LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

OFFICE OF
THE PREMIER

LIMPOPO PROVINCIAL RESEARCH ETHICS COMMITTEE (LPREC)

GENERAL STANDARD OPERATING PROCEDURES AND GUIDELINES

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LIST OF ABBREVIATIONS

DG: Director General

DDG: Deputy Director General

DOH: Department of Health

LPG: Limpopo Provincial Government

LPREC: Limpopo Provincial Research Ethics Committee

LPR^2: Limpopo Policy Research Repository

MRC: Medical Research Council

NHREC: National Health Research Ethics Committee

OTP: Office of the Premier

PhD: Doctor of Philosophy

P, M&E: Planning, Monitoring & Evaluation

REC: Research Ethics Committee

SOP: Standard Operating Procedure

TOR: Terms of Reference

DEFINTIONS

Confidentiality: The condition in which the researcher knows the identity of a research subject but takes steps to protect that identity from discovered by others.

Committee: A group of people/members appointed to manage the function of LPREC.

Chairperson: The presiding officer of a LPREC meeting.

Co-opting: appoint to membership of a committee by invitation of the existing members.

Non-affiliated: Not associated with LPREC.

Researcher: A person who carries out academic or scientific research.

Research Ethics: The application of fundamental ethical principles to research activities which include the design and implementation of research, respect towards society and others.

Whistle-blower: A person who reveals information about the activity within research conducts that is deemed illegal, immoral, illicit, unsafe or fraudulent.

Whistleblowing procedures: An act of informing someone in authority about alleged research misconduct (fabrication, falsification or plagiarism), fraud, maladministration and non-adherence to approved. research procedures, guidelines or policies from research studies approved by LPREC.

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the researchers/departments/municipalities with a clear systematic procedure to follow when applying for ethics approval.

2. Purpose of the LPREC

The purpose of the LPREC is to ensure good quality research conduct in the province by approving research proposals on the basis of methodological and ethical soundness.

3. Appointment of members of LPREC

2.1 Nominations for members of LPREC are done by the Director General (DG) of the Limpopo Provincial Administration through a letter directed to the head of institutions.

2.2 The nominated members will be appointed by DG.

2.3 Members will receive a formal notice of appointment detailing the terms and conditions of their appointment.

4. Roles and functions of LPREC

LPREC reports to the Director General.

3.1. The Director General

The functions of the DG shall include the following:

3.1.1 Ensure adequate provision of resources for the functioning of the committee.

3.1.2 Support the secretariat.

3.1.3 Recognise membership to the Committee by issuing formal certificates of recognition at the end of their term.

The limitations of the functions of the DG include administrative functions of the LPREC and shall not be involved in decision making of the committee.

3.2 Chairperson

The functions of the chairperson shall include but not be limited to:

3.2.1 Review the agenda and minutes of the meeting in consultation with the secretariat.

3.2.2 Sign the minutes.

3.2.3 Sign the Ethical Clearance certificate.

3.2.4 Chair the LPREC meetings and facilitates discussions.

3.2.5 Report to the DG through the Deputy Director General (DDG), Planning, Monitoring and Evaluation (PC M&E) on the activities of the committee.

3.2.6 Serve as the link between the LPREC and other stakeholders.

3.2.7 Refer, at his or her sole discretion, submission/s for expedited review.

3.3 Deputy Chairperson

The functions of the Deputy Chairperson shall include but not be limited to:

4.3.1 Assume duties of the responsibilities of the Chairperson if the chair is not available or if a need arises.

3.4. Secretariat

The functions of the secretariat shall include but not be limited to:

3.4.1 Receive documents and acknowledge receipt of proposals and related documents from the researchers.

3.4.2 Draw up the agenda.

3.4.3 Distribute the agenda to members of the committee.

3.4.4 Organise committee meetings.

3.4.5 Scribe the minutes for the committee meetings.

3.4.6 Communicate the outcome of the review of the proposal or any process of the committee to the researchers.

3.4.7 Keep and file records of the committee, including those specified in the DOH guidelines 2024"Ethics in Health Research: Principles, Structures and Process".

