

**TERMS OF REFERENCE FOR THE**

 **LIMPOPO PROVINCIAL RESEARCH ETHICS COMMITTEE (LPREC)**

# Acronyms

# DG: Director General

# DOH: Department of Health

# DPME: The Department of Planning, Monitoring and Evaluation

# LPR2 : Limpopo Policy and Research Repository

# LPREC: Limpopo Provincial Research Ethics Committee

# LRF: Limpopo Research Forum

# NHREC: National Health Research Council

# RECs: Research Ethics Committees

# TORs: Terms of References

# 1. Preamble

The Terms of Reference (ToR) describe the formal character of the committee and it combines institutional requirements with the statutory requirements. The ToR includes the scope of the LPREC’s responsibilities, its relationship to researchers, its accountability, responsibilities and the mechanisms of reporting.

The National Department of Health (2015) sets out that it is mandatory that every organisation/institution, health agency and health establishment at which research involving human participants is conducted, must establish, or have access to a registered Human Research Ethics Committee. The Limpopo Provincial Government must ensure that all research involving human participants is designed and conducted ethically in accordance with the National Department of Health Research Council (NHREC) guidelines and LPREC Terms of Reference, reviewed and monitored in accordance with the National Statement.

Declaration by representatives of Research Ethics Committees in South Africa:

*In the interests of protecting human research participants, we, as representatives of the Limpopo Research Ethics Committee declare that the committee should be:*

* 1. Autonomous and free of any conflict of interest that impact on ethical decision-making processes based on the Department of Health guidelines “Ethics in Health Research: Principles, Structures and Processes (2015)”, the Constitution of South Africa and other relevant guidelines.
	2. Adequately supported by the Limpopo Provincial Government in order to ensure optimal human research participants' protection.

**2. Values**

* 1. The LPREC is anchored on the following values:

2.1.1Accountability

* + 1. Research merit and integrity
		2. Respect for human beings
		3. Human dignity
		4. Justice
		5. Beneficence
		6. Innovation
		7. Responsiveness

**3. Objectives**

3.1To protect the rights and welfare of research participants.

* 1. To establish standardized and uniform research ethics management systems and processes.
	2. To promote common research ethics approaches and understanding among departments municipalities and independent researchers.
	3. To assist researchers to conduct research that is ethically sound.
	4. To develop research ethics capacity in departments and municipalities.
1. **Functions**

4.1 Review all research protocols/proposals.

* 1. Approve all research protocols that involve human participants.
	2. Promote and monitor good ethical practice in the province.
	3. Protect the rights and welfare of research participants.
	4. Approve, reject, and require amendments to a research proposal on ethical and criteria approval grounds.
	5. Disseminate information on research ethics issues; and
	6. Audit the activities of research projects to ensure their compliance with research ethics.
1. **Scope of Responsibility**
	1. The LPREC is responsible for reviewing, approving and monitoring research protocols where humans are involved in research and where this research is undertaken by researchers utilizing Limpopo Provincial Government facilities
	2. Ensure that members of LPREC undergo orientation and training in research ethics.
	3. LPREC will coordinate training to the departmental and municipality R&D coordinators
	4. Safeguard the dignity, rights, safety and well-being of all participants involved in research projects considered by this committee.
	5. Ensure that the research ethics needs of the Limpopo Provincial Government are met.
	6. Collaborate with the National Health Research Ethics Council for South Africa and other applicable Research Ethics Committees, provincially and nationally.
	7. Ensure continual registration with NHREC.
	8. Periodically familiarize itself with possible changes in legislation pertaining to research ethics.
	9. Regularly inform departments, municipalities and independent researchers about ethical requirements regarding research and make guidelines regarding research ethics readily available.
	10. The Terms of Reference and composition of the LREC might change as circumstances dictate.

**6. Accountability and Reporting**

6.1 LPREC is an advisory Committee of the Director General (DG) of the Limpopo Provincial

 Administration mandated to:

 6.1.1 Approve human research on ethical grounds

 6.1.2 Terminate human research approval on ethical grounds

 6.1.3 Suspend human research approval on ethical grounds

 6.1.4 Withdraw human research approval on ethical grounds

 6.2 LPREC is accountable to the DG through the Deputy Director General (DDG)-Planning,

 Monitoring & Evaluation) (PME). The LPREC shall bring to the attention of the DDG:

 (PME) any issues relating to human research ethics that may constitute breaches of the

 Limpopo Provincial Government research ethics Policy, DoH and NHREC requirements.

