

UNIVERSITY OF THE
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SIGNATURE:

A handwritten signature in black ink, appearing to read 'V. Reddy', is written over a light blue horizontal line.

Prof Vasu Reddy

DVC: Research and Internationalisation

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TERMS OF REFERENCE (ToR)

1. Introduction and objective

The University of the Free State (UFS) General/Human Research Ethics Committee (hereafter GHREC)'s terms of reference (ToR) are aligned with section 73 of the National Health Act 61 of 2003, which requires institutions to establish Research Ethics committees (RECs) and register with the National Health Research Ethics Council (NHREC). The Act requires all "health and health-related research" involving human participants to undergo ethics review by a registered REC. The GHREC is registered with the National Health Research Ethics Council (NHREC)

Registration number: REC-112922-058

The ToR is also aligned with the national health research ethics guidelines requirements and the University of the Free State Research Integrity and Ethics Policy as approved by the UFS Council on 24 June 2022.

In addition, the GHREC functions within the framework of all relevant promulgated Acts of Parliament and international treaties and conventions to which South Africa is a signatory, interpreted in a manner appropriate to research that falls within the mandate of the GHREC.

2. Institutional Ethics infrastructure

The UFS Ethics infrastructure is governed by the UFS Senate Research Ethics Committee (SREC).

The UFS SREC has established the GHREC as an inter-faculty REC constituted in terms of the University of the Free State Research Integrity and Ethics Policy and the SREC ToR.

Administrative support for the GHREC is managed by the Directorate: Research Development (DRD) Office.

3. The purpose of the GHREC

3.1 The GHREC aims to review research to safeguard the dignity, rights, safety, and well-being of all actual or potential participants in research conducted at and under the auspices of the UFS. The GHREC, independently and on an ongoing basis, reviews the ethical risks related to and embedded in research. The GHREC is responsible for acting in the interest of research participants and participating communities by ensuring that the research proposal submitted for review meets the norms and standards prescribed in the national ethics guidelines.

3.2 The GHREC also considers the interests and needs of the researchers, the Norms and Standards of the relevant disciplines, and has due regard for the

applicable laws and relevant institutional requirements. In executing its duties, the GHREC will ensure that it is free from bias and influence that could affect its independence.

- 3.3 Provide research ethics advice and guidance to researchers and other members of the university community.

4. Mandate, scope of operations and authority of the GHREC

The GHREC is mandated to fulfil its functions in accordance with the National Health Act 61 of 2003 as outlined in the Department of Health Ethics in Health Research guidelines (2015) or the latest edition.

The principal objectives and mandate of the General/Human Research Ethics Committee (GHREC) are to:

- 4.1 conduct independent ethics review of research involving human participants and general research, to ensure the proposed research complies with the ethical norms and standards outlined in the national ethics guidelines, and that research proposals are methodologically sound and feasible within the available resources,
- 4.2 ensure consistency in reviewing the ethical aspects related to research involving human participants, including support services research and research within the Directorates.
- 4.3 independently make decisions on whether to approve, request modification or reject research proposals for lack of compliance with ethics norms and standards,
- 4.4 ensure appropriate reporting occurs to fulfil the oversight obligation of the GHREC to monitor the welfare of participants in studies approved by the GHREC,
- 4.5 review research proposals from researchers affiliated with the UFS only, without levying a review fee. The Committee does not conduct reviews for external applicants except in cases with an agreeable motivation and an agreement, where a review fee will be applicable.¹ A review fee will be levied as provided in the UFS Research Integrity and Ethics Policy,²
- 4.6 ensure confidentiality of all REC matters pertaining to research proposal review and approvals, monitoring and reporting, and safeguard REC data in order to ensure confidentiality and compliance with POPIA,

¹ SOP Section 1.

² UFS Research Integrity and Ethics Policy, SOP para 8.

- 4.7 establish Standard Operating Procedures (SoPs) that systematically describe all the processes and procedures involved in its working, including institutional arrangements and reporting,
- 4.8 establish and make accessible appropriate documentation, including application forms, guidance documents, review guidance, information and consent document guidance, as well as report templates, among others, to facilitate appropriate processing of applications and to assist researchers in complying with requirements.

5. Constitution of the GHREC

The GHREC is constituted in terms of the University of the Free State Research Integrity and Ethics Policy.

