health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Mpumalanga Provincial Health Research Ethics Committee (MPHREC)'s Ethics Policy

MPUMALANGA
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i. **Abbreviations**

- **MPHREC:** **Mpumalanga Provincial Health Research Ethics Committee**
- **NDP:** **National Development Plan**
- **NHRD:** **National Health Research Database**
- **PHRC:** **Provincial Health Research Committee**
- **R&D:** **Research and Development**

1. Introduction

Research and the evidence that research yields are critical elements for improving healthcare outcomes. Therefore, health research systems are vital for research generation, dissemination, and utilisation in addressing the health needs of the population. Developing a research and ethics policy is crucial to ensuring that research activities are conducted responsibly, ethically, and in compliance with relevant regulations and standards. This policy outlines the principles and guidelines for conducting research within Mpumalanga Provincial Department of Health's jurisdiction. It is designed to ensure that all research activities adhere to the highest ethical standards and contribute to the advancement of knowledge while protecting the rights and well-being of research participants.

2. Scope

This policy applies to all researchers, including departmental' staff, students, and affiliated researchers, involved in research activities under the auspices of Mpumalanga Provincial Department of Health.

3. Guiding Principles

4.1 Integrity and Honesty

Researchers must conduct their research with integrity and honesty, ensuring the accuracy and reliability of research findings.

4.2 Respect for Persons

Researchers must respect the dignity, rights, and autonomy of all research participants, obtaining informed consent and ensuring confidentiality and privacy.

4.3 Beneficence and Non-maleficence

Researchers must aim to maximize benefits and minimize harm to participants, ensuring that the risks are justified by the potential benefits.

4.4 Justice

Researchers must ensure fair distribution of the benefits and burdens of research, avoiding exploitation of vulnerable populations.

4.5 Transparency and Accountability

Researchers must maintain transparency in their research activities and be accountable for their conduct and the outcomes of their research.

4. Legislative Framework

4.1 The South African Constitution, Act 108 of *1996:*

The Bill of Rights as enshrined in the Constitution stipulates the right to bodily and psychological integrity, including the right of subjects not to be subjected to medical or scientific experiments without their informed consent. The Constitution further guarantees freedom of expression including academic freedom and freedom of scientific research.

4.2 White Paper on Science and Technology 1996:

The White Paper on Science and Technology highlights the need for new knowledge to assist in consolidating democracy, the protection of human rights and the accountability of public authorities in South Africa. It further advocates for ongoing policy research in areas such as health care, education and employment creation, which are central to improving the quality of life of millions of poor South Africans. Most importantly, the policy underlines the active and continuous involvement of social scientists in government policy processes.

4.3 National Research & Development Strategy (NRDS), 2002:

The NRDS focuses more on research in science and technology as well as government funding thereof. In brief, the Strategy identifies three key priorities, namely:

7.3.1 The establishment of a cluster of innovation programmes, particularly in biotechnology, information technology, manufacturing technology and technology for poverty reduction.

7.3.2 Strengthening and refocusing state-funded science, engineering and technology research in areas of South African advantage (for example, in astronomy, palaeontology and indigenous knowledge) and in 'strategic basic' research areas related to areas of industrial and social needs.

7.3.3 Lastly, the NRDS advocates for a creation of a holistic basis for R&D policy by creating a clear distinction between the roles of sector departments (such as Agriculture, Health, Rural Development, Land and Environmental Affairs and the Department of Science and Technology), which should play an integrative role across the whole of government. Although the roles are distinguished within the NRDS, integration remains a focus of policy development.

4.4 Helsinki Declaration

The Helsinki Declaration regulates human experimentation in the medical community. It serves as a cornerstone document on human research ethics.

4.5 Mpumalanga Vision 2030 Strategic Implementation Framework

The Mpumalanga Vision 2030 Strategic Implementation Framework (2013-2030) is a direct implementation response to the National Vision 2030. It affirms the province's approach towards realizing the adopted and articulated national vision and development plan. The Mpumalanga

Provincial version seeks to ensure that the province and other stakeholders work with common purpose for the development of the province and all of its constitutive geographical areas. In terms of research and development, the plan emphasizes the promotion of innovation and the development of knowledge. It further suggests service-linked scholarships that can be provided in key areas such as nursing, teaching and social work.