3.4.8 Advise and guides the committee on relevant regulation and policy that are related to the committee.

3.4.9 Archived records will be kept for a maximum period of five years, after completion of research, after which records will be disposed of.

3.4.10 Seek and utilise other expert assistance in consultation with the Chairperson., if the need arises.

3.4.11 Co-opt or appoint alternative members and replace regularly needed expertise, in consultation with the Chairperson.

3.4.12 Identify training needs for the committee.

3.4.13 Facilitate the approval process of all documents of the committee.

3.4.14 Liaise with the departments, municipalities, universities, research institute and independent researchers on research matters.

3.4.15 Execute any other tasks assigned by the committee.

5. Roles of LPREC members

4.1 Attend meetings regularly as per NHREC guidelines.

4.2 Review proposals as allocated to ensure ethical and scientific merit, with the main aim of protecting the rights of the research participants in line with the NHREC guidelines.

4.3 Serves as a general reviewer on all research by actively participating in the discussion of all other proposals.

4.4 May be delegated to review proposals that should be expedited.

4.5 Perform any other duties/functions assigned to them such as active monitoring

4.6 Members who will not attend meeting are expected to submit reviews to the secretariat a day before the meeting by 13h00

4.7 All members who attend meetings are expected to submit reviews the day after the meeting.

4.2 Co-opted / alternate members

4.2.1 To contribute their professional, specialist and general knowledge and skills to the Committee.

4.2.2 Attendance shall be recorded in the official minutes of the meeting.

4.2.3. The co-opted members will complete and sign declaration and confidentiality forms

4.2.4. The co-opted members' roles will only be limited to the assigned proposal(s)

6. CONDITIONS OF OFFICE

5.1. Term of office

5.1.1 The term of membership is five (5) years, and at the end of members' term, nomination, election and co-option processes shall be put in place, following defined procedures.

5.1.2 To ensure the blending of the advantages of experience with those of new perspective, members of the LPREC may be re-elected or re-appointed for two or more terms of office.

5.1.3 A member can be replaced in the event of resignation, death or long-term unavailability or any other action not commensurate with the responsibilities laid down in NHREC guidelines.

5.1.4 A member may resign from the committee with reasons in writing.

5.2. Confidentiality

All members should maintain absolute confidentiality of all discussions during the meetings and upon being appointed to the Committee, sign a confidentiality form declaring the fact that they will maintain absolute confidentiality.

5.3. Code of conduct

Upon appointment members are expected to sign a code of conduct.

5.4. Conflict of interest

5.3.1 A Committee member should declare a conflict of interest, whenever applicable.

5.3.2 No Committee member may participate in the review of any proposal in respect of which a member has a conflict of interest, except to provide information that may be requested by the Committee.

5.3.3 Members who have conflicting interests are required to disclose such interest and recuse themselves from deliberations of the relevant proposal.

5.5. Compensation of members

5.4.1 The Limpopo Provincial Government (LPG) will not remunerate members who serve on the Committee.

5.4.2 Only non-affiliated and co-opted members shall be provided with accommodation, Subsistence & Travelling allowance at a rate determined by government. This allowance is only applicable when then non-affiliated members attend physical LPREC meetings, or any assignments related to the functions of the Committee.

5.4.3 The LPG will pay for ethics training of members

5.5. Recognition of membership

The DG will, at the end of the term of office provide members with formal certificates of recognition.

5.6. Induction, orientation and training of members

At the start of a new member's term, prior to participation in the Committee activities, the following induction and orientation will be provided:

5.6.1 The Ethicist will present a brief overview of the principles of ethics and morals.

5.6.2 The Secretariat will make available the TOR and SOP, legislation and guiding documents, and explain the administrative procedures, with which a member must be familiar.

5.6.3 The Chairperson will induct the members on the responsibilities, functions, procedural matters and operations of the Committee.

