health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

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

REF: ToR/01/07/ 2023: Research & Epidemiology

MPUMALANGA
THE PLACE OF THE RISING SUN

Table of Contents **Page**

1. BACKGROUND INFORMATION

1.1 Mpumalanga Province provides a rich arena for health and health-related research because of its excellent health care infrastructure and geographic location as it shares borders with other African Countries (eSwatini and Mozambique). The rate of migration from the said bordering states is high for both economic opportunities and healthcare services. To ensure that residents of Mpumalanga Province are fairly and respectfully treated by researchers, the Provincial Department of Health in Mpumalanga has identified a need to establish the Mpumalanga Department of Health Research and Ethics Committee (MPHREC). This need emanated from: a substantial increase in a number of requests from clinicians and allied staff members to conduct research earmarked for service improvement and publication in scientific journals; staff members registering with academic institutions lacking ethics committees; a lack of an accredited research and ethics committee in the province; ethics committees in academic institutions only assisting registered students for ethical clearance despite having MoUs with the department; to promote high ethical standards, and a need to safeguard the rights, dignity and well-being of prospective participants.

1.2 The primary role of the MPHREC is to protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research. Consequently, the primary responsibility of each MPHREC member is to decide independently whether the proposed research protects the interests of participants adequately and adheres to exemplary standards in research activities. The standard operating procedures have been developed to ensure that the review of research studies maintain a balance between the benefit of research and its results (that may be translated into improved health) and the respect for the participants.

1.3 The National Ethics Research and Ethics Committee (NHREC) and the National Health Research Committee (NHRC) are prescribed by the National Health Act, Act No. 61 of 2003 (Chapter 9). The Regulations have been drafted in relation to the two bodies including the regulation on conducting research on human subjects. The main aim of the bodies is to regulate the research activities and to strengthen research capacity in the provinces through Provincial Research Committees. The membership of these bodies includes academics and community members.

2. MAIN PURPOSE OF THE TERMS OF REFERENCE

2.1 The purpose of this document is to outline the terms of reference for the MPHREC in terms of the composition, roles, responsibilities, general principles and the work procedures.

3. APPOINTMENT OF THE MPHREC MEMBERS

3.1 As in line with the Ethics in Health Research Guidelines of 2015, and the Provincial Health Research and Ethics Guidelines of 2022,

- the Honourable Member of the Executive Council (MEC) as recommended by the Head: Health appoints the Provincial Health Research and Ethics Committee.

4. COMPOSITION OF THE MPHREC

4.1 The MPHREC shall comprise of about 18 members;

4.2 The following members were nominated to form part of the MPHREC:

4.2.1 Chairperson;

4.2.2 2X Vice Chairpersons;

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

4.2.3.1 Representative of Legal Services;

4.2.3.2 Representative of Head Office;

4.2.3.3 Representative of Ehlanzeni District;

4.2.3.4 Representative of Gert-Sibande District;

4.2.3.5 Representative of Nkangala District;

4.2.3.6 Representative of the Nursing profession;

4.2.3.7 Representative of a Medical Officer;

4.2.3.8 Representative of a Tertiary Hospital;

4.2.3.9 Representative of CEOs forum;

4.2.3.10 Representative of Community-Based Structure;

4.2.3.11 Representative of an Academic Institution;

4.2.3.12 Representative of Pharmacy Professional;

4.2.3.13 A lay person;

4.2.3.14 A Biostatistician/Statistician.

4.2.4 The following are Ex Officio Member/s of the committee:

4.2.4.1 Scriber: Research and Epidemiology;

4.2.4.2 The Accounting Officer shall co-opt or appoint alternative member/s (subject specialist) for needed expertise on a particular field of study.

5. RESEARCH ETHICS QUALIFICATIONS OR EXPERIENCE

5.1 Members to be appointed must have adequate experience in research and ethics;

5.2 In case an appointed member has the relevant research experience and/or qualification, but does not have adequate experience in research ethics, it is the responsibility of the Accounting Officer to provide ethics training to the member.

