics in Health Research' Guidelines (March 2015). The National Health Act per 73 requires institutions to establish Health Research Ethics Committees (HRECs) which are registered with the NHREC and requires all 'health research' involving human participants to undergo prior ethics review by a registered research ethics committee. Committees are registered by the National Health Research Ethics Council after an assessment of eligibility and compliance with the governing legal and ethics framework.

2. PURPOSE OF THE TERMS OF REFERENCE

The University of Fort Hare (UFH) Health Research Ethics Committee's Terms of Reference provide guidelines and a minimum standard for the Research Ethics Committee's (REC's) operational management of the research ethics process within the University of Fort. It ensures the essential purpose of the URECs to protect the dignity, rights, safety, and well-being of all human participants in *health* and *health-related* research. This is achieved through *independent*, *prospective* and *ongoing ethics* reviews of all health-related research studies undertaken by staff, registered students, and affiliates of the University.

The terms of reference should be read in conjunction with all the other SOPs of the Ethics Office and URECs, as well as national and international documentation.

3. AUTHORITY

The UFH Health Research Ethics Committee (UFH HREC) is established as a sub-ethics committee of the UFH UREC and derives its authority from National Health Research Ethics Council (NHREC). Administrative support is managed by the UFH Faculty of Health Sciences Ethics Office. The UFH HREC is registered with the NHREC in accordance with the National Health Act 61/2003. The UFH HREC issues health-related ethical clearance certificates to applicants.

4. MANDATE

The UFH HREC is mandated to fulfil its functions in accordance with the National Health Act 61/2003 as outlined in the Department of Health 'Ethics in Health Research' guidelines (2015). It reports quarterly to UREC and annually to the NHREC at REC meetings.

The UFH HREC reviews health or health-related research proposals for members of the Faculty of Health Sciences or elsewhere in the University. Researchers with no affiliation to the University of Fort Hare may approach the UFH HREC to review their research proposals. The UFH HREC may exercise its discretion on a case-by-case basis to decide whether to review the proposal or whether to refer the applicant to the UFH UREC to access appropriate expertise and capacity to evaluate the application. A fee may be levied for such a service.

5. SCOPE OF OPERATIONS

The mandate of the UFH HREC is to:

- conduct rigorous ethics review, prospectively, of all health or health-related research proposals to ensure that the welfare and other interests of participants, and researchers are properly protected and that the proposed research is compliant with ethical norms and standards (retrospective review is not permitted);
- ensure that research proposals are scientifically sound and feasible;
- decide whether to approve, require amendments or reject the proposals for lack of compliance with scientific or ethical norms and standards, and
- ensure appropriate reporting occurs to fulfil the oversight obligation of the UFH HREC to monitor the welfare interests of participants.

The UFH HREC must establish a Code of Conduct for its members that describes the expectations of members, a Confidentiality Agreement and a Conflict of Interest Declaration.

The UFH HREC must ensure a transparent and inclusive recruitment and appointment process for members of the REC.

The UFH HREC must establish Standard Operating Procedures (SOPs) that systematically describe all the processes and procedures involved in its work including its institutional arrangements and reporting obligations. It must ensure that the SOPs are systematically reviewed every three to four years or more frequently as necessitated by research ethics changes.

The UFH HREC must establish appropriate documentation (application forms, guidance documents, review guidance, information & consent document guidance as well as report templates amongst others) to facilitate the appropriate processing of applications and to assist researchers to comply with requirements.

6. MEMBERSHIP

The members of the UFH HREC are constituted in accordance with legal requirements and recommendations of the National Department of Health, as set out by the National Health Research Ethics Council (NHREC), (established as a statutory body under the National Health Act No 61 of 2003), in the NHREC guidelines entitled, "Ethics in Health Research: Principles,

Processes and Structures (Department of Health, 2015)” as well as the South African National Standard: The Care and Use of human for Scientific Purposes.

- The UFH HREC should be independent, multi-disciplinary, multi-sectoral, and pluralistic.
- The UFH HREC should consist of:
 - at least nine members, with a quorum being a simple majority
 - where members are more than 15, the quorum may be 33%
 - includes at least one layperson
 - at least one member with knowledge of, and current experience in the professional care, counselling or health-related treatment of people.
 - at least one member with professional training and experience in qualitative research methodologies
 - members with professional training and experience in quantitative methodologies
 - a member with expertise in bio-statistics
 - a member with expertise in research ethics
 - at least one member who is legally qualified

7. SELECTION AND APPOINTMENT

Members are appointed for *three years* (per the appointment terms) and may be re-appointed for another single term. A break of at least two years is recommended before a member can be re-appointed after two terms. Updated CVs of all UFH HREC members should always be on file in the applicable administrator’s office. Consideration should be given to succession planning.