health
Department of Health
NORTHERN CAPE

Policy on Conducting Health Research

Version control

Version:	V01
Publishing Date:	March 2014
Review Date:	After 3 Years but no later than 5 Years from the Publishing Date
Responsible Manager:	Director for Research and Development
Approved by the Head of Department:	Date: 25/03/2014

Ms GE Matlaopane

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Policy Aim

1. This policy aims to provide a standard framework for support and guidance for conducting health research[1] projects within the Northern Cape Province to respond to the critical health challenges of the Province and ensure that research is conducted in accordance with ethical standards of clinical trials and non-clinical research activities.

Policy Scope

2. This policy applies to all staff of the Northern Cape Department of Health as well as registered students at universities, researchers or stakeholders of the department seeking to undertake health related research involving research participants such as patients, staff of the department, community health workers and/or other resources in the Northern Cape Province.

Policy Statement

3. It is the policy of the Northern Cape Department of Health:

3.1. To provide a framework that applies for all health related researches within the Northern Cape Province involving health staff, patients or resources of the department.

3.2. To establish rational, transparent, and collective decision-making processes around the proposed health related researches within the Province.

3.3. To protect the welfare and rights of research participants through ensuring ethical considerations on all research activities.

3.4. To align the proposed research activities to the Provincial research priority areas.

3.5. To ensure effective communication (internally and externally) about the principles and policies on which the research activities in the Province are founded.

[1] The National Health Act 61 of 2003 defines Health research as any research which contributes to knowledge of the biological, clinical, psychological or social processes on human beings; improved methods for the provision of health services; human pathology; the causes of disease; the effects of the environment on the human body; the development or new application of pharmaceuticals, medicines and related substances; the development of new applications for health technology

3.6. To co-ordinate, grant, assist and monitor all health research projects by implementing policy on conducting health research and the Standard Operating Procedures.

3.7. To ensure that services are not overburdened by researches and to avoid an overlap.

3.8. To ensure that research findings are made available or disseminated to the appropriate audience and officials for planning and monitoring purposes.

3.9. To efficiently utilise research funds within the province.

3.10. To develop research database that is accessible to researchers and to share information that are public good.

3.11. **A research proposal may be denied approval if:**

3.11.1. The proposed research is a duplication which burdens health facilities and increases their workload.

3.11.2. Proposed facilities are unable to accommodate the researcher.

3.11.3. There is only partial submission of required documents.

3.11.4. There are issues that may negatively impact in health facilities and patients.

3.11.5. Researchers do not have the appropriate skills to complete the research.

Roles and Responsibilities

4. The roles of the Accounting Officer or his/her delegate is responsible:

4.1. To establishing a Provincial Health Research and Ethics Committee (PHREC) in accordance with the Health Research Policy, 2001, of the National Department of Health.

4.2. To put systems in place for the smooth functioning of the Provincial Health Research and Ethics Committee.

5. The roles of the Research and Development Directorate:

5.1. Provide support including training for provincial research and ethics committee activities.

5.2. Design and develop the standard format which will serve as a guide for approval of research proposals.

5.3. Ensure that all health related research activities within the Northern Cape Province are conducted in full compliance with all applicable legislation, ethical standards, guidelines, regulations and policies.

5.4. Support and collaborate with research stakeholders to increase, manage and structure the external and internal funding for research.

5.5. Chair the PHREC and set the agenda for the committee meeting.

5.6. Engage with respective manager(s) to acquire their permission before approval of research proposals within their sphere of influence.

5.7. Implement decision of actions made by PHREC.

5.8. Create an enabling environment and maintain and enhance the quality of research undertaken within the province.

5.9. Develop research database for information communication and dissemination.

6. The roles of the Provincial Health Research and Ethics Committee (PHREC)

6.1. Support and advise the actions of the Research and Development Directorate in identifying health research priorities within the province.

6.2. Critically review and assess research proposals to be conducted within the province for approval or rejection based on the pre-determined criteria.

6.3. Make recommendations to the Accounting Officer and Member of the Executive Council on research projects that are not adhering to the Research Policy and standards of the Provincial and National Department of Health.

6.4. Liaise with stakeholders, especially with research institutions, to initiate research proposals, mobilise resources for research undertaking, and support in the translation of research findings in policy development and delivery of services in the Province.

6.5. Ensure that research findings are used to inform policy and resource decision making authorities to benefit health service delivery and population health outcomes.

6.6. Conduct the provincial health research priority identification process every three (3) years.

6.7. Review and approve budget and research proposals to be undertaken by staff that involves the Department's resources.

6.8. **The following proposals must be submitted to the PHREC:**

6.8.1. All health research proposals (clinical and non-clinical) to be conducted within the Northern Cape Province at public health facilities.

6.8.2. All community-based or laboratory-based research proposal that affects the health care workers at public health facilities.

6.8.3. Research proposal that recruits patient or staff from public health facilities as well as community healthcare workers to participate in the study.

6.8.4. Health research proposals that do not fall into the categories 3.11.1 to 3.11.3 and secondary data analysis do not require approval. However, researchers are encouraged to inform and submit their proposals and findings to the Research and Development Directorate.

7. The roles of the Researcher

7.1. Submit proposal with all required documentation[2] to the Research and Development Directorate.

7.2. Have the appropriate skills and ability to complete research.

7.3. Submit final reports to the Research and Development Directorate within three months after completion of the study.

7.4. **The approval process is as follows:**

7.4.1. Research that will be conducted at a Tertiary institution, specialised hospital and district hospital requires approval from the relevant institution manager.

7.4.2. Clinical trials proposal must be accompanied by an approval letter from the Medicine Control Council and be registered on the National Clinical Trials Register.

7.4.3. Proposals written in other South African official languages must be accompanied by a summary note in English.

7.4.4. Research from foreign (non-South Africans) institutions must acquire approval from the National Department of Health in addition to the PHREC.

7.4.5. Published work must include all acknowledgements of those involved in the project including the relevant government stakeholders.

[2] These include approval letter form the accredited Ethics Committee, consent form, questionnaire and qualifications of the principal researcher

7.4.6. Researchers must submit final reports to the Research and Development Directorate within three months after completion of the study.

Review and Distribution

8. The Director for Research and Development is the responsible manager for this policy and for ensuring it is reviewed and updated.

9. 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).

10. The Director for Policy & Planning will distribute updated versions to:

10.1. Member of the Executive Council for Health

10.2. Head of Department of Health

10.3. All Chief Directors, Directors and Deputy Directors (who will in turn distribute to their staff as appropriate.)

10.4. The Chairperson(s) of all Hospital Boards and Clinic/Community Health Centre Committees.

Acknowledgements and Sources

11. Health Research Policy in South Africa, 2001

12. National Health Act 61 (63) 0f 2003 as amended.

13. Department of Health. Ethics in Health Research: Principles, Structures, and Processes, 2004 p.59. Department of Health

14. Northern Cape Research and Ethics Committee. Guidelines for Approval of Health Research in the Northern Cape