6. INDUCTION FOR NEW MPHREC MEMBERS

6.1 Induction is an important process that gives new MPHREC members key information about the committee and what is expected of them;

6.2 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 in order to begin the induction process.

6.3 New MPHREC members will be provided with ethics training requirements identified during the initial review meeting.

7. GUIDING PRINCIPLES FOR THE MPHREC

The MPHREC adheres to the following broad principles:

7.1 At all times act in the best interest of the health establishment and in such a way that the credibility and integrity of the health establishment is maintained;

7.2 Avoids conflicts of interest of members;

7.3 Helps and not hinders research;

7.4 Must familiarize themselves with related financial legislations;

7.5 Must guard against perverse incentives;

7.6 Perform the functions of office in good faith, honestly and in a transparent manner;

7.7 Promote and monitor good ethical practice in the province;

7.8 Provide for standardised and transparent ethics' procedures.

8. SPECIFIC FUNCTIONS OF THE MPHREC

The MPHREC shall:

8.1 Give advice and technical support on research proposal development;

8.2 Classify research proposal as either:

- 8.2.1 No risk proposals,
- 8.2.2 Low risk proposals,
- 8.2.3 Medium risk proposals, or
- 8.2.4 High risk proposals.

8.3 Review minimal, low or medium risk research proposals received that involve human participants;

8.4 Approve, reject, and require amendments to a research proposal on ethical and criteria approval grounds;

8.5 Formulate own procedures for dealing with expedited research applications;

8.6 Enforce ethical considerations on all research activities within the Province in accordance with ethical standards of clinical trials and non-clinical research activities;

8.7 Ensuring that informed consent is obtained;

8.8 Manage the process of priority setting and assist in the development of health research priorities and research agenda in the province;

8.9 Promote the use of health research in healthcare practice and policy development at all levels of the health care system;

8.10 Disseminate information on research ethics issues and support the Provincial Health Department's research activities including training, conferences and research conducted in provincial health facilities;

8.11 Conduct random monitoring of research projects conducted within the Province;

8.12 Audit the activities of research projects to ensure their compliance with research ethics;

8.13 At least once a year, MPHREC submit a report on the status and progress of its work to the NHREC as in line with the Ethics in Health Research of 2015;

9. THE WORKING METHOD OF MPUMALANGA HEALTH RESEARCH AND ETHICS COMMITTEE

9.1 All applications (Low, Medium and High risk) are submitted in writing/electronically via email to the MPHREC's secretariats at least six weeks before the planned start date of the project for assessment. An application form will be made available on Department's website (MPHREC Module). Applications are approved during face to face meetings of MPHREC, and all meetings must have minutes.

9.2 Approved applications receive a certificate of approval and an MPHREC reference number. No project may commence before such a number has been issued. Where practical, verbal feedback on projects can be given at MPHREC meetings. All verbal feedback must be minuted. All feedback and correspondence must be electronically filed by the secretariats under the particular MPHREC reference number.

9.3 Approved research project must be submitted to MPHREC at least once a year, in writing on the appropriate form – in this context the term "oversee" means nothing more than the annual feedback; the MPHREC assumes no further responsibility for the research. Should a research leader fail to do this, the certificate of approval will be withdrawn, and in which case the project must be discontinued. The certificate of approval can be re- issued if a satisfactory report with reasons for the failure to report is provided.

9.4 Any changes to the original proposal must be brought up for consideration (in writing) to the Secretariat of the MPHREC for assessment and approval. The work covered by the changed applications may not start until a new letter of approval has been issued. A new MPHREC approval certificate will also be issued.

9.5 Any problems experienced during a research project must be reported to the secretariat of MPHREC, who will bring it to the notice of the chairperson to initiate relevant processes to resolve the problem.

9.6 The NHREC will monitor the work of the MPHREC through visits. The NHREC will deal with cases where there are disputes and could not be resolved by MPHREC, especially where a decision could not be made in relation to the approval of research applications by MPHREC.

