



health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA



Terms of Reference for the Mpumalanga Provincial Department of Health Research and Ethics Committee

REF: ToR/01/05/2024: Research & Epidemiology



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DEFINITIONS AND ABBREVIATIONS

1.1 Head: Health	The accounting officer responsible for signing MPHREC SOPs and other relevant documents.
1.2 MDoH	Mpumalanga Department of Health.
1.3 MEC:	Member of the Executive Council, responsible for appointing MPHREC members.
1.4 Members with Specialist Expertise	Subject specialist(s) invited to MPHREC meetings for needed expertise on a particular field of study, and do not have the voting rights, and this include the secretariat.
1.5 MPHREC	Mpumalanga Provincial Health Research Ethics Committee.
1.6 MPHRECTC:	Mpumalanga Provincial Health Research Ethics Committee's Technical Committee.
1.7 NHREC	National Health Research Ethics Council.
1.8 REC	Research Ethics Committee.
1.9 SOP:	Standard Operating Procedures.
1.10 ToR:	Terms of Reference.

1. INTRODUCTION

- 1.1 The Mpumalanga Department of Health has established a Health Research Ethics, named Mpumalanga Provincial Health Research Ethics Committee (MPHREC) in terms of the National Health Act 61 and the National Department of Health's 'Ethics in Health Research' Guidelines (NDoH 2024).
- 1.2 The MPHREC Terms of Reference are designed to ensure that the MPHREC is compliant with the requirements of the National Health Act and the National Guidelines 2024.
- 1.3 The MPHREC Terms of Reference are also aligned with the Mpumalanga Department of Health Research Policy (accessible on www.mpuhealth.gov.za).
- 1.4 The National Health Act, section 73, requires institutions to establish Research and Ethics Committees (RECs) which register with the National Health Research Ethics Council (NHREC).
- 1.5 It is a requirement from the NHREC that all 'health research' involving human participants undergo prior ethics review by a registered research ethics committee before commencement.
- 1.6 RECs are registered by the NHREC after an extensive assessment of their eligibility and compliance with the relevant legal and ethics framework.
- 1.7 The essential purpose of the MPHREC is to protect the dignity, rights, safety, and well-being of all human participants in research involving human subjects as participants.

2. AUTHORITY

- 2.1 The MPHREC operates under the authority of the Mpumalanga Department of Health (MDoH), and it is tasked with review of research proposals, protocols, and methodologies to ensure they comply with ethical standards and regulatory requirements.
- 2.2 MPHREC members are appointed by the Honourable Member of the Executive Council (MEC) for Health, as recommended by the Head: Health.
- 2.3 The department entrusts the MPHREC with the responsibility of evaluating the ethical implications of proposed research and providing approval or recommendations accordingly.
- 2.4 Administrative support is managed by the Chief Directorate: Integrated Health Planning on behalf of the Mpumalanga Department of Health, with the Directorate: Research and Epidemiology providing the secretariat function.
- 2.5 MPHREC is registered with the NHREC in accordance with the National Health Act 61 of 2003. Its registration number is REC-270922-059.

3. MANDATE

- 3.1 The MPHREC is mandated to fulfil its functions in accordance with the National Health Act 61 of 2003 as outlined in the National Department of Health's 'Ethics in Health Research' Guidelines of 2024 and reports annually to the NHREC.
- 3.2 The MPHREC reviews health or health related research protocols for employees of Mpumalanga Department of Health (MDoH).
- 3.3 Research with no affiliation to MDoH but are affiliated with the Mpumalanga Provincial Government (sister departments and local municipalities) may approach the MPHREC to review their research protocols.
- 3.4 Researchers with no affiliation to the Mpumalanga Department of Health may also approach the MPHREC to review their research protocols. However, MPHREC may exercise its discretion on a case-by-case basis to decide whether to review the protocol or whether to refer the applicant elsewhere to access appropriate expertise and capacity to evaluate the application.
- 3.5 A fee may be levied in future for such a service to researchers not affiliated with Mpumalanga Provincial Government, details will be made available on www.mpuhealth.gov.za.

4. SCOPE OF OPERATIONS

- 4.1 The MPHREC is authorised to:
 - 4.1.1 Review minimal, low or medium risk research proposals (see MPHREC SOP Annexure 12) received that involve human participants and conducted within Mpumalanga Province.
 - 4.1.2 Conduct independent rigorous ethics review, prospectively (retrospective review not permitted), of all health or health-related research protocols to ensure that welfare and other interests of participants and researchers are properly protected and that the proposed research complies with the ethical norms and standards outlined in the national ethics guidelines.
 - 4.1.3 Ensure that research protocols are scientifically sound and feasible within available resources.
 - 4.1.4 Decide whether to approve, to require amendments or reject the protocols for lack of compliance with scientific or ethics norms and standards.
 - 4.1.5 Ensure appropriate reporting occurs to fulfil the oversight obligation of the MPHREC to monitor welfare interests of participants.

