



Foundation for Professional Development Research Ethics Committee (FPDREC)

Terms of Reference

June 2025

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INTRODUCTION

The National Health Act (Act 61 of 2003) established a National Health Research Ethics Council (NHREC) within the South African National Department of Health and mandates that every institution, health agency and health establishment at which health research is conducted must establish or have access to a research ethics committee (REC) registered with the NHREC. Section 72 (1) of the National Health Act (NHA) requires that proposals to conduct 'health research' must undergo independent ethics review before the research is commenced. Ethics review of proposed 'health research' must be conducted by a registered REC. The Foundation for Professional Development Research Ethics Committee (FPDREC) is registered with the NHREC, Registration number REC-030711-033, after an assessment of eligibility and compliance with the governing legal and ethics framework.

The Terms of Reference (ToR) of the FPDREC is a legal document setting out the formal character of the committee and how it fits within the Foundation for Professional Development (FPD). It includes the delegated and inherent authority, the scope and the nature of its powers, its responsibilities, its relationship to non-affiliated researchers, its accountability responsibilities, its dual governance mode, the mechanisms for reporting and remuneration for members. The ToR directs the life and operation of the FPDREC on a semi-permanent basis, and an approval process within FPD. These processes assist with transparency and dissemination.

The FPDREC reviews health, educational and social-related research studies, proposals, and protocols to ensure that the research will promote and positively influence health, education and social environments. The committee should ensure that research proposals stand up to scientific and ethical scrutiny appropriate to the disciplines concerned and should review research proposals and protocols prospectively to ensure that they meet the accepted ethical norms and standards before research commences.

The ToR of the FPDREC is aligned with the Standard Operating Procedures (SOPs) of the committee; Guidelines for Research Ethics Evaluation of FPD; the provisions of the NHA; and the South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024 Third Edition, (Guidelines) published by the Department of Health.

AUTHORITY

Taking into consideration the provisions of the NHA and the Guidelines, FPD Board and Management approved the establishment of the FPDREC as a committee of FPD. It functions

independently and is not attached to or based in a single cluster or division in FPD and derives its authority from the FPD Board. However, the committee must simultaneously advance the strategic mission and vision of FPD, viz. to become a leader in building a better society through education and capacity development and always be aligned to this mission and vision. The FPD liaison person for any matters relating to the functioning of the committee is currently the Deputy CEO.

The main role of the FPDREC is to promote the conduct of ethical research endeavors from employees and students enrolled in various courses registered with the institution, which might require research activities for course compliance and completion. All of these research activities are generally classified as being low-risk in terms of possible medico-legal sequela. The committee does not review any clinical trial research applications. In particular, the committee should contribute to the safeguarding of the dignity, rights, safety, and wellbeing of all actual or potential research participants and communities, while taking into account the interests and needs of researchers and the integrity of FPD.

Following various requests from external persons and organisations, the need has been identified to expand the reach of the committee and FPD approved the extended authority of the committee to also include applications for ethical review from external applicants. This expansion is in line with the NHREC ethics in health research guidelines of 2024, viz. that researchers without affiliation to an institution or organisation with a REC could approach a registered committee to request it to review its health research protocols. For the review of such external applications, a fee for service could be levied.

MANDATE

The FPDREC functions within the ambit of the National Health Act, 2003 (Act 61 of 2003); the Guidelines; the Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, Second Edition, 2006; as well as the Belmont Report and the Declaration of Helsinki, 2013.

It reports annually to the NHREC and to the FPD Board and Management.

The FPDREC reviews research designs and proposals for FPD employees and students. External researchers may approach the FPDREC to review their research proposals. The FPDREC 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 standard review fee, the amount to be set by the FPDREC, will be charged for external research exclusively or research that is externally funded. The fee is payable upon submission of the proposal for review. Monies thus collected may be spent on the operations of the FPDREC.

The FPDREC does not review research studies that involve drug research, biomedical research involving human tissue or studies involving animals or plants. Where appropriate, the FPDREC will refer the application to an external review committee.

FPDREC espouses the constitutional values of human dignity, equality, social justice, and fairness and affirms the constitutional principles of academic freedom and freedom of scientific research.

