KWAZULU-NATAL PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

KWAZULU-NATAL DEPARTMENT OF HEALTH PROVINCIAL HEALTH RESEARCH AND ETHICS COMMITTEE (PHREC)

TERMS OF REFERENCE

2025

HEALTH SERVICE DELIVERY PLANNING, MONITORING & EVALUATION

HEALTH RESEARCH & KNOWLEDGE MANAGEMENT

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ACRONYMS AND ABBREVIATIONS

AIDS	Acquired Immune Deficiency Syndrome
DOH	Department of Health
HIV	Human Immunodeficiency Virus
HOD	Head of Department
HRKM	Health Research & Knowledge Management
IP	Intellectual Property
KZN	KwaZulu-Natal
NDOH	National Department of Health
NHRC	National Health Research Committee
NHREC	National Health Research Ethics Council
NHRD	National Health Research Database
PDOH	Provincial Department of Health
PHRC	Provincial Health Research Committee
PHREC	Provincial Health Research and Ethics Committee
PI	Principal Investigator
RECs	Research Ethics Committees
SA	South Africa
TB	Tuberculosis

PREFACE

Research is a strategic tool that has revolutionised public health by using the knowledge generated to improve the health of populations. Research also has important implications for service delivery since it forms the foundation of policy and programme development. Over the past two decades, and accelerated by diseases such as TB, HIV and AIDS, health research in South Africa has been strengthened and the importance of research has been recognised across many sectors. However, the oversight of such research has not kept pace with the volume and diversity of research conducted in the country. It is critical that national and provincial departments of health maintain the oversight of human participant health research for two reasons. Firstly, as stewards of the health of the public, health departments must ensure that patients, participants, and volunteers are protected from the potential adverse effects of research, which may be physical, psychological or social. Vigilant oversight of the ethics of research is fundamental to protecting human participants, as well as to the maintenance of a just and transparent society.

Secondly, as potential users of the results of health research, health departments must remain informed of all relevant research findings that may impact on health or on service delivery. Research is only beneficial when its results are beneficial and utilised; health departments therefore have an obligation to engage with researchers at all levels and at all stages of the research process. Initially, engagement may be in the form of guiding research into areas of local importance. Later, engagement should be in the form of assimilating and acting on the results of research, where it is of benefit to communities. Such engagement with researchers should be reciprocal and collegial, to ensure that the potential benefits of research are maximised and reach the intended populations.

LEGISLATIVE BACKGROUND

The South African National Health Research Policy (2001) (https://www.gov.za/sites/default/files/gcis_document/201409/healthresearch0.pdf) came into effect in order to promote the ethical practice and conduct of research that contributes towards the improvement of the health and welfare of the South African population.

Building on this policy, the National Health Act, 2003 (Act No. 61 of 2003) (https://www.gov.za/sites/default/files/gcis_document/201409/a61-03.pdf) as amended, established statutory bodies to coordinate and regulate research. The National Health Act (2003) established the National Health Research Committee (NHRC), whose function would be to coordinate health research, manage the process of priority setting in the country and give advice on the policy implications of research.

In 2009, by means of the KwaZulu-Natal Health Act, the Provincial Health Research and Ethics Committee (PHREC) was established. These Terms of Reference are developed to guide the structure and functioning of the Provincial Health Research and Ethics Committee in KwaZulu-Natal (KZN). This policy should be read and effected in conjunction with the KwaZulu-Natal Health Act (Act No. 1 of 2009) (https://www2.kznhealth.gov.za/legislation/kznhealthact.pdf).

'South African Ethics in Health Research: Principles, Processes and Structures', 3rd edition (NDOH 2024) (https://www.health.gov.za/wp-content/uploads/2024/05/NDoH-2024-Health-Research-Guidelines-3rdEdition-v0.1.pdf), which replaced the second (2015) edition, is a national guide to ensure that research is conducted in accordance with the highest ethical norms and standards for conducting research responsibly and ethically.

1. PURPOSE, GOALS AND OBJECTIVES

1.1. Purpose

The purpose of the Terms of Reference of the PHREC is to provide an enabling framework for the co-ordination of research that contributes to optimal health for all persons in KwaZulu-Natal in line with the Mission and Vision of the Provincial Department of Health (PDoH) (https://www.kznhealth.gov.za/vision-and-mission/)

1.2. Goals

1.2.1. To co-ordinate health research involving human participants which are conducted at provincial health facilities.

1.2.2. To promote adherence to ethics in all health research involving human participants taking place at provincial health facilities.

1.2.3. To align provincial health research with the priorities and strategic goals of the provincial and national health departments, and provincial health needs.