5.6.4 All members shall be required to attend at least one ethics training workshop every three years and proof of attendance should be recorded by the secretariat.

5.6.5 Ethics training arranged by OtP will be paid for by government

5.6.6 Copies of ethics training certificate to be provided

5.6.7

5.6.8 The Committee Secretariat shall endeavour to update members on any new developments regularly by making available any new information, inviting experts to address Committee, or paying for members to attend seminars or workshops on recent ethics developments.

5.6.9 The Committee will endeavour to update the Limpopo Policy and Research Repository (LPR^2) which will be a website used to upload ethics documents.

7. Ethical guidelines

The Ethical guidelines of the Committee shall be read together with the Helsinki Declaration, the Department of Health, South Africa Clinical Trials Guidelines 2020 (Good Clinical Practice), Ethics in Health Research: Principles, Structures and Processes, Guidelines from the MRC and the rules and regulations that follow the National Health Act (Act 61 of 2003) as amended as well as the Department of Health Ethics in Health Research: Principles, Structures and Processes, Guidelines (2024) as amended.

8. Proposals for Review

8.1. Types of proposals

All research that includes human participants shall, before the commencement of such research, be submitted for review.

8.2. The research proposal and supporting documents

8.2.1. Research proposal

The research proposal shall:

(a) Adhere to an acceptable and standardised format.

(b) Have a clear title with accurate date and principal investigator/researcher and/or supervisor's information.

8.2.2. Supporting documents

The supporting documents should include but not be limited to the following:

a) Application letter

b) Application for review form

c) A sample of informed consent to participate in the research

d) A sample of informed consent for case reports/access to files

e) A sample of informed consent from parent/legal guardians/curator/proxy/ authorised person for minors and other vulnerable groups

f) Conflict of interest statement

g) Any other written document, leaflet which will be provided to the participants

h) Child assent form

i) Data management form

j) Ethical clearance from university

k) Proof of registration

l) Data management tool

m) Sample of a gatekeeper permission letter (where applicable)

N.B. *The researcher is responsible for the submission of all documents to all relevant structures.*

8.3. Forms and other standard declaration documents

(a) The required forms are available electronically from the LPR[2]

8.4. Completion of forms

(a) Where indicated, forms must be duly completed and signed

(b) Incomplete and unsigned documents shall be returned, and this might delay the review process.

10. Submission Procedures

a) An applicant shall submit a proposal:

(i) That has been approved by the university if the researcher is a registered student.

(ii) That has been pre-reviewed by the concerned department/municipality

b) The applicant shall submit the research proposal and supporting documents three weeks before the meeting.

11. Review Procedures

The LPREC's task is to review research proposals and their supporting documents, to make recommendations regarding the issuing of a clearance certificate allowing the research to proceed to

the concerned department or municipality to sought permission to use their facilities. The review process should not be obstructive, and clearance certificates should not be withheld for minor issues.

11.1 The types of review process

11.1.1 Reviews at a Full Committee Meeting

(a) 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.

(b) 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.

(c) After offering clarifications the researcher / supervisor shall be excused from the meeting to allow the committee to make decisions regarding the proposal.

(d) 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.

11.1.2 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.

11.1.3 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.

11.1.4.1 Criteria for Expedited review

Expedited research should meet the criteria required and must not be carried out by LPREC members who are in a position of dependence with the applicant that could be perceived as a conflict of interest. The following serves as the criteria required for the Committee to expedite research projects:

(a) Minimal risk

(b) No vulnerable population

(c) Information is recorded so that subjects are not mentioned

(d) No extraction of blood or human experimental procedures

(e) Minor revisions after previously conditional approved

(f) Annual renewal of ethical clearance

(g) Researching on outbreak investigations, epidemic conditions or prospective collection of biological specimens for research purposes by non-invasive means e.g. hair and nail clippings.

11.2 Submission and review turnaround time

The researchers should submit their proposals to the secretariat three weeks before the date of the next review meeting.