4.1.6 When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable, for example, the poor and the economic or socially marginalised, children (under 18 (eighteen) years old), people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a medical clinic.

5. INTERNAL REPORTING AND ACCOUNTABILITY

5.1 Notwithstanding independence in research ethics oversight, the MPHREC reports to and is accountable institutionally to the Mpumalanga Department of Health.

5.2 Approval for amendments to the MPHREC's Terms of Reference, Standard Operating Procedures (SOPs) and any other forms or policy-related documentation must be obtained from the Head: Health.

6. COMPOSITION OF THE COMMITTEE

6.1 The MPHREC shall comprise of about 18 members.

6.2 The following are categories of members for the MPHREC:

6.2.1 Chairperson

6.2.2 2X Vice Chairpersons

6.2.3 Representative of the following Directorates/ Sub-directorates/ Division/ Districts:

6.2.3.1 Representative of Legal Services

6.2.3.2 Representative of Head Office

6.2.3.3 Representative of Ehlanzeni District

6.2.3.4 Representative of Gert-Sibande District

6.2.3.5 Representative of Nkangala District

6.2.3.6 Representative of the Nursing profession

6.2.3.7 Representative of a Medical Officer

6.2.3.8 Representative of a Tertiary Hospital

6.2.3.9 Representative of CEOs forum

6.2.3.10 Representative of Community-Based Structure

6.2.3.11 Representative of an Academic Institution

6.2.3.12 Representative of Pharmacy Professional

6.2.3.13 Two lay persons

6.2.3.14 A Biostatistician/Statistician.

6.2.4 Members with Specialist Expertise

6.2.4.1 Subject specialist(s) may be invited to MPHREC meetings for needed expertise on a particular field of study.

6.2.5 Secretariat

6.2.5.1 Secretariat function is provided by the Directorate: Research and Epidemiology.

7. RECRUITMENT AND APPOINTMENT PROCESS

- 7.1 A call for nomination is released through the MPDOH website for a period of a calendar month, including the application form (Annexure 1).
- 7.2 Members are nominated from all branches or divisions of the department, including districts and institutions of Higher Learning.
- 7.3 All nominations are received by the Directorate: Research and Epidemiology for selection of suitable candidates according to the guidelines.
- 7.4 An adhoc panel is established to review the applications and nomination and select members meeting the criteria as per the 2024 NHREC guidelines.
- 7.5 The MEC: Health appoints all members (Annexure 2) as per the recommendation of the panel (Clause 7.4).
- 7.6 Both the Chairperson and the Vice Chairperson are appointed during the first meeting of the committee through nomination and voting process.

8. TERMS OF OFFICE

- 8.1 The Chairperson will serve a non-renewable term of office of five consecutive years from their date of appointment.
- 8.2 The Vice-Chairpersons can serve a term of office of five consecutive years from their date of appointment, renewable once, if supported by a simple majority of voting MPHREC members and based on adequate performance as determined by the MPHREC after a performance review conducted at the end of each five-year term.
- 8.3 All other MPHREC member's terms of office are five years' renewable twice.

9. RESEARCH ETHICS EXPERIENCE AND TRAINING

- 9.1 Members to be appointed must have appropriate experience in research and ethics, except for a layperson.
- 9.2 All members of the MPHREC, including the Secretariat, are required to have successfully completed research ethics training, renewable every three years, and evidenced with a certificate from an accredited training institute.
- 9.3 Laypersons are encouraged to complete research ethics training however this is not mandatory.
- 9.4 Training must be in the form of a course dedicated to research ethics and must include an assessment.
- 9.5 Records of research ethics training (e.g., course completion certificates) must be forwarded to the Secretariat for filing as soon as they are available.
- 9.6 Additional training courses or learning opportunities, such as conferences, workshops, informal training at MPHREC meetings, continuing professional development and any other learning opportunities that are not assessed can be valuable.

10. INDUCTION FOR NEW MPHREC MEMBERS

- 10.1 Induction is an important process that gives new MPHREC members key information about the committee and what is expected of them (see SOP for MPHREC Induction).
- 10.2 Following the confirmation of their appointment, new MPHREC member (s) will be invited to a meeting with the chairperson and the secretariat for an introduction to begin the induction process.
- 10.3 New MPHREC members will be provided with induction training which includes an understanding of the role of the ethics committee members, responsibilities, code of conduct, integrity, confidentiality agreements, and management of conflict of interest.
- 10.4 Research ethics training as described in Clause 8 must be completed prior to, or at the very least within one month of, their initiation of MPHREC membership.

11. KEY RESPONSIBILITIES

The chairperson and vice Chairperson(s) of the MPHREC shall be elected by members of the committee.

