

**UNIVERSITY OF CAPE TOWN
FACULTY OF HEALTH SCIENCES
HUMAN RESEARCH ETHICS COMMITTEE**

TERMS OF REFERENCE

1. INTRODUCTION

The University of Cape Town's Faculty of Health Sciences Human Research Ethics Committee's (HREC) Terms of Reference are aligned with the University of Cape Town's Research Ethics Code for Research Involving Human Participants as well as with the National Health Act 61/2003 and the Department of Health's 'Ethics in Health Research' Guidelines (2015). The National Health Act per s 73 requires institutions to establish 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.

These Terms of Reference should always be read in conjunction with the University of Cape Town's Research Ethics Code for Research Involving Human Participants, the University of Cape Town's Faculty of Health Sciences HREC Standard Operating Procedures, and the University of Cape Town's Policy and Procedures for Breach of Research Ethics Codes and Allegations of Misconduct in Research.

2. AUTHORITY

The University of Cape Town's Faculty of Health Sciences HREC is established as a Faculty Committee of the University and derives its authority from the Dean of the Faculty of Health Sciences. It functions as a Dean's Advisory Committee of the University of Cape Town's Faculty of Health Sciences. Administrative support is managed by the Faculty of Health Sciences Research Ethics Office. The University of Cape Town's Faculty of Health Sciences HREC is registered with the National Research Ethics Council (NHREC) in accordance with the National Health Act 61/2003. Its registration number is REC-210208-007.

3. MANDATE

The University of Cape Town's Faculty of Health Sciences 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 annually to the National Research Ethics Council (NHREC) and to the Dean of the Faculty of Health Sciences, University of Cape Town.

The University of Cape Town's Faculty of Health Sciences HREC functions in compliance with, but not limited to, the most updated versions of the following documents and guidelines:

- The SA National Health Act 61/2003
- The SA Department of Health (2015) Ethics in Health Research: Principles, Processes and Structures (2nd ed). Department of Health, Pretoria, South Africa
- The SA Department of Health (2006) South African Clinical Trial Guidelines: Good Practice for Clinical Trials with Human Participants (3rd ed). Department of Health, Pretoria, South Africa
- South African Health Products Regulatory Authority Guidelines; and laws and regulations with regard to the Control of Medicines
- Declaration of Helsinki (2013)
- The Belmont Report (1979)
- The US Office of Human Research Protections 45 CFR 46 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services); 21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 612; 21 CFR 812 (*Note: Common Federal Rule (CFR) applies across all US states and abroad, when research is funded by the US federal government*)
- International Ethical Guidelines for Health-related Research Involving Humans (2016) (4th ed) Council for International Organizations of Medical Sciences (CIOMS), Geneva
- ICH Harmonised Tripartite Guideline: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) 2018
- ICH Harmonised Tripartite Guideline: Clinical Investigation of Medicinal Products in the Paediatric Population E11 2000

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

4. SCOPE OF OPERATIONS

The primary function of the University of Cape Town's Faculty of Health Sciences HREC is to protect the safety, rights, dignity and welfare of human participants in health or health-related research. The mandate of the University of Cape Town's Faculty of Health Sciences HREC is to:

- Conduct rigorous ethics review, prospectively, of all health or health-related research proposals to ensure that 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, to require amendments, or to reject the proposals for lack of compliance with scientific or ethics norms and standards.

- Ensure appropriate reporting occurs, at a minimum annually, to fulfil the oversight obligation of the University of Cape Town's Faculty of Health Sciences HREC to monitor welfare and other interests of participants.
- Suspend or terminate approval of research not conducted according to sound ethical and scientific principles or regulatory requirements; or that is associated with unexpected harm to participants.
- Audit, or have a third-party audit, the conduct of the research to verify compliance with the University of Cape Town's Faculty of Health Sciences HREC requirements.
- Respond to complaints from investigators, participants or whistle-blowers about the unethical conduct of a study.

The University of Cape Town's Faculty of Health Sciences HREC has established Standard Operating Procedures (SOPs) that systematically describe all the processes and procedures involved in its work, including its institutional arrangements and reporting obligations. The University of Cape Town's Faculty of Health Sciences HREC will ensure that the SOPs are systematically reviewed every three to four years, or more frequently as necessitated by research ethics changes.

The University of Cape Town's Faculty of Health Sciences HREC has established appropriate documentation (application forms, guidance documents, review guidance, information & consent document guidance as well as report templates amongst others) to facilitate appropriate processing of applications and to assist researchers to comply with requirements. The University of Cape Town's Faculty of Health Sciences HREC will ensure that appropriate documentation is regularly updated to facilitate the application process and compliance with research ethics guidelines.

5. COMPOSITION

The University of Cape Town's Faculty of Health Sciences HREC members are appointed by the Dean of the Faculty of Health Sciences on the recommendation of the HREC Chair for three-year renewable terms.

The University of Cape Town's Faculty of Health Sciences HREC must ensure a transparent and inclusive recruitment and appointment process for members of the HREC.

The composition of the University of Cape Town's Faculty of Health Sciences HREC must meet standards laid down in the Department of Health 'Ethics in Health Research' Guidelines (2015), and requirements specified in the US Federal Wide Assurance. The HREC aims to meet these requirements as far as reasonably possible.

In line with these requirements, the University of Cape Town's Faculty of Health Sciences HREC membership must satisfy the following requirements:

- At least nine members
- 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. Such a member might be e.g. a medical practitioner, psychologist, social worker or nurse
- At least one member with professional training and experience in qualitative research methodologies
- Members with professional training and experience in quantitative research methodologies
- A member with expertise in bio-statistics
- A member with expertise in research ethics
- At least one member who is legally qualified
- Ethnically and culturally diverse members and an appropriate mix of males and females
- At least one scientific member with expertise in areas of research regularly reviewed by the committee

The University of Cape Town's Faculty of Health Sciences HREC has established a Code of Conduct for its members that describes the expectations of members, a Confidentiality Agreement and a Conflict of Interest Declaration.

As the Full Committee membership is greater than 15, in accordance with the Department of Health 'Ethics in Health Research' guidelines (2015), the quorum is 33%. A quorum must be maintained for each vote. If a quorum fails, further studies cannot be approved and must be held over until the next convened meeting.

The University of Cape Town's Faculty of Health Sciences HREC has established an EXCO to deal with matters between meetings, duly authorised by the Full Committee. The EXCO's current constitution includes the Chairperson and two Deputy Chairpersons of the HREC. The EXCO's membership may be increased on an ad hoc basis to manage specific tasks as required by the Full Committee.

The University of Cape Town's Faculty of Health Sciences HREC may establish subcommittees to deal with specific aspects of the work of the HREC on an ad hoc basis. The term 'subcommittee' refers to a group of Full Committee members organised to manage a specific task or make a particular recommendation relating to the functioning or standard operating procedures of the HREC. Subcommittees will be dissolved once the ad hoc task is deemed to be satisfactorily completed.

6. APPROVAL PROCESS

These Terms of Reference were approved by the Faculty Board on 12th March 2019.

Signed by Dean

C. Williamson

[name]

C. Williamson

[signature]

24 MARCH 2019

[date]