



UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences

Faculty of Health Sciences **Research Ethics Committee**

Terms of Reference
of the
Faculty of Health Sciences Research Ethics
Committee

1. Purpose of this document

This document sets out the Terms of Reference for the Faculty of Health Sciences Research Ethics Committee (FHS REC), University of Pretoria, as accepted by unanimous resolution of the Faculty of Health Sciences Research Ethics Committee on 27 September 2023. It replaces all previous documents in this regard. It should be reviewed within 3 years after this date of approval.



_____ Date: 27 September 2023

Signed by the Chairperson

The mandate and authority of the FHS REC, its composition, commitments, responsibilities and operational framework are set out here. The Standard Operating Procedures (SOPs) of the FHS REC are documented separately but operate within the operational framework of this document.

Abbreviations used in the document are as follows:

DoH Guidelines:	Department of Health (2015). Ethics in Health Research: Principles, Processes and Structures (2 nd Edition).
FHS REC or REC:	Faculty of Health Sciences Research Ethics Committee, University of Pretoria
FHS:	Faculty of Health Sciences
NHA:	National Health Act No 61 of 2003
NHREC:	National Health Research Ethics Council
SOP:	Standard Operating Procedure

2. Mandate and authority of the FHS REC

2.1 Legal and institutional mandate and authority

The FHS REC is tasked with the ethics of all health-related research as defined in the National Health Act (no 61 of 2003) and all quantitative and qualitative research in the Faculty of Health Sciences, conducted by researchers affiliated to the University of Pretoria, Steve Biko Academic Hospital, and other sanctioned health institutions in the province or, at the discretion of the FHS REC, elsewhere. Some studies may additionally require approval of an animal research ethics committee. It operates inclusively in terms of the National Health Act (61 of 2003), and policy documents of the University of Pretoria, specifically the Policy and Procedures for Responsible Research S4083/00 as amended 2007, and the Code of Ethics for Scholarly Activities S4755/12, as well as international and local research ethics guidelines.

The FHS REC thus is mandated by the University of Pretoria and health institutions to give effect to the South African Constitution that states: *“Everyone has the right to bodily and psychological integrity, which includes the right not to be subjected to medical or scientific experiments without their informed consent”*; as well as Section 73 of the National Health Act (2003), which states

“(1) Every institution, health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

(2) A health research ethics committee must-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and

(b) grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.”

2.2 Scope of its mandate and authority

The scope of research with which the FHS REC is tasked, extends to all health-related research as defined by the National Health Act and all quantitative and qualitative research done in the Faculty of Health Sciences. Quantitative and qualitative research is defined as all scholarly inquiry that seeks to contribute to knowledge or understanding, using quantitative or qualitative methods descriptively, inferentially or interpretatively. The scope of research for ethics review usually excludes conceptual, comparative texts research, and literature reviews.

Health-related research include all quantitative and qualitative research done in the Faculty of Health Sciences, research on health services, clinical research, clinical trials, education of students and workers in health matters, health practices, research on health personnel in the Faculty of Health Sciences. This scope is not confined to research on human participants but include research on chemicals or instruments, research using audits and surveys, health related laboratory research, in vitro and ex vivo health research, research on data already collected for clinical or educational purposes, secondary research on data already collected as part of another research project, case reports and case series for publication and conference presentations, and service delivery statistics for degree or publication purposes.

It is a legal imperative that **all health research conducted at the University of Pretoria and its affiliated institutions** be reviewed by the FHS REC in terms of the **National Health Act (2003)** as well as the policies of the University of Pretoria.

The FHS REC adheres to the definition of health research as defined in section 1 of the National Health Act, being any research that contributes to knowledge of-

- “(a) the biological, clinical, psychological or social processes in human beings;*
- (b) improved methods for the provision of health services;*
- (c) human pathology;*
- (d) causes of the diseases;*
- (e) the effects of the environment on the human body;*
- (f) the development or new application of pharmaceuticals, medicines and*
- (g) the development of new applications of health technology”.*

The REC is mandated to review and approve all health-related research prior to commencement of research activities, or prior to performing analyses on existing data. No ethics approval may be granted *ex post facto*.

When substantive amendments are made to a study, the REC is mandated to review these for approval prior to their being implemented, unless harm to participants would be expected if not implemented at once.

The REC further is mandated to monitor the execution of studies and also to suspend a study when a reasonable ethical concern arises.