11.1 Chairperson

- 11.1.1 To ensure that the MPHREC is appropriately constituted and adequately resourced.
- 11.1.2 To Chair MPHREC meetings and to ensure that correct procedure is followed at these meetings.
- 11.1.3 To ensure, together with the Secretariat, that all required items appear on each MPHREC agenda prior to the meeting and that minutes taken during each MPHREC meeting are an accurate representation of the meeting's transactions.
- 11.1.4 To deal with any queries related to MPHREC reviews or other matters discussed at MPHREC meetings, together with other MPHREC members and researchers as required.
- 11.1.5 To ensure that all MPHREC-related documentation (including the Committee's Terms of Reference and Standard Operating procedures) is reviewed from time to time and updated or amended as necessary.
- 11.1.6 To advise MPHREC members or any other person on any matter pertaining to research ethics as required.
- 11.1.7 To take the required actions, as set out in the MPHREC Standard Operating Procedures, in response to any report or evidence of unethical or unprofessional conduct, or scientific misconduct (see MPHREC SOP).
- 11.1.8 To liaise with and submit any documentation or information required by the National Health Research Ethics Council.

11.2 Vice-Chairperson

- 11.2.1 To assume any of the Chairperson's responsibilities (as set out in Clause 111.1) if requested to do so by the Chairperson, or if the Chairperson is unavailable to discharge these responsibilities.
- 11.2.2 To assist the Chairperson with decision-making in relation to research proposal reviews or other matters of relevance to the MPHREC or research ethics on an ad hoc basis.
- 11.2.3 To assist with expedited review of research proposals when required.

11.3 Secretariat

- 11.3.1 To receive research proposals for consideration by the MPHREC and process these as required.

- 11.3.2 To screen research proposals submitted for consideration to the MPHREC in order to ensure that documentation is correctly completed, and to refer back to researchers any such documentation which contains errors or is incomplete.
- 11.3.3 To compile, together with the Chairperson, an agenda for each MPHREC meeting listing all pertinent matters for consideration by the Committee and to ensure that such agendas (and attachments) are distributed by electronic mail to all MPHREC members within at least seven working days of a meeting.
- 11.3.4 To distribute an attendance register at each MPHREC meeting and record attendance data in the minutes for each meeting.
- 11.3.5 To record the minutes of each REC meeting, draft these minutes after each meeting and send them to the Chairperson for review.
- 11.3.6 To collate all completed research proposal reviews after MPHREC meetings and ensure that these are returned to the responsible supervisor or researcher(s) within five working days of the MPHREC meeting.
- 11.3.7 To draft, forward to the Chairperson for signing, and finally distribute all result and ethical clearance letters related to research proposal reviews.
- 11.3.8 To deal with ad hoc enquiries regarding research proposal review or any other matter related to administrative functions of the MPHREC.
- 11.3.9 To exercise due care and diligence in confidentiality, restricted access (where applicable), record keeping, archiving and considerations of business continuity related to all MPHREC functions.

11.4 Ordinary Members

- 11.4.1 To attend MPHREC meetings on dates published by the Secretariat, and to be punctual in discharging this responsibility.
- 11.4.2 To conduct research proposal reviews as allocated by the MPHREC Chairperson and to do so diligently, with sufficient time in hand and according to the procedures set out in the MPHREC Standard Operating Procedures (see MPHREC SOP).
- 11.4.3 To uphold the guiding principles and code of conduct of the MPHREC as set out in Clauses 17 and 18, below.
- 11.4.4 To ensure compliance with Clause 9 regarding research ethics training.

11.5 Members with Specialist Expertise

- 11.5.1 To provide expert advice in their area of expertise to the Committee when required.

11.6 *Lay persons*

11.6.1 To provide lay person perspectives, guidance and advice on any matters related research proposal reviews, or research ethics in general.

12. **MPHREC MEETINGS**

12.1 *Meeting Dates*

12.1.1 The MPHREC meeting dates are decided for all meetings in a calendar year, in advance, by the Secretariat in consultation with the Chairperson.

12.1.2 A minimum of one MPHREC meeting per quarter will be held to review and approve research studies.

12.1.3 MPHREC meeting dates are published by the secretariat.

12.1.4 Furthermore, the MPHREC will sit on an ad hoc basis as mandated by the need to develop/review urgent studies.

12.1.5 Special meeting dates are communicated by the Secretariat, in consultation with the Chairperson or a Vice-Chairperson, at least two calendar weeks before the meeting date.

12.1.6 Procedures at special MPHREC meetings are identical to those for quarterly MPHREC meetings as described in Clause 12.1.2, and as set out in Clauses 12.2 - 12.7 below.

12.2 *Meeting Attendance*

12.2.1 Meeting attendance for MPHREC members is compulsory. Members not able to attend a meeting should notify and communicate their apologies to the Secretariat.

