



University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR THE SELECTION, APPOINTMENT AND FUNCTIONING OF THE UFH HREC

1. DOCUMENT HISTORY

| Date | Version No | Reason for revision |
|-----------------|------------|---------------------|
| 11 July 2018 | 1 | Newly formulated |
| 31 January 2022 | 2 | Updated |

2. PURPOSE

The purpose of this standard operating procedure is to provide a framework for the selection, appointment and functioning of members of the UFH HREC that provide operational management of the research ethics processes.

3. The Functions of UFH HREC

The UFH HREC reviews all research applications and amendments for ethical suitability as well as scientific merit to ensure that:

- the research conducted will improve health within the broader framework of healthcare, prevent illnesses and disabilities and improve healing
- human subjects involved in research are treated with respect and dignity, and their well-being is a higher priority.
- The researcher's health, safety, and position (potential exposure to chemicals and micro-organisms/liability) are always protected.
- the research is valuable and scientifically responsible.
- written permission and informed consent are obtained at all times.
- approval is given to research proposals that adhere to the scientific and ethical standards and requirements of UFH HREC.
- the research provides a favourable benefit-risk ratio, and sufficient motivation is provided in cases where this is impossible.
- all incidents and adverse events are monitored and managed.
- all ongoing research studies are monitored to ensure they adhere to the approved proposal and legal requirements.

4. COMPOSITION OF THE UFH HREC

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, counseling 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

5. 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.

5.1 The selection and appointment of the Chairperson:

As soon as the UFH HREC becomes aware of a vacancy in this position, the Faculty Management of the UFH FHS, in consultation with the UFH HREC, suggests possible candidates, based on their experience and knowledge of research ethics. A qualification in research ethics may not be a requirement but will be advantageous. The CVs of the possible candidates are submitted to the Head of the Ethics Office. The Head and Ex-Officio and the Chairperson then have preliminary discussions with the suggested candidates on the roles and responsibilities of this position. This is confirmed and approved by the Health Research Ethics Committee. The UFH HREC is then informed to finalise the appointment. A formal letter of appointment is sent by the UFH HREC setting out the term of office; where to find the necessary information for new members; and given the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the UFH HREC. The NHREC is also notified. The UFH HREC can appoint an acting chairperson to act for a limited period.

5.2 The selection and appointment of the Vice-Chairperson

As soon as the UFH HREC becomes aware of a vacancy in this position, a possible Vice-

Chairpersons is nominated from the existing UFH HREC members. The Head and Ex-Officio of the UFH HREC and the chairperson have preliminary discussions with the nominated candidates on the roles and responsibilities of this position. A final decision is made during the next UFH HREC meeting and confirmed by the UFH HREC. A formal letter of appointment is sent by the UFH HREC setting out the term of office; where to find the necessary information for new members; and given the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the UFH HREC.

5.3 The selection and appointment of committee members

As soon as the UFH HREC becomes aware of a vacancy in this position, nominations are requested from the members. The Chairperson has preliminary discussions with the nominated candidates on the roles and responsibilities of this position. During the next UFH HREC meeting, a final decision is confirmed by the ethics committee. A formal letter of appointment is sent by the UFH HREC setting out the term of office; where to find the necessary information for new members; and given the assurance that the members are indemnified from personal liability against claims that may arise in the course of the ordinary business of the UFH HREC.

5.4 Sub-committees

The UFH HREC will establish various sub-committees, from within its membership, as per the needs and requirements.

5.5 Co-opted members, observers and visitors

The UFH HREC will co-opt members as and when needed. Observers and visitors will only be allowed in exceptional cases and for specific purposes. Researchers can be invited to discuss their applications and be present to clarify uncertainties.

6. TRAINING

Training of all HREC members is critical. The UFH HREC members will receive ethics training and attend refresher courses in research ethics and training in good clinical practice (GCP). The training sessions will take place at least once a year. Administrative staff assigned to UFH HREC should also be involved in the induction and regular ongoing training to ensure that they are able to perform their HREC duties optimally. UFH HREC members should have documented proof of research ethics training. UFH HREC members who review clinical trials should additionally have good clinical practice (GCP) training, as evidenced by a certificate of training.