4.6 National Development Plan (NDP) Vision for 2030

The NDP acknowledges that knowledge production is no longer the preserve of universities as other research institutions including even government departments have emerged. It is in this light that the Plan calls for a reconfiguration of a framework to harmonize the knowledge production system and further encourages government departments to collaborate in developing a broad enabling framework and policy that will encourage world class research and innovation.

4.7 Promotion of Access to Information Act 2 of 2000

The Act gives effect to the Constitutional right of access to any information held by the State and any information that is held by another person and that is required for the exercise or protection of any rights.

4.8 Protection of Personal Information Act 4 of 2013

The POPI Act sets out the minimum standards regarding accessing and 'processing' of any personal information belonging to another. The Act defines 'processing' as collecting, receiving, recording, organizing, retrieving, or the use, distribution or sharing of any such information.

4.9 The National Health Act 61 of 2003

Section (3) prescribes the establishment of the National Health Research Committee whose functions are to determine the health research to be carried out by public health authorities, ensure that health research agendas and research resources focus on priority health problems, develop and advice the Minister on the application and implementation of an integrated national strategy for health research and co-ordinate research activities of public health authorities.

4.10 National Health Research Policy of 2001

It serves as a framework for coordination and management of research in South Africa proposes the establishment of Provincial Health Research Committees (PHRC's) in all provinces that will serve as a link to the National Health Research Committee. The Directorate: Health Research within the Cluster Health Information Evaluation and Research is responsible for coordination of Research within the National Department of Health.

4.11 South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd ed of 2024.

These guidelines provide a strengthened guide to ensure that, in South Africa, health research is conducted responsibly and ethically.

5. General Principles

5.1 Research is, at the most basic level, a human activity. This implies that research is never value-neutral or mechanistic. Researchers have preconceptions determined by social, political, cultural and gender influences. These preconceptions influence both their theories and findings.

5.2 In general, all research involving humans, or research requiring access to private data belonging to an organisation, requires ethical clearance meaning that a research proposal must be submitted to the any local accredited REC for review before it is conducted.

5.3 Quality improvement studies must be forwarded to the Head: Health for approval. The request is submitted together with a summary proposal (indicate how data collection is going to be conducted) and a detailed data collection tool. However, if there is any possibility that such activities might lead to a publication, or that publication may at some future time be desired, then prospective ethical clearance must be sought. Retrospective ethical clearance will not be considered under any circumstances.

5.4 The use of departmental data for publication/ presentation to conferences must be approved by the Head: Health. The request is submitted together with evidence that information was shared internally with the relevant programmes or districts. This includes data to be presented by department's partners.

5.5 The identity and records of the participants/facilities are as far as possible kept confidential (except when required for legal reasons). This is to avoid any form of hardship, discrimination, or stigmatization as a consequence of having participated in the research.

5.6 The research findings should be brought into the public domain so that its results are generally made known through scientific and other publications. This would help in consolidating the scientific knowledge base of the field being studied and would prevent the undue replication of studies which pose risks to some subjects.

5.7 All research studies cleared by international RECs, must be submitted to any local accredited REC before conducted locally.

5.8 All research studies are submitted to the Department through the NHRD website for further handling (http://nhrd.health.gov.za). The application is accompanied by a detailed proposal, a letter of support (Annexure 2) signed by the relevant CEO/District Manager/ Senior Manager at institution. Preferably as follows:

Research conducted at:	**Appropriate signatory on the support letter**
Provincial Office	Head: Health, DDG or Responsible/ designated Senior Manager

District	Head: Health, DDG, District Manager or designated Senior Manager
Hospital	Head: Health, DDG, CEO or designated Senior Manager
CHC and Clinic	Head: Health, DDG, District Manager or designated Senior Manager

6. Research Standards

6.1 All research must have a sound aim and demonstrate a clear link to strategy, policy, practice or producing new knowledge.