12.2.2 Members not present at a MPHREC meeting who have been requested to complete one or more research proposal reviews must ensure that these completed reviews are forwarded to the Secretariat before the MPHREC meeting.

12.2.3 Members not present at a MPHREC meeting may still be requested, and will be expected to, complete research proposal reviews. Not attending a MPHREC meeting does not nullify the responsibilities set out in Clause 11.4.2. MPHREC members not attending meetings who have taken leave are not expected to complete research proposal reviews.

12.2.4 Members not following the procedure in Clause 11.4.1 will be recorded in the minutes as absent from the meeting in question.

12.2.5 Members absent from at least three consecutive MPHREC meetings will be removed from the Committee.

12.3 *Meeting Agendas*

- 12.3.1 Meeting agendas are compiled by the Secretariat, in consultation with the Chairperson.
- 12.3.2 Any MPHREC member may request an item to be added to any MPHREC agenda, however this must be done in consultation with the Chairperson or a Vice-Chairperson. Such requests must be in writing.
- 12.3.3 Apart from research proposals for consideration, all other items must be clearly identified as being items for (i) noting, (ii) discussion or (iii) proposed motions.
- 12.3.4 Urgent items may be added to a meeting agenda when called for at the beginning of the meeting, however this is at the discretion of the Chairperson.

12.4 *Quorum*

- 12.4.1 A quorum is constituted by 33% availability of MPHREC members.
- 12.4.2 If at any meeting, a quorum is not formed, the meeting shall stand adjourned to a day, time, and place to be decided by the MPHREC.
- 12.4.3 A quorum will include at least 1 (ONE) member whose primary area of expertise is non- scientific.

12.5 *Conflicts of Interest*

- 12.5.1 MPHREC members are required to sign a confidentiality agreement (Annexure 3) and to declare any conflicts of interest (Annexure 4) at each MPHREC meeting using an appropriate form.
- 12.5.2 Conflicts of interest must be declared either at the beginning of an MPHREC meeting, or any point during a meeting where the declaration is relevant to the item under discussion.
- 12.5.3 The presence of a co-investigator, who is a MPHREC member and whose research proposal is under consideration in an MPHREC meeting, is taken as a conflict of interest and must be recorded as such in the meeting minutes.
- 12.5.4 However, a pragmatic approach is taken that co-investigators in this position are not required to recuse themselves from the meeting and may contribute to discussions related to the research proposal under consideration to clarify any relevant matters.

- 12.5.5 Co-investigators in this position may not however be factored into the decision-making process related to such research proposals when evaluating consensus amongst members, or when voting occurs.
- 12.5.6 With the exception of Clause 7.4, conflicts of interest declared in a meeting must be considered by the meeting and a determination must be made by consensus regarding the materiality of the conflict.
- 12.5.7 Materiality of a conflict of interest means the significance of the conflict in relation to a specific matter or context to the degree that it is (i) of consequence in determining the matter and (ii) might reasonably affect a person's judgement or decision-making in the matter.
- 12.5.8 If any declared conflict of interests is considered to be material, the member who has declared the conflict of interests must reclude themselves from the meeting for the duration of discussions and decisions relating to the declared conflict.
- 12.5.9 An MPHREC member who has recluded themselves in terms of the procedures described above will be considered to be present when determining if the meeting is quorate but will not be considered when determining whether a simple majority has been reached during voting on a decision related to the member's conflicted position.

12.6 *Nominations and Voting: Chairperson/Vice-Chairperson*

- 12.6.1 Nomination of Chairperson/Vice-Chairpersons is conducted during the first meeting of the MPHREC through a vote at a duly constituted REC meeting.
- 12.6.2 Ordinary members of the MPHREC have one vote each, with the exception of the Chairperson who does not vote. Ex Officio members and observers have no voting rights.
- 12.6.3 In the case of a single nomination for Chairperson or Vice-Chairperson, the MPHREC must decide by consensus whether the nominated member is suitable for the nominated position. The nominated member must recuse themselves during these deliberations.
- 12.6.4 If there is consensus that the nominated member is suitable for the nominated position, the nominated member will be duly appointed to the position.
- 12.6.5 In the case of more than one nomination, the MPHREC must decide by consensus whether the nominated members are all suitable for the nominated position. The nominated members must recuse themselves during these deliberations.

12.6.6 If there is consensus that all nominated members are suitable for the nominated position, MPHREC members with voting rights will vote to decide which of the nominated members should be appointed.

12.6.7 The nominated member achieving a simple majority is duly appointed to the position. In the event of a split decision, the Chairperson will cast the deciding vote.

