



**Foundation for Professional  
Development Research Ethics  
Committee (FPDREC)**

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**Terms of Reference**

**November 2022**

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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. RECs must review 'health research' proposals and protocols to ensure that the research will promote health, contribute to prevention of communicable or non-communicable diseases or disability or result in cures or alleviation of suffering caused by communicable or non-communicable diseases or disability. RECs must ensure that research proposals stand up to scientific and ethical scrutiny appropriate to the disciplines concerned and must review research proposals and protocols prospectively to ensure that they meet the accepted ethical norms and standards before research commences.

The Terms of Reference of the Foundation for Professional Development Research Ethics Committee (FPDREC) are aligned with the SOP and Guidelines for Research Ethics Evaluation of Foundation for Professional Development (FPD), the provisions of the NHA and the Department of Health's 'Ethics in Health Research' Guidelines (March 2015) (Guidelines). Research Ethics Committees are registered by the National Health Research Ethics Council after an assessment of eligibility and compliance with the governing legal and ethics framework.

## AUTHORITY

Taking into consideration of the provisions of the NHA and the Guidelines, the Foundation for Professional Development Research Ethics Committee is established 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.

The main role of the FPDREC is to promote the conduct of ethical research in FPD and other bodies. In particular, to contribute to the safeguarding 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.

The FPDREC is registered with the NHREC in accordance with the National Health Act 61/2003. Its registration number is (REC-030711-033).

## **MANDATE**

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 National Health Research Ethics Council (NHREC) and to the FPD Board.

FPDREC reviews research designs and proposals for FPD employees. 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, may be charged for exclusively external research or research which is externally funded. The fee is payable upon submission of the proposal for review. Monies thus collected may be spent on the operation of the FPDREC.

The FPDREC does not generally review research studies that are longer in duration than one year and will not review research proposals 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 review, prospectively, of all research proposals to ensure that the welfare and other interests of participants, and researchers, are properly 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.  
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 to provide FPDREC with secretarial and administrative support through the appointment of a secretary and the provision of offices and other administrative infrastructures.

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 signature of chairperson.
- Keeping records and receipts.
- Organising and maintaining a registry of research proposals reviewed by the FPDREC.
- Keeping record of all research that obtained ethics clearance.
- Signing a confidentiality agreement.
- Preparing the meeting agenda and minutes, as well as distributing relevant documentation to FPDREC members a week in advance before meetings.

## **COMMITTEES AND MEETINGS**

The FPDREC will endeavour to meet ten (10) times a year or more frequently if the need arises. Meetings can be a face-to-face meeting, by teleconference or videoconference or where one of those members is absent, by the receipt and consideration of the member's views in writing. Members will be furnished with all documents which will be deliberated on at the meeting at least one (1) week before the meeting date.

A quorum at meetings is a simple majority if membership is below fifteen (15) members.

The FPDREC may establish an EXCO to deal with matters between meetings, duly authorised by the full committee.

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 must establish a Code of Conduct for its members that describe the expectations of members, and, inter alia, the adherence to a Confidentiality Agreement and a Conflict of Interest Declaration.

## **RECRUITMENT OF MEMBERS**

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

The FPD Managing Director and the FPDREC must ensure a transparent and inclusive recruitment and appointment process for members of the Committee. In addition to the regular members, FPDREC may co-opt members to provide the Committee with special expertise or guidance not adequately available in its regular membership. The duration of the membership of co-opted members must be based on the need of the FPDREC for their special expertise.

## **STANDARD OPERATING PROCEDURES (SOP's)**

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

## **HONORARIA**

The FPDREC may recommend that members who are not employees of FPD receive honoraria for work on the Committee. The FPDREC must record all reimbursements and payments received in relation to the work.

## **RECORD KEEPING**

The FPDREC must establish appropriate documentation and record-keeping of the full study record, from application to study closure, is maintained to facilitate appropriate processing of applications and to assist researchers to comply with requirements. Documentation

should include application forms, guidance documents, review guidance, information & consent document guidance as well as report templates amongst others.

## APPROVAL PROCESS

These Terms of Reference were approved by FPD Board on (date).

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*Gustaaf Wolvaardt*  
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Signed by the FPD Managing Director

Date: 6/28/2023