6.2 The quality of design, implementation and analysis of research must be reviewed independently to ensure it meets ethical standards, achieves a high level of rigor and is potentially beneficial to the service user, and/or the organization/department, and/or likely to generate useful new knowledge.

6.3 Attention must be given to systems for ensuring confidentiality of personal information and to the security of these systems.

6.4 Researchers should respect the diversity of human culture and conditions and take full account of ethnicity, gender, disability, age, economic status and sexual orientation in the research design, undertaking and reporting.

6.5 It is essential that existing sources of evidence, especially literature searches/systematic reviews, be considered carefully prior to undertaking research.

6.6 Research or consultation which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.

6.7 Data collected in the course of research must be retained for an appropriate period to allow further analysis by the original or other research teams and to support monitoring of good research practice by regulatory and other authorities.

6.8 Preferably, there should be free access to information both on the research being conducted and on the findings of the research once these have been subjected to appropriate review. This information must be presented in a format understandable to the public. Reports need to be clear and take language and other needs into account.

7. Research Governance within the Department

7.1 Mpumalanga Provincial Health Research Ethics Committee (MPHREC)

7.1.1 The Provincial Health Research Committee shall:

7.1.1.1 Review minimal, low or medium risk research proposals (see MPHREC SOP, 2024) received that involve human participants and conducted within Mpumalanga Province.

7.1.1.2 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.

7.1.1.3 Ensure that research protocols are scientifically sound and feasible within available resources.

7.1.1.4 Decide whether to approve, to require amendments or reject the protocols for lack of compliance with scientific or ethics norms and standards.

7.1.1.5 Conduct random active monitoring of research projects conducted within the province (see MPHREC Terms of Reference).

7.1.1.6 Ensure appropriate reporting occurs to fulfil the oversight obligation of the MPHREC to monitor welfare interests of participants.

7.1.1.7 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.

8. Research Approval Process

8.1 All research protocols involving human participants must undergo ethical review and approved by any accredited Independent Local Research Ethics Committee.

8.2 The *role of the Researcher/Principal Investigator:*

8.2.1 Without an accredited Independent Local Research Ethics Committee Clearance

8.2.1.1 The researcher develops a detailed research protocol (see annexure 1).

8.2.1.2 It is advisable that a proposal be submitted for scientific evaluation to any research committee, such as PHRC or Research Forum before submitted to the MPHREC.

8.2.1.3 Researcher completes the Letter of Support Form (LoS) (Annexure 2) indicating resources required to conduct the research.

8.2.1.4 LoS Form is presented to the relevant facility/district/directorate for support as a way of introducing your research to the relevant authority.

8.2.1.5 Once Los Form is signed and supported, the researcher completes and sign the MPHREC research application form (See MPHREC SOP, 2024).

8.2.1.6 Upload a detailed proposal, Signed Application Form, and Signed LoS Form on the http://ndrd.health.gov.za.

8.2.2 With an accredited Independent Local Research Ethics Committee Clearance

8.2.2.1 Researcher completes the Letter of Support Form (LoS) (Annexure 2) indicating resources required to conduct the research.

8.2.2.2 LoS Form is presented to the relevant facility/district/directorate for support as a way of introducing your research to the relevant authority.

8.2.2.3 Once Los Form is signed and supported, the researcher upload a detailed proposal, Ethics Certificate, and Signed LoS Form on the http://ndrd.health.gov.za.

8.3* The *role of the Relevant/Designated Senior Manager:

8.3.1 Upon receipt of the Completed LoS Form (Annexure 2), evaluate if the institution/facility is able to accommodate the researcher's needs in terms of resources listed.

8.3.2 The Senior Manager may invite the researcher for presentation should further clarity be required regarding availability of resources to accommodate the research. However, this process should be completed within two weeks so that the research process is not severely delayed. Furthermore, the Senior Manager may request additional relevant information/documents from the researcher.

8.3.3 Once satisfied with provided details, the Senior Manager indicates final decision on the Los Form, either supported or not supported. At this stage, even when research is supported, the research process may not start pending clearance from the PHRC through the NHRD.