12.7 Meeting Minutes

12.7.1 Meeting minutes are compiled by the Secretariat and reviewed by the Chairperson.

12.7.2 At every MPHREC meeting, minutes of the previous meeting must be proposed for approval by the meeting after giving MPHREC members an opportunity to identify anything in the minutes requiring correction. The names of MPHREC members proposing and seconding approval of the previous meeting's minutes must be recorded in the minutes.

12.7.3 Meeting minutes must clearly identify (i) members present, members who have given apologies and those absent from the meeting, (ii) conflicts of interest, (iii) additions to the agenda, (iv) noted items, (v) discussed items, (vi) resolutions and the result of each research proposal review (for each individual reviewer).

13. DOCUMENTATION AND ARCHIVING

13.1 Research Ethics Review-related Documents

13.1.1 All research proposals, MPHREC forms and templates (listed as Annexures in the MPHREC SOP), letters (e.g., clearance letters), correspondence, meeting agendas and minutes are considered to be confidential and treated as such.

13.1.2 All hard copies of the above documents are kept in a filing system that has restricted access to only the Secretariat, Chairperson and Vice-Chairpersons.

13.1.3 Electronic copies of documents (e.g., clearance letters or meeting minutes) are stored on a computer hard drive with restricted access to the Secretariat, Chairperson and Vice-Chairpersons.

13.1.4 Hard copies of all documents for active research projects are filed as described above in 13.1.2 and these documents are transferred to a storage facility six months after conclusion of the project, in line with the Department's policies on document filing and preservation.

13.2 Terms of Reference (ToR) and Standard Operating Procedures (SOPs)

- 13.2.1 Originals of the MPHREC Terms of Reference and SOPs are stored on a computer hard drive with restricted access to the Chairperson and Secretariat.
- 13.2.2 Copies of these documents are placed online, with access for all MPHREC members and (via the Department's website) all members of the department, and researchers.
- 13.2.3 Terms of Reference and SOPs are routinely reviewed annually and revised if necessary, or at other times if urgent revision is required.
- 13.2.4 Terms of Reference and SOPs are clearly version controlled, with a major version number increment per annual revision (if any revision is carried out) and a minor version number increment per revision other than annual revisions.
- 13.2.5 Previous document metadata are retained in the document as the document history.

14. MPHREC TECHNICAL COMMITTEE (MPHRECTC)

14.1 Composition

- 14.1.1 The MPHREC Technical Committee is composed of the Chairperson, Vice-Chairperson, four ordinal MPHREC members and any local ordinal MPHREC member who is part of MPHREC.
- 14.1.2 The MPHREC members volunteer to serve in the MPHRECTC.
- 14.1.3 Both the Chairperson and Vice-Chairperson of the MPHRECTC are nominated during the first meeting following the procedure outlined in Clause 12.6.
- 14.1.4 An MPHREC Chairperson is permitted to attend and contribute to the function of the MPHRECTC.
- 14.1.5 All ethical review processes, procedures and standards are the same as they apply to the MPHRECTC and the MPHREC and role of the Secretariat for the MPHREC is the same as it is for the MPHREC.

14.2 Functions

- 14.2.1 Develop draft Policies, ToRs, SOPs and annual report for the MPHREC.
- 14.2.2 Review and update procedures, guides and related material for ethics audits and make these easily accessible.
- 14.2.3 Conduct Active and Passive monitoring on approved research projects.
- 14.2.4 Assist in the logistical arrangements for MPHREC events/functions.

15. RAPID ETHICS REVIEW

- 15.1 In a public health emergency, preparations for research must occur rapidly. Speedy processing of ethics review applications is desirable.
- 15.2 The MPHREC will carefully assess the nature of the research to determine the appropriate review process.
- 15.3 Careful ethical reflection is essential, notwithstanding any perceived urgency. It is possible to review and approve a protocol without undermining the substantive protections (see SOP for Expedited and Rapid Review).
- 15.4 Furthermore, given that all registered RECs undergo a robust registration process and subsequent quality assurance audits, it follows that the procedures for reciprocal recognition of review decisions is useful in a time-pressured situation (see SOP for Reciprocal and Joint Review).
- 15.5 The possibility of reciprocal recognition of reviews should occur in a collaborative, harmonious manner, bearing in mind that each REC bears the responsibility of protecting the safety, rights and interests of participants enrolled in the studies it has approved.

16. MPHREC GUIDING PRINCIPLES

16.1 Integrity and Honesty

- 16.1.1 Members of the MPHREC must act in good faith and in the best interest of the research participants.
- 16.1.2 Members of the MPHREC should avoid conflicts of interest and bias. In cases where a conflict cannot be avoided, it should be disclosed to the committee in full at the earliest opportunity, and then proactively managed.
- 16.1.3 Members of the MPHREC should act ethically.

