

**GUIDELINES:**

**SUBMISSION OF A RESEARCH PROPOSAL**

**TO THE PROVINCIAL HEALTH RESEARCH AND ETHICS COMMITTEE (PHREC)**

**AND THE PROCESS OF ETHICAL REVIEW PROCESS**

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# **INTRODUCTION**

According to the NDoH 2015 Ethics in Health Research Principles, Processes and Structures Guidelines, health research is vital for the advancement of health care services for the people of South Africa. The guidelines define "research involving human participants" as any social science, biomedical, behavioral, or epidemiological activity that entails systematic collection or analysis of data intended to contribute to generalisable knowledge or new knowledge, in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or (ii) become individually identifiable through investigators’ collection, preparation, or use of biological material or medical or other records. Research involving human participants can be conducted in the Northern Cape Province through in person or through an electronic medium (e.g., telephone, computer, E-mail or internet).

In research involving human participants to ensure that South Africa’s people are fairly and respectfully treated by researchers and that all research conducted in the country stands up to ethical scrutiny. To ensure this, the NDoH 2015 Ethics in Health Research Principles, Processes and Structures Guidelines promote the establishment of Research Ethics Committees (REC). The main purpose of this committee is to safeguarding that research is conducted in accordance with the highest ethical norms and standards. Accordingly, all researches /investigations involving human participants must undergo ethical review processes by the REC.

The Northern Cape Department of Health Provincial Health Research Ethics Committee (PHREC) accepts proposals directly from the researchers submitted via its secretariat or from the National Health Research Database (NHRD), where proposals are submitted to the respective REC by the responsible researchers or research institutions. The guidelines provide explanation on the process of ethics review and the expectations from researchers by PHREC on proposals that are intended or involve human participants in their research, or use health care facilities, practitioners, health facility administrators, policy makers in the department, and community representatives.

**SECTION ONE: GATE-KEEPER’S PERMISSION**

**Guidelines for Submitting a Research Proposal to the Northern Cape Department of Health Provincial Health Research and Ethics Committee (PHREC) for**

**Gate-keeper’s Permission**

1. **Guidelines for Submitting a Research Proposal to the Northern Cape Department of Health Provincial Health Research and Ethics Committee (PHREC) for Gate-keeper’s Permission.**
   1. **Provincial Health Research Ethics Committee (PHREC)**

The Provincial Health Research and Ethics Committee (PHREC) was established in 2012 by the accounting officer of the Northern Cape Department of Health, in accordance with the Health Research Policy, 2001, of the National Department of Health [1]. The PHREC has the responsibility, among many others, to critically review and assess research proposals that sought to be conducted within the Northern Cape Province for approval or rejection based on the pre-determined criteria [2].

The Northern Cape Province currently does not have institutions of higher learning or health science or research institution that has the Research Ethics Committee (REC) which is accredited by the National Health Research Ethics Council (NHREC). As a result, the PHREC (which is registered and provisionally accredited by the NHREC, HREC registration number REC-120515-046;) has the dual responsibility of reviewing proposal submitted to the Northern Cape Department of Health, for: -

1. ***Gate-keeper’s permission, and***
2. ***Ethical clearance*** 
   1. **Application for Gate-keeper’s Permission**

The PHREC uses the electronic system, called the National Health Research Database (NHRD), to manage and review research proposal for gate-keeper’s permission. The NHRD was commissioned for establishment in 2014 by National Department of Health, and this system has been functional in Northern Cape Province since 2015. This system serves as a repository of all health related research which has been and is currently being conducted in South Africa. The main use of the NHRD is to monitor and manage health research for the National Health Research Committee (NHRC), and the nine Provincial Health Research Committees (PHRC’s). However, researchers can also use this system to apply for gate-keeper’s permission to various PHRC’s [3]. The type of research in terms of its level of risk, complexity, size and/or type of the physical or social structure often influence the complexity of the approval process and the participant recruitment procedures.

* 1. **Gate-Keeper’s Permission Research Proposal Reviewing Process**

Research involves recruiting participants within the province may include:

* Staff (employees) of the department
* Patients in the facility
* Individuals reside within the Province
* Belong to a defined community within the Province (e.g., tribal community, a racial group, members of a religious group, affected communities with certain type of disease)

Research that involves recruitment of participants from physical or social structures must address specific issues such as:

* Gate keeping Permissions at different levels or stages
* Obtaining ethics clearance from at least one Research Ethics Committee(s),

A gatekeeper is someone who controls access to a structure or section of a structure; for example, a district health manager, health facility manager, director of a health program or a committee established to function in line with. The Northern Cape has five districts, each having its independent administration; Kimberley Tertiary Hospital, and West End Specialized Hospital, also both having their own administrations. In each of these five districts, the PHREC has established the District Health Research Coordinating Committees (DHRC) for research coordination on behalf of the Districts. The functions of these committees include among others, reviewing proposals requesting permission to be conducted at that particular district of a facility to provide gate keeping permission. However, some of Health Facilities such Kimberley Hospital, West End Specialized Hospital and others may not have an internal research ethics committee member although gatekeeper permission clearance must be obtained from them. In such cases, the Medical Director is responsible for reviewing proposal requesting permission to be conducted at that facility.