1.2.4. To promote the use of scientific evidence for decision making in the KZN Department of Health.

1.2.5. To ensure that scientists consider communities benefit and gain access to effective interventions.

1.3. Objectives

1.3.1. To put into effect a research approval process that promotes adherence to high scientific and ethical standards and in line with national and international guidelines.

1.3.2. To set provincial research priorities through a consultative process with stakeholders.

1.3.3. To ensure linkages between Provincial and National research priorities.

1.3.4. To develop a communication strategy that enables the dissemination of research findings in the KZN Department of Health.

1.3.5. To establish collaborative relationships with Provincial, National and International researchers, research institutions, funders and users in the public and private sector that may include access to interventions, local intellectual property (IP), and local skills to manufacture or produce biomedical interventions.

2. INSTITUTIONAL FRAMEWORK

2.1. Provincial Health Research and Ethics Committee (PHREC)

The Provincial Health Research and Ethics Committee (PHREC) is established in terms of the KwaZulu-Natal Health Act (Act No. 1 of 2009) and its Regulations.

The Provincial Health Research and Ethics Committee is guided by the following principles:

2.1.1. Inclusive representation of members of the broad community of KZN, including the research community.

2.1.2. Research stewardship based on high ethical standards, and on national and provincial health priorities.

2.1.3. Promotion of and influence on the research agenda and implementation of outcomes within the province.

2.2. Composition of the Provincial Health Research and Ethics Committee

The composition of the Provincial Health Research and Ethics Committee is as prescribed by the KwaZulu-Natal Health Act (Act No. 1 of 2009) (below), and the Guidelines of the National Health Research Ethics Council. It will include:

2.2.1. The Head of Department (HoD) or his or her nominee as chairperson.

2.2.2. Two officials from the Department designated by the Head of Department.

2.2.3. Three representatives from registered tertiary educational institutions which have been accredited to provide health care training within the province.

2.2.4. A representative from the private health sector in the province.

2.2.5. A representative from organized local government in the province.

2.2.6. A representative from each health research ethics committee registered with the National Health Research Ethics Council as contemplated in section 73 of the National Health Act (https://www.health.gov.za/wp-content/uploads/2024/11/Human-Research-Ethics-Committees-registered-with-the-NHREC.pdf) in the province.

2.2.7. Two medical practitioners employed at public health care establishments within the province who are specialists in a particular medical field.

2.2.8. A representative of traditional health practitioners in the province and

2.2.9. Any other representative which the responsible Member of the Executive Council may deem necessary.

The term of office for members of the Provincial Health Research and Ethics Committee is five (5) years.

2.3. Functions of the Provincial Health Research and Ethics Committee:

The Health Research Policy in South Africa (2001) identified Provincial Health Research Committees (PHRCs) as important mechanisms for coordinating health research and facilitating efficient use of limited research resources. PHRCs were established to liaise with researchers to ensure that the greatest health needs of each province are being addressed. The function of PHRCs is assisted by the National Health Research Database (NHRD) system (https://nhrd.health.gov.za/). The focus of PHRCs is also to monitor the effect of research activities on services. Hence, they perform a gate-keeping role by managing access to health facilities.

The KwaZulu-Natal Provincial Health Research and Ethics Committee is responsible for the co-ordination and oversight of all health research involving human participants which are being conducted at provincial health facilities.

The Provincial Health Research and Ethics Committee may amend these Terms of Reference when deemed necessary by a simple majority of its members and with the endorsement of the Chairperson and may formulate other policies or guidelines to guide its relationships with stakeholders nationally and provincially, and to guide the conduct of research in the Province.

2.3.1. Ethics Functions:

The Provincial Health Research and Ethics Committee must:

2.3.1.1. Approve only that research which has been given final ethics approval by an ethics committee accredited by the National Health Research Ethics Council (NHREC) of South Africa (https://www.health.gov.za/wp-content/uploads/2024/11/Human-Research-Ethics-Committees-registered-with-the-NHREC.pdf).

2.3.1.2. With the support of facility/district and/or programme managers (as appropriate), provide site access to provincial health facilities for research purposes.

2.3.1.3. Provide an oversight role on health research conducted in provincial health facilities according to this Research Policy and the standards of the Provincial and National Departments of Health and the Guidelines of the National Health Research Ethics Council.

2.3.2. Research Functions:

2.3.2.1. Manage the process of priority setting and assist in the development of health research priorities in the province in accordance with the National Health Research Policy (2001) and in line with provincial health needs.

