Northern Cape Department of Health



**POLICY ON CONDUCTING HEALTH RELATED RESEARCH**

**WITHIN THE NORTHERN CAPE PROVINCE**

**VERSION 2**

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| Summary  | This policy provides a framework for conducting health related research within Northern Cape Province to comply with good ethical practice.  |
| Version  | Two (DRAFT) |
| Responsible Manager  | Director for Research and Development  |
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| Approved by and date: | Mr S Jonkers (Head of Department)

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| Signature  | Approved Date  |

 |
| Effective date |  |

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# **Policy Aim and Purpose**

Conducting Health Related Research Policy (the policy) aims to ensure that those conducting health related research within the Northern Cape Province are committed in accordance with the highest possible standards of ethical conduct and research integrity, and to respond to critical health challenges of the Province as well as that of the country. This policy describes the legislative framework; the role of PHRECs; membership composition; operational procedures; and standard operating procedures for PHRECs.

# **Policy Scope**

This policy applies to all staff of the Northern Cape Department of Health, students registered at universities, research institutions, members of university, and any other person seeking to undertake health related research involving human participants in their research such as patients, staff of the department, community healthcare workers; as well as human biological materials and data collected from living or deceased persons, including human embryos, fetuses, fetal tissue, reproductive materials, and stem cells in the Northern Cape Province.

# **Legislative Framework**

Section 73 of the National Health Act (NHA) requires every institution, health agency and health establishment at which health research is conducted, to establish or have access to an REC, which is registered with the National Health Research Ethics Council (NHREC).

# **Principles**

The National Department of Health, Ethics in Health Research Principles, Processes and Structures 2015 guides institutions and researchers in responsible research practices and promotes research integrity, adopts the Code’s Principles of Responsible Research Conduct. Research should reflect core values such as:

* Respect for research participants,
* Justice and fairness in the research participant’s selection
* Beneficence and non-maleficenceto do good while avoiding harms
* Scientific merit and integrity,
* Honesty in the development, undertaking and reporting of research
* Rigour in conducting high-quality research
* Transparency in declaring interests and reporting research methodologies and findings
* Accountability for the conduct of research
* Promotion of responsible conduct through establishment of research ethics committees, and strengthening of review processes, to protect the rights, safety and welfare interests of individuals involved in research, particularly vulnerable participants; as well as to protect safety and other interests of researchers
1. **Definitions**
* **Human Research Ethics Committee (HREC)** is a committee constituted in accordance with the National Statement to review and, where appropriate, approve and monitor the ethical and scientific aspects of human research studies.
* **Health Related Research**, for the purposes of this policy, has the same meaning as used by both the Code and the National Statement, which define research as ‘original investigation undertaken to gain knowledge, insight and understanding.
* **Ethics review reflects** of the ethical considerations implicated in the research. These include participants’ welfare, rights, beliefs, perceptions, customs and cultural heritage, including other material to be used to inform potential participants should be included in the ethics review application, such as information sheets, consent forms, questionnaires, advertisements, and letters.
* **Expedited review** based on the nature of research approval it may be approved by sub-committee of the PHREC. Expedited review should apply, in principle, only to research that poses no more than minimal risk of harm.
* **Confidentiality** imposes the duty on researchers/ investigators effectively securing any access to participants’ personal information. Records that may identify participants must be kept safe and confidential, and should not be made publicly available unless so required by local laws or regulations. Confidential information must not be released without the participants’ consent.

# **Policy Statements**

All research under the scope of this policy conducting research involving human participants must:

* Comply fully with the National Department of Health, Ethics in Health Research Principles, Processes and Structures 2015 <https://ahrecs.com/resources/ethics-health-research-principles-processes-structures-2nd-ed-south-africa>
* Understand and comply with the Northern Cape Conducting Health Related Research Policy, and SOPs
* Seek ethical approval from the Provincial Health Research Ethics Committee (PHREC) for all human research regarded as lower risk. Ethics assessment may not be required for all research involving humans that have ethics approval from accredited institution.
* All those under the scope medium and higher-risk conducting research involving therapies, including clinical and non-clinical trials of medicine, medical devices must apply to NHRC and comply fully with the requirements of the National Department of Health, Ethics in Health Research Principles, Processes and Structures 2015
* All necessary ethics approvals must be obtained before commencing conducting the research
1. **It is the policy of the Northern Cape Department of Health**
	1. To provide a framework that applies for all health related researches within the Northern Cape Province involving research participants which include staff, patients or resources of the department.
	2. To establish rational, transparent, and collective decision -making processes around the proposed health related researches within the department.
	3. To protect the welfare and rights of research participants through ensuring ethical considerations on all research activities.
	4. To align the proposed research activities to the provincial research priority areas.
	5. To ensure effective communication (internal and external) about the principles and polices on which the research activities in the province are founded.
	6. To co-ordinate, grant, assist and monitor all health research projects by implementing policy on conducting health research and the Standard Operating Procedures (SOPs)
	7. To ensure that services are not overburdened by researchers and to avoid an overlap.
	8. To ensure that research findings are made available or disseminate to the appropriate audience and officials for planning and monitoring purpose.
	9. To efficiently utilize research funds within the province.
	10. To develop research database that is accessible to researchers and to share information that are public good.

# **Roles and responsibilities**

**The roles and responsibilities of Accounting Officer or his/her delegates**

* 1. Appoint a Provincial Health Research Ethics Committee (PHREC) members in accordance with the National Department of Health,2015, Ethics in Health Research Principles, Processes and Structures.
	2. Support the training and refresher courses as PHREC members should be expected, at least once during a term of appointment.
	3. Support systems in place for the smooth functioning of the Provincial Health Research Ethics Committee (PHREC).
	4. Appoint the PHREC members, who is suitably qualified, for a period of three years, renewable based on performance.
	5. Ensure that adequate administrative support and resources are provided so that the work of the PHREC can be done in compliance with these minimum standards.
	6. Ensure procedures and criteria for recruitment and appointment of REC members should be in place, transparent and accessible.
	7. Provide for all PHREC members a formal appointment letter that sets out, at a minimum, the term of office.
	8. Ensure that opportunities for training and refresher courses in research ethics (human and animal) and Good Clinical Practice (GCP) should be made available or accessible for committee members.
	9. Provide indemnify for all committee members from personal liability and should ensure that adequate public liability insurance exists. The institution should take legal responsibility for the decisions and advice of the PHREC, provided that members act in good faith.
1. **The role of research and Development Directorate**
	1. To provide support including organizing training for Provincial Health Research Ethics Committee (PHREC)
	2. Design and develop the standard format which will serve as a guide for approval of research proposals
	3. Ensure that all health related research activities within the Northern Cape Province are conducted in full compliance with the all applicable legislations, ethical standards, guidelines, regulations and policies.
	4. Chair the PHREC and set the agenda for the upcoming meeting
	5. Engage with respective district and/or facility managers to acquire their permission before approval of a research proposal within their sphere of influence
	6. Implement decision of actions made by PHREC
	7. Create an enabling environment and maintain, and enhance the quality of research undertaken within the province
	8. Develop research database for information communication and dissemination
2. **The Role and responsibilities of Provincial Health Research Ethics Committee**
	1. Critically review and assess proposals to do health research. If all standards are met, then the PHREC may approve the proposal, with or without additional conditions based on the pre-determined criteria The PHREC is to protect the interests (rights and welfare) of the research participants who volunteer to take part in scientifically sound research.
	2. Each PHREC member work independently to be objective, informed and to act without fear or favour in their scientific and ethical reviews to decide independently whether the proposed research protects the interests of participants adequately and keeps to exemplary standards in research activities.
	3. The PHREC must develop its Terms of Reference (TOR) and Standard Operating Procedures (SOP). The ToR and SOPs should be accessible to the institutional members, researchers and other interested persons, usually via internet or intranet sites.
	4. Make recommendations to the Accounting Officer and Member of the Executive Authority on research projects that are not adhering to the research policy and standards of the provincial and national Department of Health.
	5. All PHREC should be trained and provide proof of research ethics training, refreshed at least once within the period of appointment.
	6. The PHREC should consists of at least nine members with a quorum being a simple majority. It should include at least one layperson, at least one member e.g. a medical practitioner, psychologist, social worker or nurse at least one member with professional training and experience in qualitative research methodologies, a member with expertise in bio-statistics/qualitative research methodologies, a member with expertise in research ethics and at least one member who is legally qualified.
	7. Capacitate themselves in good ethical and research aspects and, act in good faith.
	8. Declarations regarding confidentiality and conflict of interest for each meeting.
	9. PHREC members must not review or make decisions about research proposals in which they are involved personally or financially. When such a proposal is to be discussed, the member concerned should declare the potential conflict and offer to recuse herself from the meeting for that time.
	10. PHREC members, are expected to attend all meetings, diligent performance of responsibilities, maintenance of confidentiality, and consideration of potential conflicts of interest.
	11. The PHREC has the authority from time to time, to appoint, a standing or ad-hoc subcommittee to investigate or finalise certain matters under its jurisdiction, in compliance with applicable norms, rules and regulations.
	12. The PHREC functions on behalf of the Northern Cape Department of Health to:
3. Provide independent oversight of human research projects;
4. Provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active;
5. Determine the compliance of a human research project with the National Department of Health Ethics, principle, structure guidelines approve or decline ethical approval; and
6. Provide advice to the researchers on how to promote awareness of the ethical conduct of human research.
7. **Accountability**
	1. The PHREC is directly accountable to the Accounting Officer of the Department under which is constituted.
	2. The PHREC provides an annual report to the Accounting Officer of the Department or delegate at the end of each financial or calendar year.
	3. The PHREC brings to the attention of the Accounting Officer or delegate issues of significant concern. 3.4 The PHREC provides the annual reports on behalf of the Northern Cape Department of Health to the National Health Research Council (NHRC)
8. **. The Role of the Researcher**
	1. Submit proposal with all required documentations to Research and Development Directorate and/or secretariat of the PHREC
	2. Have appropriate skills and ability to complete research
	3. Conduct the study in accordance with the highest possible standards of ethical conduct and research integrity
	4. Responsible for the collection, management, storage, retention and disposal of any research data, primary materials and records used or created in the conduct of a research project, particularly in relation to human participants.
	5. Submit progress and final reports to the Research and Development Unit within three months after completion of the research
	6. Declarations of conflict of interest regarding the research before each meeting
	7. Report all adverse events and unanticipated problems
	8. Article for publication must submitted to the PHREC before publishing and must acknowledge those involved in the project.