12. LPREC Review Process

12.1 Pre-review and processing of applications

12.1.1 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

12.1.2 If documents are missing, forms not fully completed, the secretary will communicate electronically in writing with the researcher to rectify the problem as soon as possible.

12.1.3 Only applications that have successfully pre-reviewed will be further processed.

12.1.4 The secretariat allocates reviewers among LPREC members

12.1.5 If a committee member believes that they cannot be a reviewer for any reason, including lack of expertise or a conflict of interest, the Secretariats should be notified immediately.

12.1.6 .

12.1.7 The reviewer is requested to review the application and present a review form.

12.1.8 The secretariat will ensure that members of the committees receive research proposals/protocols and other supporting documents to be reviewed within 10 working days of the scheduled meeting.

12.2 Responsibilities of the Reviewers

Reviewers must:

(a) Conduct an in-depth review of the proposal and accompanying documents using the standardised review form/template.

(b) Submit a completed review form/template to the secretariat no later than the day after the LPREC meeting and not later than a day before the meeting if not in attendance. The report must conclude with a recommendation (either Approved, Conditionally Approved – with minor changes, Not Approved– major modifications required (resubmission) supported by sound reasons.

(c) Lead the discussion on the initial or ongoing reviews at full committee meetings.

12.3 Reviewing process during a committee meeting

(a) The reviewer leads the discussions based on the submitted report.

(b) Researchers may be invited to attend the meeting to offer clarifications on specific matters regarding their proposals. After providing clarifications the researcher/supervisor leaves the meeting and discussions continue with the aim of reaching a decision.

(c) Committee members should pay particular attention to scientific and ethical issues, as these two elements decide whether a proposal is approved, or not.

(d) Reviews with minor modifications can be signed off by the Chairperson and secretariat only if the documents are in compliance with comments made by the committee then the secretariat will process the full approval and record in the agenda of the next meeting.

(e) The decision of the expedited review serves at the next LPREC meeting for ratification.

12.4 Recording of minutes and communication of review feedback (outcome and recommendations)

(a) The secretariat shall record all proceedings of the meetings.

(b) The outcome of the review shall be communicated to the researcher(s) by the Secretariat within 14 (fourteen) working days after the LPREC meeting.

(c) The Secretariat shall keep records of all correspondences in respect of submissions and decisions including but not be limited to:

(i) Project identification number.

(ii) Details of the principal investigator(s).

(iii) Title of the project.

(iv) Dates and correspondence pertaining to approval and non-approval.

(v) Complaints and appeals from researchers.

13. Conditions for approval

13.1 Approval is given for a duration of one year/ twelve months from the date of issuing, if an extension is necessary the renewal form must be submitted a month before the elapse of the ethical clearance.

13.2 LPREC has the right to suspend or revoke ethical clearance.

13.3 Completion and annual progress reports must be submitted to LPREC.

13.4 An applicant must respond to recommendations from LPREC within 30 working days of receiving feedback. Failure to submit within the specified time, the researcher should notify the secretariat with valid reasons. Failure to notify the secretariat will result in the proposal being treated as a new submission.

14. Monitoring of Approved Proposals and Reporting of Adverse Effects

According to the Helsinki Declaration (2013) and the NDOH Guidelines (2024) ethics committees must monitor adherence to approved proposals to minimise risks and protect participants. The frequency and type of monitoring must be in accordance with the degree of anticipated risk to participants.

14.1 Active monitoring of approved proposals

(a) LPREC has the right to monitor the research it approves.

(b) The monitoring process shall be transparent and open. Amongst others, it will include but not be limited to the following: random inspection of research project, data and signed consent forms, and records of interviews. Approval letter should indicate that such monitoring may take place.

14.2 Passive monitoring of approved proposals

(a) Each approved proposal must be monitored at least once annually until the research is completed.

(b) The applicant must submit at least one annual progress report to LPREC containing but not be limited to the following:

(i) Progress to date, or outcomes in the case of completed research.