 6.3. LPREC will make the Terms of Reference, Standard Operating Procedures and membership

 information publicly available by posting them on Limpopo Policy Research and Repository

 (LPR2).

 6.4 LPREC will provide annual reports to:

 6.4.1 NHREC

 6.4.2 DG

 6.4.3 Limpopo Research Forum (LRF)

 6.5. LPREC will liaise with departments and municipalities on matters of significant ethical concern.

**7. Composition**

The compositions of the LPREC shall comprise of the following:

* 1. Consist of members who, collectively, have the qualifications and experience to review and evaluate research proposals involving human participants
	2. Be independent, multi-disciplinary, multi-sectoral and pluralistic.
	3. LPREC will ensure a balance in terms of age, gender and race.
1. **Composition of the Limpopo Provincial Research Ethics Committee will be as follows:**
	1. Chairperson
	2. Deputy Chairperson
	3. A representative from South African Local Government Association (SALGA)
	4. Person with legal training
	5. Clinical psychologist
	6. Member (s) with qualitative research methodology experience
	7. Member (s) with quantitative research methodology experience
	8. Medical Doctor(s)
	9. Social worker
	10. Statistician
	11. Epidemiologist
	12. Lay person
2. **The quorum of the meeting shall be 33% of the total number of committee members.**
3. **Appointment of members**
	1. The Chairperson and Deputy Chairperson will be appointed or elected at the first seating of the LPREC.
	2. The members will be recruited by officially requesting nominations from the institutions
	3. Members will be officially nominated by the head of institutions
	4. Members will be appointed by the DG in writing. The letter of appointment will include date of appointment, duration, indemnity and termination.
	5. The committee members will perform the functions of LPREC for a duration of 5 years.
	6. Members will be inducted and oriented.
	7. Members will be expected to participate in ethics training as required
	8. Members are expected to be familiar with the NHREC guidelines and other legislation as
	9. A member may resign at any time upon giving notice in writing to the Chair.
4. **Liability and Coverage**

The Provincial Administration will provide legal protection in respect of liabilities that may arise in the course of bona fide conduct of your duty as a committee member.

1. **Applications, Review and Approvals**
	1. **Application for Review**

Research proposals/protocols shall be submitted electronically to the secretariat of the committee. Application forms and templates are electronically obtainable on the website: <http://policyresearch.limpopo.gov.za/>. Researchers will be encouraged to use this facility in order to access these documents.

 Attached to the proposal should be the following documents:

* + 1. a completed application form (obtainable from the secretariat).
		2. data collection tool.
		3. informed consent form.
		4. information sheet.
		5. a letter from the university signed by the research supervisor/promoter and the Head of Department: this is in cases where research projects are for academic purposes.
		6. An ethical clearance certificate/letter from the university if the university has an ethical committee.
		7. Monitoring schedules and responsible persons and their contact details for all proposal/protocols and studies involving moderate increase over minimal risks; and
	1. **Research Proposals/Protocols Review Process**
		1. Subsequent to the application for ethical review, the secretariat shall pre-review the proposal and check if all necessary documentations are attached, this shall be done using a standardised checklist to ensure that the application forms and proposals adhered to standards requirements of the committee.
		2. In the event that forms are not fully completed and proposals having deficiencies the secretariat shall advise researchers accordingly in writing.
		3. Only applications which have successfully passed the secretariat’s pre-review stage will be further processed into being pre-reviewed by the committee prior to the sitting of the full committee meeting.
		4. Should there be a proposal that requires specialised expertise and committee members do not possess such, then a specialist/expert will be sought to be part of that particular review.
	2. **Reviews at a Full Committee Meeting**
		1. The chairperson shall lead the review process and should the chairperson be unavailable, the deputy chairperson shall assume responsibilities of the chairperson. In the absence of both the chairperson and deputy chairperson, members of the committee shall elect one LPREC member to lead the review process. Whoever is leading the meeting shall be the person signing off minutes and decisions of the meeting together with the secretariat.
		2. Should there be a need to have researchers presenting their proposals in order to clarify some of the queries that may arise during the pre-review and/or review stage then the researcher shall be invited to the meeting.
		3. After offering clarifications the researcher / supervisor shall be excused from the meeting to allow the committee to make decisions regarding the proposal.
		4. Committee members should focus an extensive attention on scientific and ethical issues, as these two elements can determine whether a protocol is scientifically and ethically sound or not.
	3. **Expedited Review**