16.2 Good Stewardship and Accountability

- 16.2.1 Members of the MPHREC should take responsibility for one's actions, admit mistakes, and learn from them.
- 16.2.2 Protect the confidentiality and privacy of sensitive information entrusted by others.

16.3 Professional courtesy and fairness

- 16.3.1 Treat all individuals with respect, dignity, and fairness, regardless of their race, ethnicity, gender, sexual orientation, religion, or any other characteristic.

16.3.2 Foster an inclusive environment that welcomes diverse perspectives and promotes equal opportunities for everyone.

16.3.3 To review independently, impartially, and objectively whether the proposed design and conduct of research is likely to protect participants' safety, rights and welfare.

16.4 *Timeliness and Responsiveness*

16.4.1 MPHREC members should fulfil their committee duties promptly, including attending meetings, reviewing proposals, and responding to ethical complaints in a timely manner.

16.4.2 Delays should be minimized to ensure efficient and effective oversight.

17. **CODE OF CONDUCT**

17.1 All MPHREC members are expected to

17.1.1 Understand and make every effort to always fulfil the responsibilities of members (Annexure 5), as further emphasised in Clause 10.3.

17.1.2 Agree to a term of office of five (5) years, which can be renewed for two (2) subsequent terms.

17.1.3 Familiarise themselves with the MPDoH's relevant documentation as well as national and international research ethics guidelines.

17.1.4 attend research ethics training sessions to keep abreast with the latest changes in this field and will need to provide proof of evidence of training at least once every three (3) years to the NHREC.

17.1.5 regularly attend MPHREC meetings and provide a reasonable reason if they do not attend such meetings but they are permitted to still provide written reviews of applications if applicable.

17.2 In addition, all MPHREC members are expected to:

17.2.1 Participate actively in MPHREC meeting discussions but allow all other members to also participate and communicate their views in an atmosphere of openness, tolerance, fairness, and mutual respect.

17.2.2 Acknowledge the expertise and discipline-specific knowledge of other MPHREC members in discussions, and respect discipline-specific differences in research paradigms, methods, and determination of academic merit.

- 17.2.3 Complete all assigned research proposal reviews diligently, and with enough time to give the attention and detailed thought required.
- 17.2.4 Allow only considerations of research ethics and how this relates to protection of participant's rights and interests to guide decision-making in the research proposal review process.
- 17.2.5 Reach decisions on ethical review of research proposals independently, by consideration of facts as contained in the research proposal, sound knowledge of the principles of research ethics and criteria for the MPHREC's decision codes.
- 17.2.6 Ask for advice or guidance from other MPHREC members if uncertain about any aspect of research proposal review.
- 17.2.7 Request clarification if required from researchers during the research proposal review process.
- 17.2.8 Write useful research proposal reviews – i.e. reviews that are concise, clear, draw attention to deficiencies or areas that require revision, clearly explain deficiencies or the need for revision and offer advice if appropriate.
- 17.2.9 Avoid critiquing research design or method unless deficiencies can be identified that have clear ethical implications.
- 17.2.10 Avoid excessive critique of grammar, punctuation, spelling or technicalities of reference style (these can be pointed out in a concise and general way in order to give feedback that may improve the quality of the research proposal, but are not of primary concern in an ethical research proposal review).
- 17.2.11 At all times uphold the duty to treat all research-related and other personal information discussed or communicated during MPHREC activities as strictly confidential.
- 17.2.12 Be constantly aware of the possibility of conflicts of interest arising during MPHREC-related activities and be familiar with the procedures outlined in Clause 12.5.
- 17.2.13 Always declare possible conflicts of interest or ask the advice of the Chairperson and other members at a MPHREC meeting if uncertain of whether a conflict of interest exists or may exist.

18. BUDGET

- 18.1 No member of the MPHREC is remunerated for his/her services. Only accommodation will be arranged for external members of the MPHREC.
- 18.2 To cover administrative costs of the MPHREC's activities, a budget is submitted annually via the Provincial Directorate: Research and Epidemiology.

19. INSURANCE COVER

- 19.1 The department of health has a professional indemnity cover for its employees in which the afore-mentioned committee member is indemnified in respect of any claim related to his or her activities as a committee member.

20. SCOPE OF APPLICATION

- 20.1 The Terms of Reference shall be applicable to all committee members.

21. TERMS OF REFERENCE REVIEW

These Terms of reference shall be reviewed every five years or amended as and when necessary.