(ii) Information concerning maintenance and security of records.

(iii) Evidence of compliance with the approved proposal.

(iv) Evidence of compliance with any conditions of approval.

(v) Changes in the methodology and ethical issues.

15. Reporting of adverse events/effects or unforeseen circumstances

15.1 Should an adverse event/effect or unforeseen circumstance (e.g. life threatening condition, death, injury, hospitalization) arise after the applicant had received the approval letter, s(he) shall report the matter to LPREC within three calendar days of such occurrence. Adverse event/effects or unforeseen circumstances may include but not be limited to the following:

(a) Serious or unexpected adverse events/effects or unforeseen circumstances.

(b) Proposed changes in the proposal.

(c) Adverse events/effects or unforeseen circumstances that might affect the continued ethical acceptability of the project.

16. Suspension or termination of a study

16.1 Where circumstances indicate that a study is non-compliant with the approved conditions, LPREC shall suspend or revoke approval after due process has been followed.

16.2 The due process shall among others include the carrying out of an investigation, interacting with the applicant and other relevant stakeholders.

16.3 The investigation coupled with other processes may result in the suspension or revocation of the study. The outcome of the investigation shall be communicated to affected parties in writing within thirty (30) days. LPREC shall also recommend remedial action where appropriate.

16.4 In the case of suspension or termination, the applicant shall comply with the recommendations and any special conditions imposed by LPREC. However, the applicant retains the right to appeal against the outcome.

16.4.1 Reasons for suspension and / or termination of a study include but are not limited to:

(a) Study not conducted in accordance with the approved proposal.

(b) Emergence of adverse events/ effects or unforeseen circumstances when conducting the study that might affect the continued ethical acceptability of the project.

16.5 In the event of non-compliance with the conditions of the approved study by the applicant, LPREC shall write to the applicant notifying them of the suspension or termination of the study and reasons thereof. The letter will be copied to respective institutions.

17. COMPLAINTS AND APPEAL PROCEDURES

17.1 Complaints

Complaints regarding LPREC related matters, should be directed to LPREC Secretariat in writing within 14 days of the outcome or facts giving rise to a complaint.

LPREC Secretariat shall upon receipt of a complaint regarding LPREC related matters, cause the complainant to complete the necessary forms to enable the LPREC chairperson to consider the complaint for inclusion in the earliest available LPREC meeting agenda for consideration, if necessary.

If the complainant is unsatisfied with the outcome of the LPREC regarding the complaint lodged, the matter may be escalated to NHREC, through institutional complaints process.

17.2 Complaints procedure

(a) Complaints should be communicated to the Secretariat, who shall upon receipt of the complaint, cause the complainant to complete LPREC complaint form, which must be duly completed, with a factual summary of the complaint, the details of the complainant and be signed by the complainant to confirm the veracity of the complainant.

(b) The LPREC Secretariat shall upon receipt of the duly completed complaint form, cause the compliant to be brought to the attention of the LPREC Chairperson within 7 days from the date of receipt thereof. The LPREC Chairperson shall after receipt and perusal of the complaint, through the Secretariat send an acknowledgement of receipt to the Complainant.

© If the facts giving rise to the complaint stems from, the Complainant disagreement with the suggestions, recommendations or decision of the LPREC, the Complainant may be permitted to make representations for the reconsideration of the suggestions, recommendations or decision of the LPREC. The complaint together with representations for the reconsideration of the suggestions, recommendations or decision shall be included in the agenda of the next LPREC meeting. The complaint together with representations shall not be tabled before the LPREC before two weeks' notice of the next LPREC meeting.

(d) The complaint together with representations shall be tabled before the LPREC for discussion and reconsideration. If a workable solution regarding the complaint can be found and the matter is resolved amicably, the complaint will be regarded as finalised, and the matter resolved. In the event, a workable agreement cannot be found, the complaint will be considered by LPREC and the outcome of the LPREC complaint shall be communicated in writing to the complainant within 7 days from the date of the meeting.