8.3.4 The signed LoS Form is returned to the researcher who will upload on the http://ndrd.health.gov.za.

- Should the research be **not supported**, the letter of support with reasons why it is not supported, may be sent directly to the Research Office for further handling.

- NB: Research permission process will not proceed to the next level without a signed letter of support by the relevant Senior Manager.

8.4 The *role of the MPHREC:*

8.4.1 Review and approved research studies (see MPHREC SOP, 2024).

9. Research without Ethics Certificate

9.1 Quality Improvement Projects (QIPs)

9.1.1 All QIP studies must be approved by the relevant authority.
9.1.2 Request for approval to conduct QIPs is sent to the Head: Health.
9.1.3 However, if there is any possibility that such activities might lead to a publication, or that publication may at some future time be desired, then prospective ethical clearance must be sought though the normal Research Approval Process (see MPHREC SOP, 2024).
9.1.4 Retrospective ethical clearance will not be considered under any circumstances.

10. Informed Consent

10.1 Obtaining Informed Consent (Annexure 3)

10.1.1 Researchers must obtain voluntary, informed consent from all research participants.
10.1.2 Participants should be provided with clear and comprehensive information about the research, including its purpose, procedures, risks, benefits, and their rights.
10.1.3 Consent must be documented in writing, with a copy provided to the participant.
10.1.4 In cases where written consent is not feasible, alternative methods of obtaining and documenting consent must be used, as approved by the MPHREC.

10.2 Confidentiality and Data Protection

10.2.1 Confidentiality

10.2.1.1 Researchers must ensure the confidentiality of all information obtained from research participants.
10.2.1.2 Identifiable information must be securely stored and only accessible to authorized personnel.

10.2.2 Data Protection

10.2.2.1 Researchers must comply with relevant data protection laws and regulations.
10.2.2.2 Personal data must be anonymized or pseudonymized whenever possible to protect participants' identities.

11. Conflict of Interest

11.1 Researchers must disclose any potential conflicts of interest that could affect the integrity of their research.
11.2 The MPHREC will review these disclosures and determine appropriate actions to mitigate conflicts.

12. Publication and Dissemination

12.1 Accurate Reporting

12.1.1 Researchers must report their findings accurately and honestly, without fabrication, falsification, or misrepresentation of data.

12.2 Acknowledgment of Contributions

12.2.1 Researchers must appropriately acknowledge the contributions of all individuals and organizations involved in the research.

12.3 Open Access

12.3.1 Whenever possible, researchers are encouraged to publish their findings in open-access journals to ensure wide dissemination and accessibility of research results.

13. Training and Education

13.1 Researchers must undergo regular training on research ethics and responsible conduct of research.

13.2 This includes understanding ethical principles, regulatory requirements, and best practices in research.

14. Management of Research outputs

14.1 Approved research reports will be kept by the department and an electronic version will be stored in the NHRD portal (http://nhrd.health.gov.za) until such time the department has created a dedicated repository for research reports.

15. Compliance and Monitoring

15.1 Compliance

15.1.1 Researchers must comply with this policy and all applicable ethical guidelines and regulations.

15.1.2 Non-compliance may result in disciplinary action.

15.2 Monitoring

15.2.1 The MPHREC will monitor ongoing research for compliance with ethical standards.

15.2.2 Researchers must submit progress reports and promptly report any adverse events or deviations from approved protocols.

16. Review and Amendments

16.1 This policy will be reviewed periodically to ensure its relevance and effectiveness.

16.2 Amendments to the policy may be made as necessary, subject to approval by the appropriate governing body.

17. Effective Date and Policy Review

This policy takes effect from the date of approval and will not have retrospective effect, and it shall be reviewed in a five-year circle or when a need arises.

18. MPHREC Ethics Policy Approval

APPROVED/ NOT APPROVED

8/8/2024

DR LK NDHLOVU **DATE**

HEAD: HEALTH

Effective date_____

ANNEXURES	
Only Use/Retrieve the Relevant Annexure	
Annexure 1	*Generic Proposal Template*
Annexure 2	*Letter of Support (Research Permission)*
Annexure 3	*Generic Information Sheet and Consent Form*

(ANNEXURE 1)

GENERIC PROPOSAL TEMPLATE

Title Page:

This should include the title of the project; name and student number (if student); your department or faculty; the name of the degree sought; the names of your supervisors/ co-investigators, and the date of submission.

i. Abstract (for some institutions)

This should include the problem under investigation; the research methodology and theoretical orientation; and the expected outcomes and implications of the research.