22. TERMS OF REFERENCE APPROVAL

APPROVED / NOT APPROVED



DR LK NDHLOVU
HEAD: HEALTH

4/6/2024
DATE

Effective date 4/06/2024

ANNEXURES

Only Use/Retrieve the Relevant Annexure

Annexure 1	Call for Nomination
Annexure 2	Appointment Letter
Annexure 3	Confidentiality Agreement
Annexure 4	Conflict of Interest Form
Annexure 5	Code of conduct

(Annexure 2) : MPHREC Appointment Letter

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health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Indwe Building, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel I: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo

Departement van Gesondheid

UmNyango WezeMaphilo

Enq: Secretariat
013 766 3766

To: Box 111
MBOMBELA, 1200

Dear Dr AAAA

APPOINTMENT TO SERVE ON MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS COMMITTEE (MPHREC)

I, Sasekani Janet Maruvin in my capacity as the Member of the Executive Council for the Department of Health, in terms of Section 41(6) of the National Health Act (Act No.61 of 2003) have great pleasure in informing you that you have been appointed as a member of the MPHREC for a period of five financial years effectively from **01 April 2022 to 30 March 2027**. Your willingness to serve as a member of this Faculty Committee is greatly appreciated.

Members are requested to familiarise themselves with the Standard Operating Procedures (SOPs) of the MPHREC as well as applicable national and international research ethics principles and guidelines. The MPHREC SOPs and other relevant documents are available on the MPHREC website (<http://www.mpuhealth.gov.za>).

Committee proceedings, all documentation presented and meeting discussion must be regarded as confidential. Members are required to sign a confidentiality agreement and to declare any conflicts of interest at each MPHREC meeting. To facilitate achieving the MPHREC quorum requirements in terms of the DoH 2024 South African Ethics in Health Research Guidelines, members are requested to attend regularly and to achieve a minimum of four meetings per annum.

Furthermore, Members are required to refresh their research ethics training at least once every three years and to produce a certificate based on assessment of the training undergone. The trainings, which are to be approved by the Department, will be arranged by the secretariat in consultation with the MPHREC chairperson. Please note, you will not receive payment for being a committee member but will claim reasonable travel expenses for attendance of MPHREC

meetings or any other agreed events, subject to the standard procedures and policies of the Department of Health

You are hereby assured that the department will provide legal protection against personal liability that may arise in the course of bona fide conduct of your duties as an MPHREC member. The Department of Health has a professional indemnity cover for its employees in which the aforementioned committee member is indemnified in respect of any claim related to his or her activities as a committee member. This includes indemnification against legal costs and costs in defense of criminal proceedings as a result of culpable homicide.

Kindly note that you are expected to sign the MPHREC code of conduct, and please liaise with the MPHREC secretariat regarding all other administrative matters including meeting dates.

We take this opportunity to wish you a very welcoming and workable research and ethics interactive relationship.

Yours sincerely



HON. SJ MANZINI (MPL)

MEC: HEALTH

DATE: 06/06/2024



(Annexure 3)

MPHREC Confidentiality Agreement

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FOR

**MEMBERS OF THE MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS
COMMITTEE**

I, the undersigned _____ (hereinafter referred to as "the
Member of the Committee") with physical address at: _____

RECITALS

- A. The National Health Research and Ethics Committee is a statutory body established in terms of the National Health Act, Act No 72 of 2003 Section 6 (c).
- B. The Members of the Committee hereby agree to be bound by the provisions of this Agreement for the duration of their service to and on the Provincial Health Research and Ethics Committee.

1. INTERPRETATION

Unless the context indicates the contrary:

- 1.1. "Confidential Information" shall mean certain proprietary or confidential information, which the Member of the Committee acknowledges to be confidential. Such information relates to functions and delegations of the National Health Research Committee as provided in Section 69 (3) of the National Health Act, until members

agree to remove the embargo on such information. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, know-how, processes, inventions, techniques, formulae, products, business operations, patient requirements, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, biological materials, litigations, letters of grievance and/or software.

2. CONFIDENTIALITY

2.1. The Member of the Committee undertakes in favour of the others that he/she will treat as confidential all information labelled as Confidential Information. The Member of the Committee agrees that he/she will not disclose such information to any person, any legal entity, or to the media, and will not use such information other than for the purposes of this agreement, subject to any prior specific written authorisation by the other members to such disclosure or use.

2.2. Confidential information shall not include:

- (a) Information which at the time of disclosure is published or otherwise generally available to the public, or later becomes generally to the public otherwise than through any act or omission on the part of the Member of the Committee; or
- (b) Information which the Member of the Committee can show by written records and to the satisfaction of the Disclosing Party, was in his/her possession at the time of disclosure and which was not acquired directly from the Disclosing party; or
- (c) Information rightfully acquired from bona fide third party who did not obtain it under pledge of secrecy to the disclosing party; or
- (d) Information which is required to be disclosed by law or a valid order of a court of competent jurisdiction or the request of any governmental or other regulatory authority, in which event the parties hereto shall use their best endeavours to seek confidential treatment of such information; or

- (e) Information which is or had been independently generated or developed by the Member of the Committee which can be shown by written records and to the satisfaction of the Disclosing Party.