5.1 Composition

GHREC consists of the following members:

- A Chairperson and Vice-Chairperson;
- Two to four representatives from the faculties of Economic and Management Sciences, Education, Humanities, Natural and Agricultural Sciences, Law, and Theology and Religion;
- A legally qualified person (usually from the Faculty of Law);
- A person with knowledge and experience in professional care and counselling;
- A person with professional training and experience in qualitative research methodologies;
- A person with professional training and experience in quantitative research methodologies;
- A statistician (expert in statistics);
- Lay members – community members who are not staff members of the UFS and not actively involved but knowledgeable in social science research;
- A person with experience in research ethics.

The multiple representatives from each faculty make it possible to have alternate members, while ensuring that all required expertise is present at each Committee meeting.

Thirty-three per cent of voting members of the GHREC constitute a quorum for decision-making.

5.2 Remuneration of committee members

All GHREC members, except the lay members, are affiliated with the institution (UFS).

The GHREC members are not reimbursed for their involvement in the Committee.

The lay members are offered an honorarium as reimbursement for costs incurred in attending meetings and compensation for their time. The Directorate Research Development (DRD) determines the value of the honorarium.

5.3 Nomination and appointment of GHREC members

- 5.3.1 The Deans of the Faculties of Economic and Management Sciences, Education, Humanities, Natural and Agricultural Sciences, Law, and Theology and Religion nominate Faculty Representatives to serve on the GHREC. The Senate Research Ethics Committee (SREC) confirms the appointment of the faculty representatives on the GHREC.
- 5.3.2 Reappointment of Faculty Representatives is subject to approval by the relevant Faculty and SREC.
- 5.3.3 The representatives of the broader community are nominated by the Senior Director: Research of the UFS, considering that it may be challenging to determine what “the broader community” is or who may be a “representative” of it. The SREC confirms the appointment.
- 5.3.4 In some instances, the GHREC may require researchers to assist in identifying a particular person representing a specific community in which the research will take place or special interest groups to be co-opted on an ad hoc basis to the GHREC by the Chairperson of the GHREC to review a particular research proposal.
- 5.3.5 Members of the GHREC are appointed for a period of three years.
- 5.3.6 The appointment of members of the GHREC is renewable twice, after which the person should stand down for at least one term. This ensures that expertise and institutional memory accumulation are retained while a balance with succession and recruitment of younger members is achieved.
- 5.3.7 The Chairperson, suitably qualified, is appointed by the institutional leadership and will serve a term of office of three years, renewable twice, for another three-year term, after which the person should stand down as Chairperson for at least one term.
- 5.3.8 A Vice-Chairperson(s) is elected by the members at the first meeting of the appointed Committee and is expected to help the Chairperson with responsibilities and inter-meeting matters. The Vice-Chairperson will step into the role of Chairperson when necessary. If needed, the Committee may appoint an alternate Vice-Chairperson to assist when the Vice-Chairperson is unavailable.

The GHREC must be representative of the research communities it serves and, increasingly, reflect the demographic profile of the population of South Africa. The GHREC should include an appropriate mix of males and females.

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The Chairperson of the GHREC can consult with or co-opt any expert they deem necessary to appraise a particular research proposal. Experts could be specialists in ethical, scientific, or legal aspects, or members of special interest groups.

Co-opted reviewers should declare conflicts of interest. Co-opted individuals do not have voting rights.

Members will receive a formal letter of appointment from the SREC after their appointment is confirmed. The letter of appointment must set out the term of office; where to find the necessary information for new members; and the assurance that members are indemnified from personal liability against claims that may arise during the ordinary business of the GHREC.

Members should sign both the appointment letters and the code of conduct to indicate acceptance of the appointment and the expectations impressed on each member. The code of conduct contains provisions for required confidentiality and a declaration of conflict of interest.

All members of the GHREC are required to have successfully completed assessed research ethics training, renewable every three years, and should participate in continuous ethics training.

All new members should receive induction and adequate research ethics training. Training must be completed prior to, or at the very least within one month of, their initiation of REC membership.

5.4 Resignation

A member must give at least two months' notice when resigning from the Committee. A member should submit a written note of resignation to the Chairperson of the Committee.

5.5 Establishment of Exco

The GHREC should establish an Exco to deal with matters between meetings, duly authorised by the full Committee.

Exco is composed of the Chairperson, Vice-Chairperson and three ordinary members of the Committee.