1. Introduction

1. Background information

Provide relevant background to the study, supported by evidence

2. Research Aim/Purpose

Provide the main aim of the study (A broader statement)

3. Research Objectives

List objectives of the study

4. Research Questions/Research Hypothesis

What are research questions to answer or what are some of the statements to test?

5. Problem Statement

Provide a concise statement about an area of concern, a condition to be improved, a difficulty to be eliminated, or a troubling question that exists in scholarly literature, in theory, or in practice that points to the need for meaningful understanding and deliberate investigation

6. Significance of the Study The significance of the study should reflect on the extent of the contribution made by the study to improve our understanding, to change a concept or to promote a new hypothesis in a particular field of research
7. Definition of Terminology Define main term used in the study, including operational definition of selected terms
8. Literature Review The literature review provides the rationale for your research topic. It should give an overview of the current research on the topic area. It should identify a gap in the research. This is important because it shows why your topic is important. The literature review should also review relevant methodologies, which show how your research is to be done
Research Methodology: this section will include a number of subsections. It should describe the type of study you propose to do as well as how you propose to do it. You need to describe your participants/subjects, your data collection procedure and method of data analysis, as well as the limitations of your project.
9. Research Strategy Explain the qualitative and/or quantitative methods that you will use to gather data for your study in detail. These methods may include focus groups, depth interviews, observation, a survey questionnaire, an experimental study, etc.
10. Target population Clearly define and delineate the target population and context of the proposed study.
11. Sample strategy Discuss the method to be used for determining the target sample size of your study. Indicate the target sample size that you wish to achieve.
12. Data collection instruments Explain the qualitative and/or quantitative methods that you will use to gather data for your study in detail. These methods may include focus groups, depth interviews, observation, a survey questionnaire, an experimental study, etc. Remember to comprehensively motivate your choice of data collection methods.
13. Pilot study

Explain in detail how you will pre-test your survey questionnaire or data collection instrument
14. Validity and reliability Discuss measures of Validity and Reliability or Trustworthiness
15. Data analysis Briefly indicate how you would validate, edit, code and clean your data in preparation for statistical and / or qualitative analysis. Mention the software programmes that you will use to code and analyse your data.
16. Limitation of the research What are the potential limitation to this study
17. Ethical considerations Discuss any potential ethical issues, benefits, confidentiality, privacy etc.
18. Proposed time frame and Budget A brief timeline for the project Include a realistic project budget in this section in which you outline the major expenses you expect to incur during your research project.
19. Bibliography A full list of all references cited in in the proposal. Any preferred referencing conventions. referencing style • Ensure consistency • Should be in chronological order

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(ANNEXURE 2)

LETTER OF SUPPORT (RESEARCH PERMISSION)

Letter of Support (To be signed by relevant Senior Managers/Responsibility Managers)

1. Study Details 2. NHRD Number:		
1.1 Name of Applicant		
1.2 Contact Number:		
1.3 Study Title:		
1.4 Data collection period to undertake the study:	Start:	End:
1.5 List of selected facilities:		
1.6 Research summary and how data will be collected (answer should not be more than the space provided):		

3. Resources Required from Facility/Sub-district/Community		
2.1 Facility Staff Required to assist with the Study	**Yes** **How many:** Nurses: Doctors: Space: Other, please specify:	**NO**
2.2 Patients / Researchers' Records/Files	**Yes** Year: From: To:	**NO**
2.3 Interviewing Patients/ participants at Facilities	**Yes**	**NO**
2.4 Interviewing Patients/ participants at Home	**Yes**	**NO**
2.5 Other, please specify:		

3 Resource flow/benefits to the Provincial Department		
3.1 The research is responsive to which National/Provincial/departmental priority/strategy/research agenda. • **State your response:**		
3.2 Resource Flow (Are there benefits to Patients/community)	**Yes** Please list: all potential remedial ideas emanated from research will be taken up for healthcare practice and policy	**NO**