The REC is mandated to consider in its review of a study the rights and interests of all stakeholders and role-players in a particular study. These include but are not limited to research participants, researchers, institutions, communities and society. Crucial interests that the REC should account for are the protection of the rights, dignity, safety, and well-being of all human participants in health-related research. All REC deliberations should be aimed at ensuring that ethical and scientific standards are maintained to protect participants from harm by weighing up the risks of harm against the likelihood of benefit. This is done by minimising risks of harm to the greatest extent possible and by balancing the risk of harm relative to the likelihood of benefit. REC deliberations should hold researchers accountable for their research activities and promote ethically sound research. Thus, in weighing the risk of harm against the likelihood of benefit, the REC's deliberations are concerned not only with current research participants, but also with societal interests and future hypothetical beneficiaries.

The REC is mandated to review and approve a study based on documents submitted to it, other sources of information, and its understanding of the context and interests of the various stakeholders and role-players.

The REC is mandated to make its approval subject to particular conditions, to require remedial action, and to withdraw its approval.

The REC is mandated to receive complaints about researchers and research studies that transgress ethical standards, to obtain further information, establish *prima facie* facts and obtain opinions in the matter of a complaint, and to refer the case to either the dean or the registrar for disciplinary action when it deems doing so is an imperative in terms of UP Policies and

Regulations, South African law, international and South African ethical guidelines or if such referral is otherwise justified.

2.3 Independence within its mandate and authority

Although the FHS REC does not have *locus standi* for purposes of court proceedings, it is a legislatively-mandated and internationally- and nationally-accredited body,

- a) which independently reaches decisions and issues resolutions;
- b) on which no pressure or undue influence from outside the REC may be exerted on the REC or its members to effect a particular resolution; and
- c) the resolutions of which may not be overturned or overruled by any office-bearer of the University of Pretoria or any other party. Objections to decisions reached should be subjected to the appeals procedure of the FHS REC with potential recourse to the National Health Research Ethics Council.

3. Members of the FHS REC

3.1 A chairperson, co-chairperson and deputy chairpersons

A suitably-qualified chairperson should be elected by the FHS REC and formally appointed to this position by the dean of the FHS. To this end, the FHS REC may involve the Executive of the FHS and/or the University in order to effect the recruitment, nomination and appointment of a suitable person. The minimum qualifications to be appointed to this position are a research doctorate; postgraduate qualifications in ethics or philosophy; and a minimum five years' experience of serving on a health research ethics committee.

The chairperson may be assisted by a co-chairperson who holds the abovementioned minimum qualifications that are required to be appointed as chairperson. The chairperson should be assisted by at least one deputy chairperson. A co-chairperson and deputy chairpersons should be elected by the members of the FHS REC. The co-chairperson and deputy chairperson(s) should assist the chairperson with responsibilities and inter-meeting matters, as well as step into the role of chairperson when necessary. The chairperson, co-chairperson and deputy chairperson(s) constitute the executive management subcommittee of the REC.

3.2 Appointment of members

When more than two vacancies arise, the FHS REC should make a call for nominations in the Faculty. The same may be done in case of one or two vacancies, or alternatively a REC member may make a nomination. Once a nominee accepts the nomination, his or her suitability for serving as a member of the FHS REC will be considered by the FHS REC. The most suitable nominees, if any is suitable, are then recommended by the REC for appointment by the Dean as member(s) of the FHS REC. The Dean may request that a nomination that was not recommended for appointment by the FHS REC be evaluated for his or her suitability by two members of a REC at another university, and/or may proceed with the appointment of no more than 50% of nominees that the FHS REC have not recommended for approval. The REC should inform nominees who are not appointed on the reasons for not being appointed.

Appointment as member of the FHS REC is by a formal appointment letter. The letter should set out at least the term of office, the assurance that members are indemnified from personal liability against claims that may arise in the course of ordinary business of the REC, and that the appointment is conditional on a written commitment to the Code of Conduct of the FHS REC. Acceptance of appointment as member of the FHS REC should be affirmed in writing.

The usual term of appointment of a member is four years, but an appointment may be renewed by the REC for a second term. The usual term does not apply to the chairperson and deputy chairperson(s), or where the replacement of a member with specific expertise is not readily available.