(e) In the event, that after reconsideration of the matter and assessment of the complaint, the complainant is still not satisfied with LPREC decision, he or she may escalate the matter by lodging an appeal with NHREC.

(f) The NHREC complaint and queries procedure shall govern the further handling and disposal of the complaints and disputes.

17.3 Whistleblowing procedures

Any member of LPREC, researcher, community or other affected parties who has/have a reasonable belief that any act, intentional or negligent that arises out of misconduct such as corruption, maladministration, harassment in all forms or non-adherence to approved research procedures, guidelines or policies has/have been committed, is encouraged to report such unethical research practices to the LPREC Secretariat using the correct procedure. Whistle-blowers will remain anonymous.

18. Violations and Recourse

Any violation by the applicant of ethics or LPREC's decisions and, terms and conditions will be dealt with in accordance with the policies and procedures of the LPG.

19. AUDITS AND REPORTING COMPLIANCE TO THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL (NHREC)

19.1 LPREC will comply with mandate of the regulatory body (NHREC).

19.2 LPREC shall report annually to the NHREC information relevant to its procedures, including:

(a) Membership and membership changes.

(b) The number of meetings held.

(c) Confirmation of participation by the required categories of members.

(d) The number of proposals processed (Approved/Not Approved/Suspended/Terminated)

(e) The number of complaints/appeals received and how they were handled.

20 LPREC's STANDARD REVIEW CRITERIA

The following criteria are used to standardise the review process:

21.1. TITLE

21.1.1 The title should describe the study as succinctly as possible.

21.1.2 There should be no abbreviations in the title.

21.1.3 The title should place the study geographically if necessary. For example, a prevalence study must be placed geographically, but a study evaluating a new laboratory method does not need to be placed geographically.

21.1.4 An incorrectly worded title on its own is not sufficient grounds for withholding a clearance certificate if all other elements of the proposal are in order. A clearance certificate should be issued with provisos/recommendations.

21.2. STUDY PROBLEM

21.2.1 If there is no separate section headed "Study Problem", this is acceptable, as long as the study problem is clearly explained under the section headed " Introduction / Background to the study / Rationale for the study / Motivation to do the study / etc."

21.2.2 If the study problem is not clear to the reviewer, and there is no research question to help clarify what the study problem is, then the reviewer should consider withholding the clearance certificate for the study.

21.3. LITERATURE REVIEW

21.3.1 Sometimes undergraduate research has this as a heading, but the literature review is generally dealt with under Introduction / Background to the study / etc. Anyone of these headings is acceptable.

21.3.2 The proposal is not the dissertation, thus only a short, to the point, literature review is required. However, if the literature review rambles, or is not particularly well written, the reviewer should not withhold the clearance certificate if the other elements of the proposal are in order. The clearance certificate should be issued with provisos/recommendations.

21.3.3 Legal acts or legislation in line with the proposed study must be acknowledged.

21.3.4 Sources should be acknowledged in the literature review.

21.3.5 However, if this is not done, the reviewer should not withhold the clearance certificate if the other elements of the proposal are in order. The clearance certificate should be issued with provisos/recommendations.

21.4. PURPOSE OF THE STUDY

21.4.1 This refers to the aim and objectives of the study. These should be clearly stated and should flow from the study problem.

21.4.2 There should be one aim, and all the objectives should fit under the "umbrella" of the aim.

21.4.3 A clearance certificate should not be issued if the aim and objectives are not clear, or are not addressed by the study design.

21.5. RESEARCH QUESTION

21.5.1 It is not necessary to state this, but if the study problem has not been well-formulated, and it is clear that the researcher is unsure of what the study problem is, it would be of help to the researcher to formulate a research question. As under point 2, the reviewer should consider withholding the clearance certificate under these circumstances.