Research proposals/protocols that may require an expedited review maybe afforded an expedited review only if they have satisfied all requirements in accordance with the research template and checklist.

The total process from submission to approval for major events such as protests and political violence shall take approximately 2 weeks. Whereas, major events such as outbreaks of deadly diseases, floods and other natural disasters shall be approved within 3 to 5 working days.

* 1. **Retrospective Review**

Notably, the LPREC shall not provide a retrospective review such as when a researcher conducts a study without getting ethical clearance and requires ethical clearance after conducting their study.

* 1. **Review Of Proposals by another REC**

In line with item 12.2.4. should LPREC be unable to review proposals/protocols then the researchers will be advised to seek ethical clearance from other RECs. This option should only be explored when the secretariat and chairpersons have perused the proposals and satisfied themselves that the researcher has adhered to requirements of the LPREC. The decision to direct researcher to approach other RECs should be guided by the following conditions:

1. That research ethics committee must be registered with the National Health Research

Ethics Committee (NHREC);

Subsequent to the attainment of the ethical clearance the researchers must provide a copy of the ethical clearance certificate to LPREC and the relevant department prior to commencing with the project in the Limpopo Province, this should be done within 7 days of the approval date. The relevant department will then provide the researcher with a permission letter to use their facilities in the province; and

1. The ethical clearance certificate must indicate the NHREC registration number.
2. **MEETINGS**

The committees shall hold 10 meetings per year or as and when it is necessary to meet.The quorum of the meeting shall be 33% of the total number of committee members.

The researchers are advised to submit their proposals to the secretariat by the 07th of every month to be tabled for the next review meeting.

The LPREC will endeavour to reach a unanimous decision concerning the ethical acceptability of a research protocol. Where a common decision is not reached, the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one layperson. Minority views will be recorded in the minutes.

Meetings will be conducted in such a way to encourage discussion, debate and the exchange of ideas.

The secretariat shall do the following:

* 1. Issue invitations of the meetings.
	2. Ensure that members of the committees notify the office if they are not able to attend the meeting.
	3. Ensure that members of the committees receive research proposals/protocols to be reviewed within 10 working days of the scheduled meeting to ensure massive participation and effectiveness during the meeting.
	4. Record minutes of the meetings and disseminate to members of the committees within 10 working days and
	5. The chairpersons of the committees may convene meetings on an ad hoc basis depending on the urgency of the matters.
1. **Procedural Matterrs**
	1. The LPREC should:
2. Perform its functions according to written standard operating procedures.
3. Maintain written records of its activities and minutes of its meetings.
4. Comply with the applicable regulatory requirement(s).
	1. All members have full voting powers, excluding the Secretary
	2. Decisions at the LPREC meeting will be taken by consensus after discussions, and whenever needed voting will be done.
	3. Invited researchers/supervisors may only provide information on any aspect of the protocol.
	4. Observers should not participate in the deliberations of the committee or the vote/opinion of the committee.
5. **Disclosure of potential conflict of interest**
	1. Researchers / supervisors and **members of LPREC** must ensure disclosure of affiliation with, or financial involvement in any organization or entity with a direct interest in the subject matter of materials of the project.
	2. LPREC members shall sign confidentiality forms on the first meeting of their term in office and will sign declaration forms every time the committee sits.
	3. Should there be any member with declaration of conflict of interests in any proposal/protocols the member shall recues him/herself from a meeting, until decisions are made on that particular proposal/protocol.
	4. This disclosure must cover the full range of potential interests.
	5. such as direct benefits like the provision of materials or facilities, and
	6. financial or in-kind support; for example, payment of travel, accommodation expenses to attend conferences.
	7. Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect decisions regarding other people.
	8. Researchers / supervisors have an obligation, at the time of reporting, proposing research, or seeking approval from LPREC or other regulatory authorities to declare any conflict or interest which has a potential to influence the project and its conduct.
	9. Members of LPREC must withdraw from the committee when discussion of projects in which they are personally involved takes place and must not use their membership to gain a favourable advantage.
6. **Safety Monitoring and Progress Report**

