

THE PREMIER

Limpopo Provincial Research Ethics Policy

Acronyms

DG	Director General
NDOH	National Department of Health
LPREC	Limpopo Provincial Research Ethics Committee
NDP	National Development Plan
SOP	Standard Operating Procedures
NHREC	National Health Research Ethics Council
TOR	Terms of Reference

Definitions

The following definitions are applicable for the purpose of the policy document:

- a) **Research ethics:** The application of fundamental ethical principles to research activities which include the design and implementation of research, respect towards society and others.
- b) **External researcher:** researchers who are not affiliated to the Limpopo Provincial Government
- c) Independent researcher: A researcher who conducts research without being employed by government to do so and without a direct instruction by the Limpopo Provincial Government
- d) LPREC: an independent provincial committee whose sole mandate is to review research proposals on the basis of their methodological and ethical soundness.
- e) **Principal Investigator:** The lead actor(s) who is at the forefront of a particular research or scientific projects
- f) Research Participant: A person who provides informed consent to voluntarily participate in a human research study
- g) Researcher: A person who carries out academic or scientific research

1. INTRODUCTION

The Limpopo Provincial Government strives for excellence in research as part of promoting evidence-based planning and policy making in the province. Research is understood to be the process of thorough of investigation, systematic discovery and or rigorous analysis that aims to uncover the truth, produce a deeper understanding and or create new knowledge. The rationale of the research ethics policy is to guide research conduct in the province.

Importantly, research is inexorably intertwined with the principles of integrity, honesty and reliability. This policy is to be read in conjunction with the LPREC Standard Operation Procedures (SOPs). It is important to recognise too that breaches of research integrity norms and standards lead inevitably to the harm of participants.

2. PURPOSE AND THE AIM OF THE POLICY

The policy seeks to sustain an environment that supports vibrant research by creating an enabling framework that guides the conduct of the research community in the Limpopo Provincial Government.

2.1. Purpose

The purpose of this policy is to guide research ethics conducts in the Limpopo Provincial Administration.

2.2. Aim

This policy aims to influence the behaviour of departments, municipalities and external stakeholders and to get researchers to collectively commit to conducting research with the utmost integrity and ethics.

3. POLICY STATEMENT

It is the policy of the Limpopo Provincial Government to independently review, approve and monitor research that involves human participants and the environment within a framework of generally accepted research ethics guidelines.

4. SCOPE OF APPLICATION

This policy applies to all researchers conducting research in the Limpopo Provincial Government, including external and independent researchers.

5. PRINCIPLES

The policy is underpinned by the following principles:

- a) Respect
- b) Free & Informed Consent
- c) Respect for anonymity, privacy and confidentiality
- d) Beneficence and non-maleficence
- e) Respect for justice and inclusiveness

6. LEGAL MANADATE AND POLICY FRAMEWORK

It is acknowledged that the ethics of research are developed and refined within an everevolving societal, political and cultural context. Nonetheless, it is necessary that the Limpopo research community conduct research within the framework of internationally acceptable moral imperatives, ethical principles and the national legal framework. This policy is thus based on the guiding principles and legal imperatives of the following three documents and their amendments.

- a) The Constitution of the Republic of South Africa (108 of 1996): The Bill of Rights (Chapter 2 of the Constitution) enshrines the rights of all people and affirms the democratic values of human dignity, equality and freedom. Section 12(2)(c) specifies the right of the individual "not to be subjected to medical or scientific experiments without their informed consent". Section 16(1)(d) states that individuals have the right to freedom of expression which includes "academic freedom and freedom of scientific research". Section 24 refers to the rights of individuals "to an environment that is not harmful to their health or well-being; and to have the environment protected for the benefit of present and future generations"
- b) National Health Act (Act 12 of 2013) as amended from time to time, specifically section 72, "National Research Ethics Council" and section 73, "Health Research Ethics Committees" which layout a framework for ethical research in South Africa and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 ("National Guidelines 2024, 3rd edition.

7. INSTITUTIONAL ARRANGEMENT

The Limpopo Province has established the Limpopo Research Ethics Committee comprised of key representatives from government departments, institutions of higher learning and communities. LPREC is established in terms of the NDoH 2024 and is registered with the National Health Research Ethics Council (registration number: REC-111513-038.