3.3 Resource Flow (Are there benefits to Facility/District)	**Yes** Please list: to create a linkage between all research stakeholders		**NO**
4 Availability of Required Clearance/s			
4.1 Ethical Clearance	**Yes** Clearance Number:	**Pending**	**NO**
4.2 Clinical Trial	**Yes** Clearance Number:	**Pending**	**NO**
4.3 Vaccine Trial	**Yes** Clearance Number:	**Pending**	**NO**
4.4 Is conducted in a village led by tribal authority?	**Yes** Date tribal authority engaged:	Not	**NO**
5 Declaration			

Declaration by Applicant:

I Mr/Ms/Dr/Prof/Adv._____ agree to submit/present the result of this study back to the CEO/Institution/District.

Estimated date of feedback: _____

--------Comment by CEO/DM/PM: **Supported / Not Supported**

_____

Signature: **Date:**

Name: _____

Stamp

(ANNEXURE 3)

GENERIC INFORMATION SHEET AND CONSENT FORM

Introduction of the enumerator

Identify yourself and the institution you are representing.

Brief introduction and background of the study

Describe the problem that this research project is trying to solve and its intended purpose.

What will the study involve?

Will the participants be requested to provide a blood sample or provide any medical or private and personal information? In the informed consent document, it is important to not deviate too far from the topic of the study with examples to explain certain concepts. But on the other hand, you should seek to make sure all the necessary information is gathered.

Your voluntary participation and right to withdrawal

Request the potential respondent for permission to participate in the study and also indicate the estimated time of the interview.

Explain to the respondent that **participation is voluntary** and not being forced to take part in this study. The choice of whether to participate or not, is the respondent's decision alone. If they choose not to take part, they will not be affected in any way whatsoever. If they agree to participate, they may stop participating in the research at any time and there won't be any penalties or prejudice.

Confidentiality and Anonymity

Explain how confidentiality and anonymity will be upheld during and after the study, thus explain what will happen to the data collected.

Should the enumerator need to tape-record the interview, they should seek permission from the researcher first.

Study risks/discomforts

The enumerator must explain any risks and harm that maybe associated with participation in the study should there be any, these risks should be explained and discussed in the informed consent document. Inserting the section on potential risks may prevent the misunderstandings about the project. Some of the risks that may need to be mentioned

include the risk to individual such as breach of confidentiality and other physical risks such as risks associated with drawing of blood or non-physical risks such as loss of privacy. There may be other unknown risks to participation that an investigator might want to share with participants. For example, research results could have the potential under certain circumstances be misconstrued and used to discriminate and/or stigmatize a population.

Study benefits associated with the study

Are there any immediate or indirect benefits from participating in the study? The consent form must clearly explain what the benefits will be. The researchers should be careful with emphasizing more on immediate benefits such as nutritional supplements, food or compensation because this may lead to false inducement. However, the points that the researcher may need to mention on the informed consent are benefits of the study to the society and likely lack of immediate benefit to participants.

How participants will be protected?

It should be emphasized in the consent form that the identity of the participants will be protected at all times, and that data will be kept secured in locked cabinets in a locked room or in password protected databases.

Who to contact if you have been harmed or have any concerns?

This research has been approved by the Mpumalanga Provincial Health Research Ethics Committee (MPHREC). If there are any complaints about ethical aspects of the research or any feeling that the respondent has been harmed in any way by participating in this study the MPHREC secretariat must be contacted on 0137663766 or chairperson on 0137663429.

CONSENT: (a consent should be documented with a signature on a separate sheet).

I have been informed of the study purpose and of my rights as a study participant. The investigator has offered to answer my questions concerning this study. I hereby:

• consent to participate in the study:	Yes	No
• allow the researcher to audio record the interview proceedings:	Yes	No
• Consent for storage and future use of my information and blood sample:	Yes	No

Participant's Name: _____ Name of Researcher/Witness_____

Signature: _____	
Signature:_____	
Date: _____	Date: _____