2.3. The confidentiality obligations contained in this Agreement shall endure beyond the confines of the Members of the Committee obligations to the Committee and without limit in time except and until any Confidential Information enters the public domain otherwise than through default of the Member of the Committee.

3. GOVERNING LAW

3.1. The law of the Republic of South Africa shall govern this Agreement. Any disputes under this Agreement shall be resolved through mediation, dispute resolution mechanism and competent court with jurisdiction in the Republic of South Africa.

THUS, DONE SIGNED AND AGREED

Signed at _____ on the ____ day of _____ 2023.

MEMBER OF THE COMMITTEE



(Annexure 4)

MPHREC Declaration and Conflicts of Interest Form

MPUMALANGA HEALTH RESEARCH ETHICS COMMITTEE (MPHREC) FORM
DECLARATION OF INTEREST

I, _____, Position in the MPHREC _____

Solemnly declare that:

1. I am acquainted with the regulations contained in the Act of Protection of Information.
2. I understand that I may not divulge information of any kind from whatever source that I might have in my possession, or might in future receive, to any unauthorized person, either verbally or in writing, without the prior approval of the Chairperson or an officer authorized by him/her to give such approval.
3. I understand that the above-mentioned regulations not only apply during my term of office, but also after my duties with the Committee have been terminated.
4. I am fully aware of the serious consequences that may result in the event of a breach or infringement of the above-mentioned regulations.

 Signature
 Date: _____

 Witness
 Date: _____

Furthermore, on conflict of interest:

Research project you wish to make a DECLARATION about	
Name of researcher (if known):	MPHREC (non-medical) Clearance number (if known):
Title of research project (if known), or topic of the project:	
Do you or your partner have any financial, academic, or other interest in the subject matter of the meeting, which may be considered as constituting a real, potential, or apparent conflict of interest?	

Yes

No

Name of the Member: _____

If yes, please provide the detail below:

Nature of interest:

Name of the entity and or individuals:

If there is anything else, or the perception by others, that could affect your objectivity and independence in the meeting? If your answer is yes, please supply details of such.

I, _____ hereby declare that the disclosed information is correct, and no other situation of real potential or apparent conflict of interest is known to me. I undertake to inform the meeting of any status changes that may be brought to light because of any issue that may arise as the meeting progresses. I also undertake to timely inform the committee of any changes in these circumstances during the period when I am still serving as a committee member.

Signature

Date: _____

Witness

Date: _____



(Annexure 5)

MPHREC Code of Conduct

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1. MPHREC Meetings

- 1.1 Participate actively in the deliberations of MPHREC meetings, and to allow all other members to also participate and communicate their views in an atmosphere of openness, tolerance, fairness and mutual respect.
- 1.2 Acknowledge the expertise and discipline-specific knowledge of other MPHREC members in discussions and respect discipline-specific differences in research paradigms, methodologies, and determination of academic merit.
- 1.3 MPHREC members may sit on an adhoc basis as mandated by the need to review urgent studies, such as disaster or outbreaks.

2. Ethical Review of Research Proposals

- 2.1 Complete all assigned research proposal reviews diligently, and timely enough to give required attention to detail.
- 2.2 Allow only considerations of research ethics and how these relate to the protection of participants' rights and interests to guide decision-making in the research proposal review process.
- 2.3 Reach decisions on ethical review of research proposals independently, by consideration of facts as contained in the research proposal, sound knowledge of the principles of research ethics and criteria for the MPHREC's decision codes.
- 2.4 Ask for advice or guidance from other MPHREC members if uncertain about any aspect of research proposal review.
- 2.5 Request clarification if required from supervisors, students, or researchers during the research proposal review process.
- 2.6 Write useful research proposal reviews – i.e., reviews that are concise, clear, draw attention to deficiencies or areas that require revision, clearly explain deficiencies or the need for revision and offer advice if appropriate.
- 2.7 Avoid critiquing research design or method unless deficiencies can be identified that have clear ethical implications.

2.8 Avoid excessive critique of grammar, punctuation, spelling or technicalities of reference style (these can be pointed out in a concise and general way in order to give feedback that may improve the quality of the research proposal, but are not of primary concern in an ethical research proposal review).

3. Confidentiality

3.1 At all times uphold the duty to treat all research-related and other personal information discussed or communicated during the course of MPHREC activities as strictly confidential.

4. Conflicts of Interest

4.1 Be constantly aware of the possibility of conflicts of interest arising during MPHREC-related activities and be able to declare them when they occur during the performance of assigned duties.

4.2 Always declare possible conflicts of interest or ask the advice of the Chairperson and other members at a MPHREC meeting if uncertain of whether a conflict of interest exists, may exist or not.

4.3 Declaration of conflict of interest is done using the prescribed form (MPHREC SOP Annexure 17).

REC Member Name: _____

Signed: _____

Date: _____