# **Documents that must be submitted to the PHREC**

* 1. All community -based or laboratory-based research proposals that affects the healthcare workers at public health facilities
	2. Research proposal that recruit patient or staff from public health facilities as well as community healthcare workers, and students within the department to participate in the study.
	3. Health research proposal that do not fall into categories 13.1 to 13.2 and secondary data analysis do not require approval. However, researchers are encouraged to inform and submit their proposal and findings to the Research and Development Directorate.

# **Proposal Approval Process**

* 1. Research that will be conducted at health facilities require gatekeeping permission from the relevant manager (district health manager, CEO or Chairperson for District Health Coordinating Committee).
	2. Clinical trials proposal must be accompanied by an approval letter from the Medicine Control Council and be registered on the National Clinical Trials Register.
	3. Proposals written in other South African official languages must be accompanied by a summary note in English translated copy.
	4. Research from foreign (non-South African) institutions must acquire approval from the National Department of Health in addition to the PHREC.
	5. Ethics approval must be obtained before a study commences, PHREC will not consider proposal/projects for approval if it is apparent that the research has already been conducted.

# **. Review and Distribution**

* 1. The Director for research and Development is the responsible manager for the policy and for ensuring it is reviewed and updated.
	2. This policy will be reviewed after 3 years but before 5 years of the last publication date. If necessary an updated version will be issued, if not a formal cover letter will be issued to supplement the cover of this policy (identifying a revised publication date).
	3. The Director for Policy and Planning will distribute the updated version to:
1. Member of Executive Council for health
2. Head of Department of Health
3. All Chief Directors, Directors, and Deputy Directors (who in turn distribute to their staff as appropriate)
4. The Chairperson(s) of all Hospital Boards and Clinic/Community Health Center Committee

# **Acknowledgements and Sources**

* 1. Health Research Policy in South Africa, 2001.
	2. National Health Act 61 (63) of 2003 as amended.
	3. Department of Health Ethics in health Research: Principles, Structures, and Processes, 2004p .59. Department of Health
	4. The National Department of Health, Ethics in Health Research Principles, Processes and Structures 2015.
	5. Northern Cape Provincial Health Research and Ethics Committee (PHREC). Guideline for Approval of Health Research in the Northern Cape.