LIMPOPO
PROVINCIAL GOVERMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF
HEALTH

PIETERSBURG/MANKWENG COMPLEX ETHICS COMMITTEE (PMREC)

PMREC COMMITTEE MEMBERS – 2022-2025/2026

NO	NAME	POSITION/DEPARTMENT	GENDER
1.	Prof TAB Mashego	Chairperson(Clinical Psychology)	Female
2	Dr Ramavhuya	Deputy Chairperson	Male
3.	Dr MA Poopedi	Research Manager and Secretariat	Male
4.	Dr C Sutton	Paediatrics and child health	Male
5.	Dr P Mangena	Internal Medicine	Male
6.	Prof Nesengani	Community representative Obstetrics and Gynaecology	Male
7.	Dr K Sathekge	Clinical Psychology	Female
8	Prof Malema	Nursing	Female
9.	Prof Themane	Qualitative/Pastor	Male
10.	ADV Seabi	Legal Representative	Female
11.	Dr Morifi (Ex Officio)	ECD	Female
12.	Dr Siebani (Ex officio)	CEO(Mankweng Hospital)	Male

INTRODUCTION

In line with national and international guidelines on ethical research, every organisation/institution, health agency and health establishment at which research involving human participants is conducted should have a duly registered Human/Animal Research Ethics Committee (REC). The Complex has an ethics committee PMREC to service both Pietersburg and Mankweng hospitals as well as individual research for the province as well as providing a service for researchers in the hospitals around the province. PMREC is one of the three committees in the province viz the Limpopo committee in the Premier' s office, and the provincial office that deals with resaerch requests for hospitals in the province.

ROLE OF PMREC

PMREC – was established in 2010 and it deals with human research ethics
The committee is currently registered with the National Health Research Ethics Committee (NHREC) as the national regulatory body.

The primary role of the RECs is to ensure the well-being, safety and protection of research participants/animals. The functioning of the RECS are guided by the requirements as stipulated by the National Health Act No. 61 of 2003, the associated regulation (Regulations Relating to Research with Human Participants, 19 September 2014), the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015), as well as the South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS 10386:2008), national and international research ethics guidelines. The committees are independent of research sponsors, investigators and from any other undue influence, such as political, institutional, professional or commercial influence. This independence is critical to ensuring that research participants' interests always come first and are not secondary to other interests.
The committee is composed of experts from various fields to ensure that research proposals receive relevant and best review outcomes. This involves allocating proposals to relevant experts in related fields to ensure that research meets the highest standards.

In line with the DOH (2015/2024) Ethics in Health Research: Principles, Processes and Structures, the two committee is tasked to ensure the protection of research participants by accomplishing a combination of the following activities:

- The prior ethics evaluation and approval of projects
- The continuing review of ongoing research
- The active promotion of principles of ethics through education and training

WHY IS ETHICAL CLEARANCE NEEDED

Ethics clearance is necessary for legal and moral reasons.

- The National Health Act requires that all research involving human participants undergoes an ethics review.
- Ethics approval must be obtained for all research proposals before a research study commences (especially those that have ethical implications).
- Researchers must obtain ongoing approval, at least annually, throughout the research activity

ETHICS REVIEW PROCESS

1. The review process entails an independent and objective assessment of the potential effect of the proposed research on potential participants and on infrastructures that provides the site or context for the research before the research is commenced.
2. RECs must review research proposals and protocols prospectively to ensure that they meet the accepted ethical norms and standards and that research proposals stand up to scientific and ethical scrutiny appropriate to the disciplines concerned.
3. As per the 2015 department of health guiding principles for ethical research, the review must ensure that ethical and scientific standards are maintained to:

    - Protect participants from harm by weighing the risks of harm against the likelihood of benefit by minimising risks of harm to the extent possible and then by balancing the risk of harm relative to the likelihood of benefit.
    - In weighing the risk of harm against the likelihood of benefit, the analysis is concerned not only with current participants or research animals themselves but also with societal interests and future hypothetical beneficiaries.
    - Hold researchers accountable for the research activities
    - Promote important social and ethical values.

Note: PMREC will not consider research studies for approval if the study has been carried out already (ie there is no retrospective evaluation).

APPLICATION PROCESS FOR PMREC

1. Application form (available on from the PMREC office or online using the links below)
2. Hospital approval (Subsection on the application form requires approval by hos[ital management and the signature of the CEO)
3. Proposal with all necessary appendices as one word/pdf document (no multiple attachments should be sent)

RESPONDING TO FEEDBACK WHERE AMENDMENTS ARE REQUIRED

1. Amend the proposal as per comments and highlight changes with a red font colour
2. Fill in the proposal resubmisson tool (research amendment form (available on the SOP)
3. Submit to the committee for review
4. Reseach should not be started before the amendment is approved

MORE ABOUT PMREC

PMREC in the complex oversees research involving human participants , ensuring adherence to ethical standards. It reviews proposals, assesses risks and benefits, ensures informed consent, and monitors ongoing research for compliance. By upholding ethical principles, the REC maintains research integrity and promotes trust in the complex and province research endeavours.