2.3.2.2. Provide advice on health-research related issues to Senior Management and departmental components in the provincial Department of Health, and to national bodies and other stakeholders where necessary.

2.3.2.3. With the support of the Secretariat, ensure that these Terms of Reference is implemented in a co-ordinated manner.

2.4 Meetings of the Provincial Health Research and Ethics Committee

2.4.1. The Provincial Health Research and Ethics Committee should meet at least annually, as prescribed by the KwaZulu-Natal Health Act (2009).

2.4.2. The quorum for a meeting shall be one half of total members plus one, as prescribed by the Regulations to the KwaZulu-Natal Health Act (2009).

2.4.3. Should a meeting of the Committee not be quorate, decisions made during the meeting should be circulated by email to all members. Members will have 45 calendar days to respond to the email to communicate their views. If no response is received after 45 calendar days, it will be assumed that members are happy with the decision(s), and it/they will be implemented.

2.4.4. For decisions that need to be taken by the Committee in the absence of a meeting, the same process will be followed as in point 2.4.3 above.

2.5. Professional Secretariat of the Provincial Health Research and Ethics Committee

The Health Research and Knowledge Management (HRKM) Component of the KwaZulu-Natal Provincial Department of Health provides the secretariat to the Provincial Health Research and Ethics Committee. Its functions are to assist the Chairperson in the following:

2.5.1. Issue invitations to the Committee members to attend meetings in a period not less than two weeks before the meeting.

2.5.2. Ensure that members inform the Chairperson in not less than five (5) days from notification of the meeting if they are unable to attend.

2.5.3. Record minutes of scheduled meetings and disseminate these to all members of the Provincial Health Research and Ethics Committee.

2.5.4. Ensure that final research reports are disseminated to the relevant managers within the KZN Department of Health within one month of receipt of the report.

2.5.5. Provide regular reports to the Committee on research applications that have been submitted on the NHRD, and the outcomes of these submissions, amongst others.

2.5.6. Provide research oversight services to public health facilities, to ensure that research does not undermine service delivery and to facilitate the collaboration between researchers and the Department of Health, where deemed necessary by the Committee and depending on budgetary and other resource constraints.

2.5.7. Examine findings and recommendations from completed health research studies, with a view to identifying new developments that may impact on health and service delivery and communicate these to relevant managers within the KZN Department of Health.

2.5.8. Maintain and update research applications submitted on the National Health Research Database (NHRD) and circulate reports emanating from ongoing and completed research projects.

2.5.9. Produce a report based on the number research applications received, outcomes of submissions, and progress/completed research study reports received, on a quarterly basis.

3. PRIORITY SETTING FOR HEALTH RESEARCH IN KWAZULU-NATAL

The purpose of priority setting in health research serves to ensure that research conducted in the province is relevant to and addresses the health needs of the province.

The Provincial Health Research and Ethics Committee must lead the research priority setting process in line with the National and Provincial Health Departments' strategic goals and priorities.

The priority setting process should:

3.1. Include all relevant stakeholders, namely, researchers, the community, policymakers, academics, funders of health research and key officials of the Public Service.

3.2. Be a consultative, iterative and equitable process.

3.3. Be conducted at least every five years (5) years.

3.4. Be informed by a situational analysis of the burden of disease.

3.5. Be formally adopted by the Department and thus guide the provincial health research agenda.

3.6. Contribute to the national priority setting agenda.

4. FINANCING HEALTH RESEARCH

The KwaZulu-Natal Department of Health encourages sound scientific and ethical research. The Provincial Health Research and Ethics Committee may support requests to funders of research for projects that are in line with the provincial research priorities.

5. COMMUNICATION AND PUBLICATION OF HEALTH RESEARCH

Sharing of information should be encouraged within the province, with due regard to protecting intellectual property. With the support of the secretariat, the Provincial Health Research and Ethics Committee must ensure that researchers:

5.1. Disseminate their findings to the facilities, districts and communities where their research was undertaken.

5.2. Share their findings with relevant Programme Managers within the KZN Department of Health.

5.3. Collaborate with PDOH and employees at local health institutions on research.

5.4. Are encouraged to publish their research findings in peer reviewed journals and use social media platforms for the benefit of stakeholders to access results in the appropriate language.

5.5. Disseminate their findings on the Department's webpage, with the permission of the principal investigator (PI).

6. CONCLUSIONS

The Terms of Reference of the Provincial Health Research and Ethics Committee provides an enabling framework for health research involving human participants that are being conducted at public health facilities in KwaZulu-Natal. The intend to ensure that such research is managed and coordinated efficiently and according to high ethical and regulatory standards.