8. DEPARTMENTAL RESEARCH SUPPORT

Limpopo Provincial departments and municipalities shall establish research committees. Research Committees shall be appointed accounting officers. The responsibilities of the research committees will be as follows:

- a) Pre-review all research applications before submission to LPREC for final review.
- b) Ensure that all supporting documentations are attached.
- c) Issue permission letters upon LPREC approval

9. RESPONSIBILITY OF ETHICS

- a) It is the responsibility of all researchers to ensure that they uphold principles of research integrity as described in this policy. Part of this commitment is to have all research that directly or indirectly, deliberately or accidentally involves human participants, especially vulnerable people and groups, considered by a research ethics committee and approved as ethical before it is implemented and/or conducted. No data involving human subjects can be collected until the provincial ethical clearance has been obtained. LPREC has the right to review all research protocols approved by the researcher's institutions before data can be collected in the Limpopo Provincial Government.
- b) It is the responsibility of the Limpopo Provincial Government through the Office of the Premier to ensure that there is an accredited and registered structure in place to promptly and independently review research protocols to be conducted in the province. The functioning of LPREC is delegated an independent body that is not affiliated to

Limpopo Provincial Government e.g. any university that resides within the boundaries of Limpopo province.

10. PROVINCIAL RESEARCH ETHICS COMMITTEE

10.1 MEMBERS OF THE LPREC

The LPREC shall be constituted as follows:

- a) Chairperson
- b) Deputy Chairperson
- c) A representative from South African Local Government Association (SALGA)
- d) Person with legal training
- e) Clinical psychologist
- f) Member (s) with qualitative research methodology experience
- g) Member (s) with quantitative research methodology experience
- h) Medical Doctor(s)
- i) Professional nurse
- j) Social worker
- k) Statistician
- I) Epidemiologist
- m) Lay person/community representative

10.2. FUNCTIONS OF THE LPREC

- a) Review all research protocols/proposals.
- b) Approve all research protocols that involve human participants.
- c) Promote and monitor good ethical practice in the province.
- d) Protect the rights and welfare of research participants.
- e) Approve, reject, and require amendments to a research proposal on ethical and criteria approval grounds.
- f) Disseminate information on research ethics issues; and
- g) Audit the activities of research projects to ensure their compliance with research ethics.

10.3. MEETINGS OF THE LPREC

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:

- a) Issue invitations of the meetings.
- b) Ensure that members of the committees notify the office if they are not able to attend the meeting.
- c) 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.
- d) Record minutes of the meetings and disseminate to members of the committees within 14 working days and
- e) The chairpersons of the committees may convene meetings on an ad hoc basis depending on the urgency of the matters.

10.4. COORDINATION OF LPREC

The activities of the LPREC shall be coordinated by the Research & Development Unit of the Office of the Premier. The Unit shall coordinate the following functions:

- a) Hosting of LPREC meetings and workshops
- b) Ethics training for LPREC members
- c) Record keeping and safeguarding of all documentation
- d) Provision of secretariate services

- e) Provision of a full-time dedicated ethics officer
- f) Management of the research repository

10.5 LPREC SUCCESSION PLANNING

The committee is taking proactive steps to address the end of term of the chairperson and ensure a smooth transition in leadership. By appointing a deputy chairperson, the committee aims to have a capable individual ready to assist with the leadership responsibilities. Additionally, in the absence of the chairperson, the current deputy chairperson automatically assumes the responsibilities of the chairperson. The committee also capacitates and empowers all members of the committee to understand the functions, processes and procedures of the committee as a mechanism building towards succession planning. Furthermore, the planned behavioural and conduct of the committee members during daily operations and functions of the committee is supporting the succession planning.

11. DEFAULT

Any policy, procedure, or guideline that does not follow the procedures and processes outlined in this policy will not be approved by the relevant authority and will remain void.

12. INCEPTION DATE

The inception date for the policy will be effective immediately after the approval by the Director General.

13. REVIEW AND TERMINATION OF THE POLICY

The policy shall be reviewed after sixty (60) months from the date of approval by the DG or sooner as per the decision or directive of the DG. This policy will remain in force until and unless it has been withdrawn and amended by the executing authority.

14. ENQUIRIES

Enquiries regarding this policy should, in the first instance, be directed to the Research & Development unit: lprecsecretariat@limpopo.gov.za or 015 287 6165/6320/6590/6552

APPROVED BY:

N.S Nchabeleng

Director-General