Guiding Documents

i)Guidelines for Payment of Trial Participants in South Africa, 2012 (230.48KB)

ii) **PMREC GUIDING DOCUMENTS**

PMREC
IMPORTANT DOCI

iii)) PMREC Terms of Reference
iv) PMREC SOP Document
v) PMREC SOP For AE.

vi) NHREC guiding Documents

NHREC Guidelines for Community Advisory Boards, 2021 (165.64KB) NHREC Guideline for Management of Complaints, 2015 (136.15KB) DoH 2015 Ethics in Health Research Guidelines (2.18MB) NHREC Constitution 2017 (108.68KB) NHREC Constitution (107.82KB)

APPLICATION PROCESS

Please note : Application process is outlined on the SOP document
All requirements pertainng to applications are outlined in the SOP

ALL APPLICANTS SHOULD SEND THEIR APPLICATIONS TO THE SECRETARIAT ON TIME , AT LEAST TWO WEEKS BEFORE THE SCHEDULED MEETING TO ALLOW ENOUGH TIME FOR THE DISTRIBUTION OF THE APPLICATIONS TO THE REVIEWERS

For all Application Enquiries

Ethics Officers/Administrators

Dr A Poopedi
Email : ananiaspoopedi@ul.ac.za

Ms K L Shai Ms K L Shai
Kokishai17@gmail.com

PAYMENT STRUCTURE

PAYMENT PROCESS:

INDUSTRY-SPONSORED CLINICAL TRIALS

1. Submit a completed and signed *Payment instruction form: clinical trial* along with your application for a new project, progress report, amendment etc.
2. You/your sponsor will receive a PMREC invoice.
3. Payment reference: **"invoice number"**
4. Please submit proof of payment to : Dr Poopedi on email: ananias.poopedi@ul.ac.za

INTERNATIONAL (A) AND NATIONAL (B)

Internal applicants

1. Submit a completed and signed *Payment instruction form: health/human research* **AND** proof of payment/internal requisition number along with your HREC application for a new project, progress report, amendment etc.
2. Interdepartmental requisitions are payable to: **IDO00035** 3. Payment reference:
   a. New project application: **"Principal Investigator's surname and initials"**
   b. Progress report, Amendment, etc.: **"Principal Investigator's surname and initials and "Ethics reference number"/Project ID No**
4. Research applications with outstanding PMREC review fees will not enter the review process.

External applicants

1. Submit a completed and signed *Payment instruction form: health/human research* along with your PMREC application for a new project, progress report, amendment etc.
2. You will receive an HREC invoice.
3. Payment reference: **"invoice number"**
4. Research applications with outstanding HREC review fees will not receive their HREC letter. ***Enquiries: Dr Poopedi: ananias.poopedi@ul.ac.za***

PMREC

PIETERSBURG/ MANKWENG RESEARCH ETHICS COMMITTEE (PMREC)
FEE STRUCTURE

INDUSTRY-SPONSORED RESEARCH

Item	Description	Price (VAT&ICRR incl)
New application	Pharmaceutical / Industry driven company sponsors an investigator to conduct a new research project	R38 435
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R23 090
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification	R4 790
Protocol amendment - Major	Any change to the protocol that requires full committee approval	R7 745
Protocol amendment - Minor	Minor amendment; administrative change; typographical change to protocol; budget change or change to the contract; minor	R2 910
Informed consent amendment	technical Any change to the content of the original informed consent form	R2 910
Additional investigator	Any additional investigator (per investigator)	R1 430

INTERNATIONAL GRANT FUNDED RESEARCH

Item	Description	Price Vat Incl
New application	International grant funded research (Total project budget > R10m)	R28 985
New application	International grant funded research (Total project budget > R5m)	R19 140
New application	International grant funded research (Total project budget R1m to R5m)	R13 050
New application	International grant funded research (Total project budget R500 000 to R1m)	R6 825
New application	International grant funded research (Total project budget R100 000 to R500 000)	R3 495
New application	International grant funded research (Total project budget < R100 000)	R1 610
Extension / Roll-over study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation	R1 610
Annual re-certification / Progress report	Annual evaluation of research progress report for re-certification	R1 610
Protocol amendment - Major	Any change to the protocol that requires full committee approval	R1 610
Protocol amendment - Minor	Small amendments, administrative changes that do not affect study design	R1 165
Informed consent amendment	Any change to the content of the original informed consent form	R1 165
Additional investigator	Any additional investigator (per investigator)	R820

NATIONAL GRANT FUNDED RESEARCH (NRF, MRC, CSIR, etc.)

New application	National grant funded research (Total project budget > R1m)	R8 720
New application	National grant funded research (Total project budget R500 000 to R1m)	R4 660
New application	National grant funded research (Total project budget R100 000 to R500 000)	R2 325
New application	National grant funded research (Total project budget < R100 000)	R1 165
Extension / Roll-over study / Sub-study	Project is extended; study rolls over to open label; re-evaluation of protocol for continuation; sub-study	R1 165

Protocol amendment - Major	Any change to the protocol that requires full committee approval	R1 165
Informed consent amendment	Any change to the informed consent that requires full committee approval	R820

Non-sponsored student research for degree purposes at UL, self- funded projects, research funded solely from a UL departmental budget research are exempt

PMREC REVIEW FEES

GENERAL INFORMATION:

1) PMREC has a graded administrative fee structure in place, which is revised annually.
2) Non-sponsored student projects for degree purposes, self-funded projects, projects funded solely from a Stellenbosch University Departmental budget, and Harry Crossley research are exempt from fees.
3) *Payment instruction form: clinical trial* or *Payment instruction form: health/human research* can be accessed from our website:

4) PMREC reserves the right to not review a research application, or to withhold an HREC letter, if administrative fees are outstanding.

The PMREC will consider a well-motivated written request for reduction of fees. A decision will be made and communicated to the researcher in writing. Decisions taken should be viewed as final.

ANNEXURES

UPDATED PMREC TOR.docx

UPDATED SOP PMREC..docx

PMREC SOP FOR AE.docx

PMREC APPLICATION FOF

PROPOSAL AMENDMENT FOF

AMENDMENT PROCESS FOR PM

PMREC IMPORTANT DOCI