7. CODE OF CONDUCT

All UFH HREC members have to sign the code of conduct. The signing of this code of conduct indicates their acceptance of the ethical principles for research at the university.

8. QUORUM AND VOTING

The following guidelines apply to meetings of the UFH HREC:

- The Committee shall only hold its meetings if the attendance quorum is 50%, of whom one must be a layperson member.
- Decisions shall be made and recorded in the minutes at scheduled or special/extraordinary meetings at which a quorum of members is present.
- In the absence of a quorum, meetings will be declared inquorate and reflected in the minutes.
- Reviews tabled and discussed by members present will need to be circulated to the full committee for a formal resolution and subsequent feedback to applicants.
- Decisions will be taken by consensus.
- Voting shall be applied where a consensus decision cannot be reached.

9. MEETINGS PROCEDURES

Procedures for meetings of the UFH HREC are as follows:

9.1 Ordinary meetings

- The Committee meets monthly as specified.
- Schedule of meeting dates and deadlines for submission of research proposals will be communicated to Committee Members by the UFH HREC administrator through emails.
- Research protocols will be submitted for inclusion on the agenda of the meeting two weeks before a scheduled meeting.
- In consultation with the Chairperson, the Administrator of the UFH HREC will draft the agenda of the meeting.
- The minutes of the previous meeting(s) and the agenda will be circulated to members at least five working days before the meeting.

9.2 Special Meetings

At the discretion of the Chairperson of UFH HREC, a special meeting may be called at any time.

9.3 Minutes of Meetings

The UFH HREC meetings will sufficiently reflect the following aspects:

- Attendance at the meetings and whether the quorum requirements were adhered to;
- Resolutions are taken by UFH HREC;
- Actions delegated to specific members or co-opted members;
- Reasons for changes made on research protocols, or non-approval of research protocols; and
- Written summary of the discussion and the consequent UFH HREC resolution.

10. PROCEDURE PROCESS FOR FUNCTIONING OF HREC

Committees have Standard Operational Procedures (SOP) that indicate the committees' functioning and the processes to be followed when ethical clearance is needed for new applications or amendments to research proposals.

Within the UFH enclave, all applications reviewed by its HREC should have prior approval from the relevant department. The applications will be reviewed by a minimum of two UFH HREC members. Expert reviews will be requested, if applicable. When reviewing an application, UFH HREC members should be encouraged to:

- be mindful of the basic ethical principles that should inform the planning, design and undertaking of health research
- be open-minded and not allow personal biases to cloud their application of these guidelines to the review of an application
- accept the consensus that ethical principles should be balanced, which might be difficult to achieve; however, divergence in opinion does enrich deliberations
- be deliberate, reflective and thoughtful in discussions about balancing ethical considerations.

10.1 Set timelines for review procedures

The members of the UFH HREC are requested to adhere to the following timelines when receiving an application:

- Five working days for the administrator to determine the completeness of a document
- Three working days for the chairperson to appoint reviewers for an application
- Five working days for members to review new applications
- Five working days for corrections and minor amendments.

The UFH HREC is also responsible for evaluating incidents, adverse and passive and active monitoring of research studies.

11. CONFLICT OF INTEREST

The UFH HREC shall, at the beginning of each meeting, declare any prior interest and/or involvement in any matter being discussed by UFH HREC to avoid conflict of interest in the UFH HREC decision-making, including reviewing of protocols. No committee member should be allowed to be part of the review of an application if any conflict of interest is present. The UFH HREC members are bound by the Confidentiality clause and Conflict of Interest clause relating to the Committee meetings.

Confidentiality clause: “I further undertake to declare to the UFH HREC any interest I may have in any research project discussed by the Committee and to excuse myself from the meeting for the duration of the discussion of such project”.