21.6 STUDY DESIGN

21.6.1 This refers to the overall design of the study, and the question that must be answered is: "Is this study well designed?" It is not a test to see if the researcher knows whether the study is a retrospective cohort study of a prospective case-control study, etc. A clearance certificate must not be withheld if the design "label" is not included in the description of the study design.

21.6.2 The study must be designed to address the aim and all the objectives. Thus the methods, data collection, and data analysis must address the aim and all the objectives. A clearance certificate should be withheld if this is not the case.

21.7.SAMPLE / STUDY POPULATION

21.7.1 It is always necessary to have a separate section for this.

21.7.2 The study population must be described.

21.7.3 The sampling procedure must be described, and it must be appropriate for the study. It is not always necessary (or appropriate) to name the sampling procedure, but when it is named, the procedure must fit the name (e.g.: if random sampling is named as the sampling procedure, the process described must be true random sampling). If the researcher has not named the sampling procedure but has described a procedure that is appropriate for the study, a clearance certificate should not be withheld. It is not sufficient, however, to name a sampling procedure, but not describe it – a clearance certificate should not be issued in this case.

21.7.4 Sample size should be calculated for statistical power if the results are to be generalized to the target population. However, when this is not the case, for example in qualitative descriptive studies, this is not necessary.

21.7.5 If help is needed to calculate sample size, the reviewer should recommend that a statistician be consulted, and the clearance certificate must be withheld. If the researcher has worked out the sample size already, it is not necessary to refer the researcher to a statistician, and a clearance certificate must not be withheld.

21.8. DATA COLLECTION

21.8.1 The data to be collected must address the aim and objectives of the study. A clearance certificate should be withheld if this is not the case.

21.8.2 In the case of questionnaires, no question should be included that does not address the aim and objectives of the study.

21.8.3 In the case of laboratory studies, no tests should be included that do not address the aims and objectives of the study.

21.8.4 It is always necessary to have a separate section for data collection.

21.9. DATA ANALYSIS

21.9.1 Data analysis must address the aim and objectives of the study. A clearance certificate should be withheld if this is not the case.

21.9.2 It is always necessary to have a separate section for data analysis.

21.9.3 If it is clear that the researcher needs help from a statistician, this should be recommended. However, a clearance certificate should not be withheld if help is needed with analysis only, and not with sample size calculation. A clearance certificate should be issued with provisos/recommendations.

21.10. BIAS

21.10.1 If the researcher has taken steps to minimize bias, this should be mentioned, but not necessarily as a separate section (e.g.: if sampling bias has been minimized by using random sampling, this can be mentioned under sampling).

21.10.2 If bias is potentially present, but the researcher has not recognized it and has taken no steps to eliminate or minimize it, the reviewer should alert the researcher to the type of bias that study is subject to and recommend that steps be taken to minimize or eliminate this bias. In this case, a clearance certificate should be withheld.

21.10.3 If the study is not subject to bias, there is obviously no need for bias to be mentioned. The reviewer should never withhold a clearance certificate if bias is not mentioned, and the reviewer cannot identify any bias.

21.10.4 If bias is present but is unavoidable (such as the bias present in all studies that use volunteers, as volunteers are different from those who do not volunteer), and the researcher does not mention this, a clearance certificate should not be withheld.

21.11 ETHICAL CONSIDERATIONS

21.11.1 There should be a separate section for this.

21.11.2 It must be clearly stated that a clearance certificate from the LPREC must be obtained before commencement with the study.

21.11.3 However, if a proposal lacks the above statement and there are no other problems with the proposal, a clearance certificate should be issued with provisos/recommendations, in studies that do not use human participants.

21.11.4 When human participants are used, an informed consent letter and consent form must be included.

21.11.5 When human participants are used, and the study is an experimental one using medication (allopathic, homoeopathic, naturopathic, and traditional) / vaccines / etc, a consent form and a patient information leaflet must be included.