3.3 Member composition

The REC should include sufficient members with the necessary qualifications and experience, including research ethics training, to be able to review and evaluate the science, the health aspects, the legal and ethical suitability of the proposed research study, as well as to account for various perspectives of a layperson, communities, societies, and the relevant institutions.

Congruent with the DoH Guidelines, the REC membership should consist of

- a) at least 16 members;
- b) for which a quorum is defined as 33%;
- c) at least one layperson;

- d) 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;
- e) at least one member with professional training and experience in qualitative research methodologies;
- f) members with professional training and experience in quantitative research methodologies;
- g) a member with knowledge of bio-statistics;
- h) two members with postgraduate expertise in research ethics; and
- i) at least one member who is qualified in law.

3.4 Independent consultants and other non-members

The REC may call upon independent consultants or from non-members for information, expertise or an opinion regarding specific studies. Independent consultants may for example be specialists in a scientific and/or professional field, or may provide expertise in ethical or legal matters. The REC may also call upon representatives of communities, patients, or special interest groups. The REC may also consult with other RECs. In all these instances, the REC will not be bound by the opinion or recommendations, but will account for these recommendations in its decision-making.

All consultations outside of the REC are subject to undertakings of confidentiality. Any conflicts of interest by any party consulted should be revealed to the REC.

3.5 Code of Conduct for REC members

All members of the FHS REC are required to affirm in writing their commitment to the following:

- 1) To diligently perform all responsibilities arising from their membership of the REC;
- 2) To regularly and punctually attend meetings of the REC;
- 3) To review accountably and reliably the research studies assigned to them;
- 4) To act constructively and with integrity in all REC-activities;

- 5) To maintain confidentiality regarding the research studies reviewed by the REC, and the deliberations at REC-meetings;
- 6) To raise and have recorded in the REC minutes a vote of dissent in case of a legitimate concern, but abide by the majority resolution of the REC;
- 7) To consider and declare any prior interest and/or involvement in any matter being considered at a REC meeting to avoid potential conflict of financial or personal interest;
- 8) To recuse themselves from REC resolutions when there is a conflict of interest;
- 9) To uphold the reputation of the REC and the University of Pretoria, and report to the REC in writing events that denigrate or damage the reputation of the REC or the University;
- 10) To familiarise themselves with relevant regulations and policies of the University of Pretoria as well as national and international research ethics guidelines;
- 11) To maintain their REC responsibilities in accordance with national and international regulatory requirements and in keeping with South African law; and
- 12) To attend at least biennially assessed research ethics training to maintain their knowledge and keep abreast of the latest developments in the field.

3.6 Attitude of REC members

The REC recognises that it has a consigned interest in promoting research. Its attitude should accordingly be constructive and conducive to good research and good research practices.

The REC upholds the principle that the primary responsibility for ethically-sound research practice rests with researchers. The role of the REC is to support and guide researchers towards better or best ethical research practice. The REC approaches the ethical review of submissions in a collaborative spirit in order to arrive at decision-making that involves the researchers. The REC is in this way a resource in the FHS for researchers.

REC members should be mindful of the basic ethical principles that should inform planning, designing and conducting health research, be open-minded and not allow personal biases to prevent their application of these principles, accept that consensus about how ethical principles should be balanced may be difficult to achieve and that divergence enriches deliberations, be

mindful of the influence that the context (social, cultural and economic) has on how to prioritise principles, and be deliberate, reflective, thoughtful and constructive in discussions about how to balance the ethical considerations of a study.

3.7 Continuous training in research ethics

All REC members should have documented proof of assessed research ethics training, refreshed at least biennially.

3.8 Remuneration of members

REC members employed by the University of Pretoria or jointly appointed by the Gauteng Health Department will not receive remuneration for serving on the REC other than their usual salary, with the understanding that their serving on the REC is part of their core university business. REC members who are not employed by the University of Pretoria or Gauteng Health Department may be given an honorarium.

4. Procedures

4.1 Meetings

The REC should meet no less than eleven times a year. Minutes of all meetings must be kept and an agenda must be available to all members before and during a meeting. Regular meetings will be scheduled annually, and notice of an *ad hoc* meeting should be given more than 24 hours in advance. Meetings will be attended in person at a particular place, unless extraordinary circumstances pertain in which case a meeting may be held using video-conferencing facilities. Meetings will be conducted orderly and REC members will all adhere to the order rulings of the person chairing the meeting.