The three ordinary members are nominated by the Committee on its first meeting following appointment and serve in this role for a three-year term.

The Exco is supported by the GHREC Secretariat.

5.6 Indemnity cover

The UFS indemnifies Committee members from personal liability and will ensure that adequate public liability insurance is in place. The UFS assumes legal responsibility for the decisions and advice of the GHREC, provided that members act in good faith.

6. Reporting

- 6.1 The GHREC reports annually to the NHREC.³
- 6.2 The GHREC submits annual reports to the SREC.⁴
- 6.3 Researchers who hold ethical approval for a study must report to the GHREC according to the conditions and requirements set out in paragraphs 5 and 7.2 of the Standard Operating Procedures of the GHREC.

³ As required by the guidelines, Ethics in Health Research: Principles, Processes and Structures, Department of Health (DoH 2015; 2nd ed. or latest version), section 4.6 iii.

⁴ For more detail on the report to the SREC, see para 13 of the SOP of the GHREC.

ANNEXURE A

RESPONSIBILITIES OF MEMBERS

The Chairperson's responsibilities are to:

- Chair REC meetings and ensure that the correct procedure is followed.
- To ensure, together with the Secretariat, that all required items appear on each REC agenda prior to the meeting and that minutes taken during each REC meeting are an accurate representation of the meeting's transactions.
- Conduct expedited reviews or delegate this task to suitably qualified individuals who may or may not be committee members.
- To deal with any queries related to REC reviews or other matters discussed at REC meetings, together with other REC members and students, supervisors and researchers as required.
- Advise and consult with researchers on research ethics-related issues or delegate this task to suitably qualified committee members.
- Participate in non-compliance investigations.
- Contribute to the development of GHREC policies and procedures.
- Consult with Chairs from other UFS research ethics committees to encourage and facilitate cross-disciplinary research.
- Represent the GHREC at national Research Ethics and Governance forums, particularly the National Health Research Ethics Council.
- To ensure that all REC-related documentation (including the Committee's Terms of Reference and Standard Operating procedures) is reviewed from time to time and updated or amended as necessary.
- Consult with Chairs from other human research ethics committees throughout the country to:
 - (i) Improve participants' welfare and safety, particularly in multi-institution research projects.
 - (ii) Develop and promote best practices in research ethics oversight.
- Consult with or co-opt any expert that the chair deems necessary for the appraisal of a research proposal.
- Represent the GHREC on the SREC.

The Vice-Chairperson's responsibilities include:

- Performing functions delegated by the Chairperson, including expedited review.
- Assume the role and responsibilities of the Chairperson when required.
- Advise and consult with researchers on research ethics-related issues.
- To assist the Chairperson with decision-making in relation to matters of relevance to the REC or research ethics on an ad hoc basis.
- Participate in non-compliance investigations.
- Contribute to the development of GHREC policies and procedures.
- General responsibilities, which accompany committee membership.

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Ordinary Members:

- Attend REC meetings on dates published by the Secretariat, and be punctual in discharging this responsibility.
- Conduct research proposal reviews as allocated by the REC Chairperson and do so diligently, with sufficient time in hand and according to the procedures set out in Section 2 of the REC Standard Operating Procedures.
- To uphold the guiding principles and code of conduct for GHREC members.

Responsibilities of the Secretariat include:

- To receive research proposals for consideration by the GHREC and process these as required.
- Screen research proposals submitted for consideration to the GHREC in order to ensure that documentation is correctly completed, and refer back to students, supervisors, or researchers for any such documentation that contains errors or is incomplete.
- To compile, together with the Chairperson, an agenda for each GHREC meeting listing all pertinent matters for consideration by the Committee and to ensure that such agendas (and attachments) are distributed by electronic mail to all REC members within at least seven working days of a meeting.⁵
- Distribute an attendance register at each GHREC meeting and record attendance data in the minutes for each meeting.
- Record the minutes of each GHREC meeting, draft them after each meeting, and send them to the Chairperson for review.
- To deal with ad hoc enquiries regarding research proposal review or any other matter related to administrative functions of the GHREC.
- To exercise due care and diligence in confidentiality, restricted access (where applicable), record keeping, archiving and considerations of business continuity related to all GHREC functions in accordance with UFS policy.

⁵ The agenda closes ten working days before the meeting date. See Section 2.2.1 in the SOP of the GHREC.