health
MPUMALANGA PROVINCE
REPUBLIC OF SOUTH AFRICA

Mpumalanga Provincial Health Research and Ethics Policy

REF: P/01/07/2023: Research

MPUMALANGA
THE PLACE OF THE RISING SUN

Table of Contents

1. Abbreviations

- **HSRC:** Human Sciences Research Council
- **KIM:** Knowledge and Information Management
- **MPHREC:** Mpumalanga Provincial Health Research and Ethics Committee
- **NDP:** National Development Plan
- **NRDS:** National Research & Development Strategy
- **PHRC:** Provincial Health Research Committee
- **R&D:** Research and Development
- **NRDS:** National Research & Development Strategy 2002
- **REC:** Research and Ethics Committee
- **SA:** South Africa
- **STATSSA:** Statistics South Africa

2. Introduction

Research and the evidence that research yields are critical elements for improving health. Co-ordination and management of research in health should be done in a systematic and comprehensive manner. It is very essential that efforts to improve health should be based on evidence based information. Research for health is the generation of new knowledge using scientific methods to assess the impact on health of policies, programmes, processes, actions or events. Health research systems are vital for research generation, dissemination and utilization in addressing the health needs of the population. Thus urges governments to develop and implement policies on research and innovation for health.

Policy making, strategic planning, interventions and monitoring progress are reliant on research output. Department of Health is still faced with insufficient baseline information or research evidence to support policy formulation and strategic planning. Government needs accurate and reliable evidence derived from research for planning purposes. Research is likely to be most productive when it is conducted within a supportive Research System established in the Province. In this context a policy for research is being drafted to build research capacities and establish co-ordination mechanisms for Mpumalanga Department of Health.

The approval of an Independent Research Ethics Committee (REC) is a requirement for all clinical and public health research studies in human subjects, especially if research findings are to be shared with a broader audience through publication in an academic journal. A REC is responsible for safeguarding the rights, safety and well-being of all study subjects. Following approval, the investigator must advise RECs of any new information or changes to the study procedures that may affect the conduct of the study and/or increase the risks of study subjects.

3. Background

South Africa has its own trail of health research policy and strategy. Immediately after its first democratic election of 1994, the country adopted the 1997 White Paper for the Transformation of the Health System in South Africa. The White Paper emphasises the importance of evidence-based knowledge for health research, which must be integrated into planning, policy development, and health programmes' management and implementation.

In 2018, the National Health Research Committee (NHRC) developed a draft health research policy in South Africa, which replaced the 2001 health research policy. A significant development in the policy includes its realignment with both the global and local socio-economic contexts to effectively and proactively address the social determinants of health by drawing on various sectors. The policy seeks to promote both national and international research capable of producing high-quality research evidence and tools for improving the healthcare outcomes of South Africans. Moreover, the policy on research for health in South Africa is accompanied by the National Health Research Strategy, which clearly outlines how the policy should be implemented, targets, timelines and main interventions, resource requirements, budgets, monitoring and evaluation, and responsible organs/individuals who must ensure the policy is implemented. Importantly for South Africa, the National Development Plan is critical of the higher education sector for its poor knowledge production that fails to translate into innovation.

Consequently, all provincial government departments and municipalities are expected to have in place a policy and research components to identify and set research goals and statistical demands; develop institutional research agenda in line with national, provincial and department's goals and priorities, and commission research to support evidence based policy making, planning and allocation of resources for developmental programmes and projects in their respective institutions.

Evidence based decision making in the development of policies, planning, budgeting etc. has valuable benefits such as:

- **Effectiveness**– ensuring that interventions achieve more good than harm;
- **Efficiency**- usage of scarce resources to maximum effect;
- **Service orientation**– ensuring that interventions address the felt needs and expectations of citizens;
- **Adaptability** - knowing when a policy/ intervention is not working as planned and when changes to policy/ intervention or its implementation are due; and
- **Accountability, trust and democracy**– ensuring that what is being done and why is transparent and thereby build trust in the beneficiaries and democratic processes.