10. ROLES AND RESPONSIBILITIES

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

10.1 Functions of the Chairperson:

10.1.1 Convene and guide committee meetings in accordance with this operating procedures and relevant regulations;

10.1.2 Take responsibility and accountability for the final approval of ethically cleared research applications that do not include high risk proposal and/or involve clinical trials;

10.1.3 Assign responsibilities and duties to any other member in his or her absence and assign responsibilities to other members of the Committee;

10.1.4 Represent the MPHREC in meetings with the NHRC, NHREC, government sectors, research and academic institutions as and when required;

10.1.5 May recommend the appointment of an additional/replacement member to the MPHREC;

10.1.6 Evaluate final reports and outcomes.

10.2 Functions of the Vice-Chairperson(s):

10.2.1 Assist the Chair in the Committee management;

10.2.2 Conduct Committee meetings in the absence of the Chairperson.

10.3 Functions of the Secretariat:

10.3.1 Screen all research proposals/applications for relevant documents and distributes to MPHREC members during meetings;

10.3.2 Liaise with researchers on review outcomes of their applications;

10.3.3 Performs administrative functions to the MPHREC, which includes:

10.3.3.1 Issuing invitations to members to attend meetings;

10.3.3.2 Availing and recording MPHREC minutes;

10.3.3.3 Coordinating logistical arrangements for the MPHREC.

11. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST AND CONFIDENTIALITY

11.1 MPHREC members shall sign confidentiality forms on the first meeting of their term in office and will sign declaration forms each time the committee sits;

11.2 Should there be any conflicted member in any research application, the member shall recuse him/herself from a meeting, until decisions are made on that particular research application;

11.3 Disclosures must cover the full range of potential interests:

11.3.1 Direct benefits like the provision of materials or facilities, and

11.3.2 Financial or in-kind support, for example, payment of travel, accommodation expenses to attend conferences.

11.4 Such disclosure should cover any situation in which the conflict of interest may, or may be perceived to, affect decisions regarding other people;

11.5 Researchers / supervisors have an obligation, at the time of reporting, proposing research, or seeking approval from MPHREC or other regulatory authorities to declare any conflict of interest which has a potential to influence the project and its conduct;

11.6 Members of MPHREC must recluse from the committee when discussion of projects in which they are personally involved takes place, and must not use their membership to gain a favourable advantage.

12. DURATION OF MPHREC MEMBERSHIP

12.1 MPHREC Members are appointed for a term of five years;

12.2 An MPHREC member may not serve for more than two consecutive terms.

13. QUORUM

13.1 A quorum is constituted by 33% availability of MPHREC members;

13.2 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;

13.3 A quorum will include at least 1 (ONE) member whose primary area of expertise is non-scientific.

14. FREQUENCY OF MPHREC MEETINGS

14.1 The MPHREC shall sit at least once per quarter to review and approve research studies;

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

14.3 Members of the MPHREC's working committee shall sit monthly in preparation of MPHREC meetings.

15. BUDGET

15.1 No member of the MPHREC is remunerated for his/her services. Only accommodation will be arranged for external members of the MPHREC;

15.2 To cover administrative costs of the MPHREC's activities, a budget is submitted annually via the Provincial Directorate: Research and Epidemiology.

16. STRUCTURE FOR RESEARCH PROPOSALS

16.1 Research proposal should comply with the following suggested guidelines:

- Cover Page: Title and Authors
- Abstract/Summary
- Background Information
- Problem Statement
- Significance of the Study
- Aim and Objectives
- Methodology: Study design, Population, Sampling, Inclusion and Exclusion Criteria, Data Collection and Analysis Techniques, Ethical Considerations, Dissemination of the findings, Budget, Time Frame and Sources Used.

17. SCOPE OF APPLICATION

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

18. TERMS OF REFERENCE REVIEW

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

19. TERMS OF REFERENCE APPROVAL

APPROVED / NOT APPROVED

DR LK NDHLOVU 6/7/2023 **DATE**

HEAD: HEALTH

Effective date 10/07/2023