SCOPE OF OPERATIONS

The mandate of the FPDREC is to:

- Conduct independent, comprehensive, timely and rigorous ethics reviews, prospectively, of all research proposals to ensure that the welfare and other interests of participants, and researchers, are protected, that the proposed research is compliant with ethical norms and standards and that the goals of research do not override the best interests of the research participants. A retrospective review is not permitted.
- Ensure that research proposals are scientifically sound, of a high quality, 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 to fulfil the oversight obligation of the FPDREC to monitor the welfare interests of participants

SECRETARIAT

FPD is responsible for providing the FPDREC with secretarial and administrative infrastructure. FPD will have executive oversight on the activities of the secretariat, bearing in mind that the committee is functioning independently.

The Secretariat is responsible for:

- Preparing communications regarding the listing of each received and approved document, the frequency of continuing review, and other obligations of the investigator or researcher.

- Obtaining the signature of the chairperson or deputy-chairperson.
- Keeping records and receipts.
- Organising and maintaining a registry of research proposals reviewed by the FPDREC.
- Keeping a record of all research that obtained ethics clearance.
- Signing a confidentiality agreement.
- Preparing the monthly meeting agenda and minutes, as well as distributing relevant documentation to the FPDREC members timeously.
- Preparing annual reports to FPD and the NHREC.
- Preparing documentation for NHREC audits

COMMITTEES AND MEETINGS

The FPDREC will endeavour to meet at least ten (10) times a year or more frequently if the need arises. Meetings can be face-to-face meetings, virtual and/or blended meetings. Members will be furnished timeously with all documents for deliberation at the meetings.

A quorum at meetings is a simple majority

The FPDREC will establish an Executive Committee (EXCO) to deal with urgent matters, duly authorised by the full committee. The EXCO will consist of the Chair, the Deputy Chair and one other member of the committee elected by the members.

The FPDREC may establish subcommittees to deal with specific aspects of the work of the Committee, e.g., undergraduate student ethics review applications. The subcommittee should be authorised to approve the applications and to report to the full committee for noting.

CODE OF CONDUCT

The FPDREC should establish a Code of Conduct that describes the expectations of members, and, inter alia, the adherence to a Confidentiality Agreement and a Conflict of Interest Declaration. The Code of Conduct should be circulated to members with a request to sign an acknowledgment that they had received a copy of the Code and that they would abide by its contents.

RECRUITMENT OF MEMBERS

The membership of FPDREC consists of at least nine (9) members but not more than fifteen (15) members.

The FPD Deputy CEO and the FPDREC should ensure a transparent and inclusive recruitment and appointment process for members of the Committee. The term to be served by a member is three years and a member is eligible to be re-appointed for a follow-up term, but shall then stand down for a full term before being eligible again to be appointed as a member.

In addition to the regular members, FPDREC may co-opt members or mentors to provide the Committee and members with special expertise or guidance not adequately available in its regular membership. The duration of the membership of co-opted members should be based on the need of the FPDREC for their special expertise.

STANDARD OPERATING PROCEDURES (SOP's)

The FPDREC should establish SOPs that systematically describe all the processes and procedures involved in its work including its institutional arrangements and reporting obligations. It should ensure that the SOPs are systematically reviewed every three to four years or more frequently as necessitated by research ethics changes.

HONORARIA

The FPDREC members should be paid honoraria for reviewing and attending meetings. Such honoraria will be managed and paid by FPD at its discretion. The secretariat should record all reimbursements and payments received concerning the functioning and work of the committee.

RECORD KEEPING

The FPDREC should establish appropriate documentation and record-keeping of the full study record, from application to study closure. This should be maintained to facilitate the appropriate processing of applications and to assist researchers in complying with requirements. Documentation should include application forms, guidance documents, review guidance, information and consent document guidance as well as report templates, amongst others. The secretariat shall maintain and manage information displayed on the website of the FPDREC.

APPROVAL PROCESS

These Terms of Reference were approved by FPD Board on

02 Day of July 2025.

Gloria Maimela

Signed by the FPD Deputy CEO

07/10/2025

Date