Furthermore, the National Health Act (NHA s73(1)) indicates that it is a requirement for every organisation/institution, health agency and health establishment at which health and health-related research involving human participants is conducted to establish or have access to a registered Human Research Ethics Committee.

4. Purpose

The purpose of the policy is to regulate the research environment that sets standards for improved research conditions in the Province and achieve development outcomes of the population.

5. Objectives

- To advance the priorities of the Provincial Department of Health through research;
- Produce evidence based information to assist the Provincial Government in its service delivery mandate;
- To facilitate the creation of knowledge, promote credibility of data collected, and benchmark against best practices;
- To make use of intellectual capacity of tertiary institutions in achieving the socio-economic development of the Province;
- To improve population development outcomes in the Province;
- To ensure that research conducted meets the accepted ethical norms and scientific standards.

6. Definitions of Terms

- **Provincial Research Forum** is a structure comprising of provincial departments, national research institutions and tertiary institutions operating in the province. They oversee the conduct of Research and ethics in the province;
- **Provincial Health Research Committee** is a structure comprising of provincial departments, research institutions/tertiary institutions, and a community based structure operating in the province with the primary purpose of managing, coordinating and supporting research in the Province;

- **Research and Ethics Committee** a multidisciplinary committee that deals with research management issues by ensuring the implementation of the research policy and strategy as well as monitoring compliance with research protocols and Standard Operating Procedures;

- **Research Information Management System** is a system designed to manage research information also known as Knowledge and Information Management (KIM);

- **Monitoring and Evaluation** in this policy refers to the Monitoring Evaluation and Reporting Plan (MERP) of the Provincial Health Research Policy implementation;

- **Repository for Strategic Information** in this instance is a warehouse for strategic information collected for decision making.

7. Legislative Framework

7.1. 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.

7.2. 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.

7.3. 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:

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

- 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;

- 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.

7.4. Helsinki Declaration

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

7.5. Ten Year Innovation Plan 2008

The Department of Science and Technology accelerates the country's transformation towards a knowledge based economy in which the production and dissemination of knowledge leads to economic benefits and enriches human endeavor. The Plan is a high level presentation of key challenges identified by the Department of Science and Technology starting from where South Africa (SA) should be in 2018. It articulates a national path of innovation building on the National System of Innovation in support of transformation to knowledge based economy.

7.6. 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.

7.7. 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.

7.8. 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.

7.9. 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.

7.10. 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.

7.11. The National Health Act (NHAs 72(6)(c))

The Act gives authority to the National Health Research Ethics Committee (NHREC) for setting norms and standards for health and health-related research that involves humans. Every organisation/institution, health agency and health establishment at which health and health-related research involving human participants is conducted, must establish or have access to a registered Human Research Ethics Committee (REC) (NHA s 73(1)). The Research Ethics Committee (REC) that review research involving human participants must register with the NHREC (NHA s 73(1)).

8. Guiding Principles

- The Provincial Department manages the approval process of research studies through the national online research website (nhrd.health.gov.za);
- All research studies must be uploaded on the online website with complete documents (detailed proposal and ethics certificate) before are reviewed and approved by the Provincial Health Research Committee;
- A support letter signed by a relevant manager at institutions must form part of required documents before a study is approved;
- Internal studies designed for improving service delivery (Service Delivery Improvement Plans - SDIPs), which do not have ethics approval must be reviewed by the PHRC and submitted to Head of Department for approval on recommendation by the Chairperson/delegated member of the PHRC (See attached Annexure);
- The pursuit of knowledge should not be regarded as the supreme goal of an individual and for personal gain;
- The researcher must respect and protect the autonomy and welfare of all participants, and must therefore obtain the informed consent of the participants;
- Content and language should be clear and understood by the intended audience;
- Researchers must uphold honesty, integrity and accountability in their work;

- Researchers should conduct research, if applicable, in accordance with the professional code of the association of which they are members;

- Researchers should at all times strive to achieve the highest possible level of scientific quality in their research.