Conflict of interest clause: “I will disclose all conflicts of interest (financial and other) that could compromise the trustworthiness of my work in research proposals, publications, public communications, and review activities”.

The researchers shall declare to the UFH HREC any potential or existing conflict of interest that may threaten the research's scientific integrity and ethical conduct at the start of the meeting. This declaration also forms an integral part of the application form (see application form).

11.1 Confidentiality

The Committee members, support- and administrative staff, co-opted members, and observers shall sign a standard confidentiality agreement on appointment to the UFH HREC to protect confidential information (see Appendix: “Statement and Undertaking by members of the Ethics Committee”). Deliberations at all meetings of UFH HREC and the contents of protocols being reviewed should be kept confidential. No information with regard to applications or research protocols will be distributed to a third party unless the UFH HREC is legally required to do so. Protocols and correspondence will be sent to Committee Members via confidential emails. Ethics Committee members/reviewers communicate the outcome of protocols and correspondence to the UFH HREC Administrator through confidential emails. The UFH HREC meetings shall remain closed except for special circumstances, when researchers are invited to attend the meetings. A meeting venue is allocated to the Research Ethics Committee for meetings. Access to the UFH HREC office and storage area is restricted and controlled by the Head of the Administration Division.

12. SECRETARIAT

The UFH Faculty of Health Sciences will provide the secretariat for the UFH HREC. All meetings will be recorded, transcribed and saved manually or electronically. Registers will be kept for all meetings including:

- agendas;
- minutes;
- signed record of attendance;
- signed record of permission to record the meeting, confidentiality, as well as conflict of interest;
- digital recording of the meeting.

12.1 Submission of applications and dates of meetings

Complete applications submitted before the closing of the agenda will be reviewed during the following meeting. Incomplete applications will stand over until all documents have been submitted/obtained. Except for submissions from students and staff members of the UFH, an administrative fee may be levied for all other applications.

13. THE REVIEW PROCEDURE

Upon receiving an application by the administrative office of the UFH HREC Office, all documentation is checked within five days for completeness, to ensure that all documents indicated in the checklist are attached. All reviewers are provided with a code to ensure the anonymity of their reviewer reports.

The application is then sent to the Ethics Administrator who, in negotiation with the UFH HREC chairperson, within three days decides on two reviewers (UFH HREC members) for each application, based on their:

- 1) research ethics expertise;
- 2) methodological knowledge;
- 3) absence of conflict of interest, and
- 4) equitable distribution of review burden across the committee.

If a study plans to recruit within a local community, a copy of the informed consent documentation is sent to one of the community representatives for review. If the nature of the study requires expertise not present in the UFH HREC, the application is allocated to an external reviewer.

The Ethics Administrator then compiles a distribution list according to the decisions made for reviewers and sends it out to the allocated reviewers within five days. The reviewers then have five working days to review and then provide their feedback on an approved reviewing template. The ethics review process should be based on a *case-by-case deliberation*.

13.1 Decision-making process

The decision-making process is based on aggregate feedback, followed by debate and reaching a consensus. If no agreement can be reached, the chairperson will call a vote. The chairperson may decide that voting must be by secret ballot. The chairperson has an ordinary vote but must exercise a casting vote in the event of an equality of votes on any matter. The chairperson may electronically submit urgent matters for review between scheduled meetings via a round-robin approach. At least two-thirds of members have to electronically confirm their involvement in the review process by indicating their approval or non-approval. Such a resolution must be recorded in the minutes of the next meeting. In cases where the UFH HREC cannot reach a consensus or some other conflict arises within the UFH HREC, the general rules for conflict resolution will be followed.

14. REFERENCE DOCUMENTS

- The National Health Act, No 61 of 2003.
- Regulations Relating to Research with Human Participants, 11 July 2018.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The Rules for the Management of Research Ethics at the University of Fort Hare, 2011
- University of South Africa, SOP for SOPs
- North -West University, SOP for SOPs