21.11.6 The proposal must explain the process of obtaining informed consent.

21.11.7 In non-experimental studies using human participants, an edited version of the LPREC consent form is acceptable.

21.11.8 In experimental studies using human participants as outlined above, both the consent form and the patient information leaflet must comply with all the elements of informed consent outlined in the Helsinki Declaration and the DOH (2024) document.

21.11.9 Patient information leaflets and consent forms must be free from grammatical errors and spelling mistakes and must be written in a language that can be clearly understood by the prospective research participants.

21.11.10 Lawful processing of personal information in line with the Protection of Personal Information Act (POPIA or the Act, No. 4 of 2013) Amended in 2021. Within the research setting, POPIA regulates the processing of personal information for research purposes, and the flow of data across South Africa's borders to ensure that any limitations on the right to privacy are justified and aimed at protecting other important rights and interests.

21.11.11 It is recommended that students/researchers must only ask participants about their biographical details only if these details have a direct bearing on the analysis and conclusion. If not, then the Protection of Personal Information Act (POPIA) as amended in 2021 prohibits the collection of personal biographical data in research if the private information has no direct or indirect impact on the analysis, findings and conclusion.

21.11.12 The ethical considerations section must explain how the ethical principles will be adhered to.

21.12 GUIDELINES FOR REFERRAL OF DISTRESSES PARTICIPANTS

There shall be a separate section for this:

(a) The research is conducted within ethical guidelines; to this effect, the following directives shall be adhered to:

(i) The researcher shall write consent letters which shall include all the information about the study with, clearly stated objectives.

(ii) The consent letter shall be signed by respondents before participation in the research. Verbal consent is also acceptable.

(iii) The researcher shall give a guarantee to the participants/participants that they will not be coerced to participate in the research.

(iv) The researcher shall inform participants/participants that they should feel free to withdraw at any time before or during the study and/or when they start to feel uncomfortable about their participation.

(v) The researcher shall not reveal the participants'/participants' identity or any related information at any point during or after the research.

(vi) The researcher shall assure participants/participants that the information they share during the interviews will remain confidential unless the participants give consent that it can be revealed.

(b) The researcher shall give a guarantee that the participant shall be protected from any form of harm and risks.

(c) Facilitate prompt professional referral of those who become emotionally or otherwise distressed as a direct or indirect result of their participation in the research. The researcher must include in the proposal and the consent letter the addresses and contact details of professional agencies to whom distressed participants/participants will be referred to.

21.13.DATA COLLECTION FORMS / QUESTIONNAIRES

21.13.1In quantitative socio-behavioural studies using questionnaires, these should always be included as an appendix.

21.13.2In quantitative laboratory studies, data collection forms must be included as an appendix

21.13.3. In qualitative descriptive studies, there is usually no need for data collection forms.

21.14. REFERENCES

21.14.1 Any academically acceptable methods of referencing.

21.14.2 If the method of referencing is the only problem with the proposal, a clearance certificate can be issued with provisos/recommendations.

21.15. OTHER COMMENTS

21.15.1A clearance certificate should be withheld if the application form has not been filled in correctly, especially if the relevant signatures are missing.

21.15.2Departments, municipalities, institutions and researchers are responsible for ensuring that all application forms are in order before the submission to the LPREC secretariat.

21.15.3 Lack of semantic hygiene on its own, (unless the proposal is incoherent) should not be a reason for withholding a clearance certificate. The clearance certificate should be issued with provisos/recommendations.

21.16. RECOMMENDATIONS

21.16.1Recommendations should be recorded in full by the Secretariat during LPREC meetings.

21.16.2The names of the researcher, the number of the proposal as listed on the agenda, and the date of the LPREC meeting, must be included on the proposal feedback sheet.

21.16.3When a clearance certificate is issued with provisos/recommendations, the researcher must submit the corrected proposal to the LPREC by the following LPREC submission date (the date must be stipulated in the letter of recommendation). However, the researcher may proceed with the study immediately.

17/6/2025

MR. NCHABELENG N.S. **DATE**

DIRECTOR-GENERAL