9. Research Standards

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

- 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;

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

- 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;

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

- 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;

- 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;

- 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.

10. Roles of the Provincial Health Research Committee

The Provincial Health Research Committee shall:

- Shall manage the National Health Research Database;
- Standardize provincial research approach to improve quality of research outputs (template for research proposal/ Approval Criteria etc.);
- Evaluate the scientific excellence of research projects conducted in the province;
- Give advice and technical support on proposal development and review;

- Lobby for and give advice on funding for research and recommend budget allocations for specific projects;
- Develop operation plan to access provincial budget to fund the activities in the committee;
- Support coordination of health research by liaising with all research stakeholders conducting research within province;
- Manage the process of priority setting and assist in the development of health research priorities and research agenda in the province;
- Promote the use of health research in policy development and service provision at all levels of the health care system, and in particular at district level;
- Promote and encourage commissioning of health research which is essential and relevant for communities within the province;
- Review protocols, preliminary and final research reports submitted to the Provincial Health Department;
- Support the Provincial Health Department's research activities including training, conferences and research conducted in provincial health facilities;
- Participate and contribute to the activities of provincial research forum in the office of the Premier;
- Participate in activities of the national research committee and national research ethics committee as needed;
- Facilitate the establishment of a Provincial Health Research and Ethics Committee.

11. Roles of the Mpumalanga Provincial Health Research and Ethics Committee

- Give advice and technical support on research proposal development;
- Classify research proposal as either:
    - 1.1.1 No risk proposals,
    - 1.1.2 Low risk proposals,
    - 1.1.3 Medium risk proposals, or
    - 1.1.4 High risk proposals.
- Review minimal, low or medium risk research proposals received that involve human participants;
- Approve, reject, and require amendments to a research proposal on ethical and criteria approval grounds;
- Formulate own procedures for dealing with expedited research applications;
- Enforce ethical considerations on all research activities within the Province in accordance with ethical standards of clinical trials and non-clinical research activities;
- Ensuring that informed consent is obtained;
- Manage the process of priority setting and assist in the development of health research priorities and research agenda in the province;
- Promote the use of health research in healthcare practice and policy development at all levels of the health care system;
- 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;

- Conduct random monitoring of research projects conducted within the Province;
- Audit the activities of research projects to ensure their compliance with research ethics;
- 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;
- Adheres to the SOP and Terms of Reference for the Mpumalanga Provincial Department of Health Research and Ethics Committee.

12. Feedback and Best Practices

Good practices should be shared provincially and nationally through:

- Workshops, seminars and conferences;
- Promotion on local, district and provincial web page;
- Publications;
- Research Information Management System /KIM;
- Promotion of the Implementation of Research Findings.

13. Quality Assurance Mechanisms

The function of quality assurance will initially be performed by the Provincial Health Research Committees. For advanced research and publication purposes external Peer Reviews will be engaged. Provincial researchers will be encouraged to publish in peer reviewed journals and seek ratings by external agencies.

Partnerships with accredited/reputable research institutions like Universities, STATSSA, HSRC, NRF, will assist in improving the quality of research conducted.

14. Management of Research outputs

Approved research reports will be kept by the department and an electronic version will be stored in the Department's Repository for Strategic Information. All Departments and Municipalities will have access to the Repository.

15. Policy Monitoring and Evaluation

Both the PHRC, MPHREC and the Sub-Directorate: Research and Epidemiology will be responsible for facilitating the implementation of this policy and for monitoring compliance.

16. 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.

17. Approval of the Policy

APPROVED/ NOT APPROVED

DR LK NDHLOVU
HEAD: HEALTH

6/7/2023
DATE

Effective date: 10/07/2023