In accordance with ethics legislations, LPREC shall monitor adherence of the approved proposals/protocols to minimise risks and protect participants. The LPREC has the right to withdraw ethical licence at any given point should the researcher deviate from the approved research protocol.

The frequency and type of monitoring will be in accordance with the degree of anticipated risks to participants.

The LPREC monitoring process will be done as follows:

1. Through annual reporting from researchers. This will provide LPREC with information on how the approved research projects are progressing from the time of approval to the completion of those projects.

The passive and active monitoring tools will be shared upon the approval of the study.

The following will be outlined on the clearance certificate:

1. Ethically approved studies must apply for renewal annually
2. Ethics approval will not be valid when an annual renewal is not granted by LPREC
3. Applications for annual renewal must be made a month before expiry date stipulated on the clearance certificate.
4. Annual must be submitted by researchers until the completion of the study
	1. **Active Monitoring**

The committee will form sub-committees which will be tasked to undertake active monitoring of research projects. The committee will sample research projects that need to be monitored and assign such sampled projects to the sub-committee to undertake monitoring of approved research projects. The sub-committees are at liberty to make follow-up reviews depending on the nature of the project.

**16.1.1 The follow-up procedure will take the following into consideration:**

1. The requirements laid down for follow-up reviews, the reviews, and the communication procedure. This may vary from the requirements and procedure for the initial decision on an application.
2. The follow-up review intervals are determined by the nature and events expected in relation to particular research projects, though each research project should undergo a follow-up review at least once a year.

 **16.1.2 Events leading to indications for a follow-up review of a study**

Indications that will make LPREC decide to make a follow up or monitoring visits of a project includes:

1. Any protocol likely to affect the right, safety, and /or well-being of the research participants or the conduct of the study
2. Serious and unexpected adverse event related to the conduct of the study or study results, and the response taken by investigators, sponsors, and regulatory agencies, when applicable
3. Any event or new information that may affect the benefit/risk ratio of the study

A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the LPREC’s original decision or confirmation that the decision is still valid.

**16.1.3 NOTE:**

In the case of the premature suspension/ termination of a research project that was approved by LPREC, the applicant should notify the LPREC immediately of the suspension/ termination.

* + - 1. **Outcome of the review**
1. A summary of results obtained in a study prematurely suspended/terminated should be communicated immediately to LPREC
	* 1. **Active Monitoring Tool**

Below is the tool to be used when committee undertakes the active monitoring exercises.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Research Project Title`** | **Stage/Phase**  | **Activities Involved** | **Start Date of the Project** | **Estimated Completion Date of the Project** | **Progress (Deliverables)** | **Recorded SAEs** | **SAEs Mitigations** | **Challenges/Comments** |
|  |  |  |  |  |  |  |  |  |
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1. **Passive Monitoring**

Researcher will report to the LPREC on an annual basis as a passive monitoring exercise. A template used for passive monitoring is developed to assist both the secretariat and the researcher when reporting is done.

1. **Handling of Complaints**

Handling of minor complaints from researchers shall be done through the secretariat and the chairperson. Complaints shall be received in writing and response of such complaints will be done in writing as well.

Major complaints shall be submitted in writing to the secretariat or chairperson and such complaints will be tabled for discussions in the committee meeting and the committee will respond to the complainant in writing.

The committee will make efforts to address complaints as presented to them, should the complainant be unsatisfied with response from the committee then the complainant can seek the intervention of the Director General (DG). Should the complainant be not satisfies with the DG’s response then the matter can be taken up with the NHREC.

1. **Charging Fees**

LPREC does not charge a service fee to review research proposals.