Quorum

A quorum for a meeting is defined as 33% of the total number of appointed REC members as on record during the preceding month, rounded upwards to count as a full person when calculated as a fraction of 0,5 or higher. It is further required to comprise at least one member of the executive management subcommittee.

4.2 Resolutions

Consensus and voting

Final resolutions may only be made at quorate meetings. Resolutions should usually be made by consensus, but when consensus is not reached, resolutions are made through voting by all members present at a meeting without allowing for proxies. The chairperson or any other member may not veto a resolution. The meeting may determine whether the voting is by secret ballot or by show of hands provided that the particular vote of each individual member remains subject to confidentiality conditions and may not be disclosed outside the meeting. The minutes should reflect the outcomes of the votes in numbers, whereby a simple majority is required for a resolution to pass.

When there is an equal number of votes for and against a resolution, the chairperson in his or her discretion may cast a deciding vote. Prior to voting, any REC member who is involved in the particular research study, or has an actual (rather than potential) conflict of interest, must recuse themselves from voting and the voting count.

Recusal and conflict of interest

A REC member may not review or participate in making resolutions about research in which they are involved personally or financially. When such a study is discussed, the member concerned should declare the potential conflict and offer to recuse themselves from the meeting for those deliberations and decision. Should the member be permitted to remain for the deliberations at the discretion of the chairperson, the member may provide information but may not participate in the final resolution.

REC members should disclose information that may lead to perceptions of a conflict of interest. It remains the REC's prerogative to decide whether there is in fact a conflict of interest and how the REC accounts for it in its decision-making process. Recusals and conflicts of interest should be recorded in the minutes of a REC meeting.

4.3 Subcommittees

The REC may delegate specific decisions to a standing or *ad hoc* subcommittee and may set criteria to be applied by a subcommittee in deriving its resolutions. The executive management subcommittee is a standing subcommittee of the REC. Resolutions duly delegated

to any subcommittee of the REC will be deemed to be made by the REC, but the REC may resolve to review and, if necessary, rescind a resolution made by a subcommittee.

4.4 Expedited approval of studies

The REC may delegate to a subcommittee the expedited approval of submissions. The REC determines the criteria by which a subcommittee may grant these approvals.

4.5 Emergency review and approval of studies

The REC determines the written procedures for the review and approval of submissions that should be processed as a matter of urgency appropriate to an emergency.

4.6 Confidentiality

Each member of the REC should maintain confidentiality regarding the research studies reviewed by the REC, as well as deliberations at REC meetings. To protect REC members and provide a safe environment for them to speak their minds, the full minutes of meetings are not to be made available outside the REC. It is the REC's prerogative which aspects of the minutes may be revealed to researchers and other parties.

4.7 Reporting and accreditation

Although the University of Pretoria accepts legal responsibility for resolutions made and advice given by the REC, the REC is accountable in terms of the NHA. For this reason, the REC should comply with the requirements of the NHREC and maintain its accreditation with the NHREC. The REC should also maintain accreditation with other organisations as may be required for fulfilling its tasks, for example, the Office of Human Research Protection of the USA Department of Health & Human Services, for the ethics approval of clinical medication trials.

A representative of the FHS REC, preferably the chairperson, will report biannually in the Senate Committee for Research Ethics and Integrity without compromising the independence of the REC (see 2.4 above).

4.8 Appeals and complaints against the REC

The REC must have written procedures in place to manage appeals and complaints. An appeal may arise when the principal investigator or another stakeholder formally objects to a specific

resolution of the REC. A complaint may arise for procedural or administrative irregularities, breach of confidentiality, unacceptable delays, or in case of a conflict of interest. The procedures should provide for the processing of an appeal or a complaint by the REC so as to reach a final resolution. In case of a complaint, the complainant may choose to escalate a complaint to the dean of the FHS once it has been considered by the REC. In the case of an appeal, the appellant may choose to escalate his or her appeal to the NHREC following the final resolution of the REC.

4.9 Complaints about a researcher or specific research

The REC should have written procedures in place for the consideration of complaints against a researcher, a specific research project or a research practice. In these instances, the REC may seek further information, foster solutions, establish *prima facie* evidence of misconduct, or formulate an opinion on the terms of ethical misconduct, mitigation, or aggravation. When there is *prima facie* evidence of a serious transgression, the matter must be referred to the dean of the FHS and, if appropriate, the registrar of the University of Pretoria, for possible disciplinary and/or corrective procedures.