***Please note the following:***

* ***Only research proposal with ethics approval, from an accredited South African Research Ethics Committee (REC), will be considered for gate-keeper’s permission.*** ***Ethics clearance must be obtained before the project can considered.***
* ***Application must be done strictly online, through the National Health Research Database (NHRD)***
  + 1. **Documents Required when Applying for Gate-keeper’s Permission to the PHREC:**

1. Full research proposal
2. Ethical clearance letter (from research ethics committee accredited with the NHREC)
3. Curriculum vitae (PI and Co-investigator if applicable)
4. Information sheet and Consent form (if applicable)
5. Data collection tool
   * 1. **The Applicant**
6. To access the database, please click on this link: <http://nhrd.hst.org.za>
7. Register and log-in
8. Select Northern Cape Province
9. Complete the form and upload all the documents mentioned in 1.2.1, and click submit
10. Automatically the system will send an e-mail to the applicant’s e-mail, that his/her application was successful and also provide the reference number for the study
    * 1. **Administrator**
11. Administrator assigns the application
12. Administrator verifies online application
13. Administrator send hard or electronic copies of the entire proposal to the PHREC chairperson and the DHRC (of the district where the study is going to be conducted), or Medical Director of Kimberley Hospital or Chief Executive officer of West End Specialized Hospital, for review and approval.
    * 1. **Application under Review**
14. During this process the reviewers can/will ask for more information or clarity and raise any concerns to the researcher through the administrator.
15. The reviewers will consider whether or not to approve the proposal based on the following criteria:

* Is the research feasible in facilities selected, within the limitation of space, staff, patients, timing and funds?
* Does the research duplicate or clash with other research in the relevant facilities?
* Does the research have the potential to answer question of answer of interest to the Province (research priority list), and provide outputs that could be implemented by the Province.

1. Reviewers send feedback to the provincial administrator
   * 1. **Decision/Feedback of the Reviewers:**
2. ***Approved***: administrator will prepare the approval letter for signature by the PHREC chairperson, and send the letter to the applicant via the database. The status of the application on the database will change to approved.
3. ***Send/revert back to the researcher for amendment***: the administrator will through the database revert the application back to the applicant to address amendments/ changes requested. E-mail from the administrator will be send to the applicant indicating areas for amendment or change.
4. ***Declined***: the administrator will prepare the letter of decline with reasons for signature by the PHREC chairperson, and the letter will be send through the database to the applicant. Status of the application will change to decline on the database.

***Note: This whole process is expected to take a period of two (4) to three (3) weeks to complete.***

* + 1. **Interim Progress Report and the Final Report**

1. For studies that will be completed within a period not exceeding one year:

* A six-month interim report is required
* A final report is required once the study has been completed

1. For studies that the study period exceeds one year:

* One-year progress report is required
* Researchers must also request extension from the PHREC to continue the study for another
* A final report must be submitted to the Research and Development Directorate using the contact details on annexure A.
  1. **Appeal process**

If the application is declined, the researcher has the right to lodge appeal to the PHREC in writing through the administrator using the contact details in annexure A.

***Structures, gatekeepers and estimated time for approval***

|  |  |  |
| --- | --- | --- |
| Research participants | Suggested gatekeeper(s) for approval | Estimated time for approvals and permissions |
| Health facility patients | DHRC in consultation with doctor, therapist, nurse supervisor, and  possibly, a caregiver or power of attorney | Take 1 or 2 weeks to provide gatekeeper(s) approval |
| Health facility staff | DHRC, in consultation with director or manager of the programme | Take 1 or 2 weeks to provide gatekeeper(s) approval |
| Data | DHRC, in consultation with director or manager of the programme | Take 1 or 2 weeks to provide gatekeeper(s) approval |
| Residents within the Province | DHRC, in consultation with chiefs if there is physical structure | Take 1 or 2 weeks to provide gatekeeper(s) approval |

**SECTION TWO: PROPOSAL FOR ETHICAL CLERANCE**

**Guidelines for Submitting a Research Proposal to the Northern Cape Department of Health Provincial Health Research and Ethics Committee (PHREC) for Ethics Clearance**

1. **Provincial Health Research and Ethics Committee (PHREC) Ethics Review Processes.**

Some research protocols may not have an ethical clearance while submitting to the Provincial Health Research Ethics Committee for consideration. In such instances, it is advisable to obtain ethics clearance from the Northern Cape PHREC. The Provincial Health Research Ethics Committee will review and determines whether the research can be ethically approved through considering its scientific integrity, ethical soundness and the take place in line within the existing ethical guidelines. The PHREC is provisionally registered with the NHREC, registration number: REC-120515-046, and it reviews research proposal for ethical clearance. The PHREC review all kind of research proposals except proposals that are regarded as high risk research proposals such as:

* Research studies involving children and need ministerial consent
* Clinical trial research studies

Subsequent to the ethical approval, gatekeeping approval must be obtained via the Provincial Health Research and Ethical Committee secretaries before recruitment of participants can begin. District Health Research Coordinating Committee, Facility manager or a medical director may provide guidance and/or endorsement for conducting the research within the facility and may provide input to the research participant’s recruitment process.

* 1. **Documents Required when Applying for Ethical Clearance to the PHREC**

1. Completed PHREC Research Ethics application form
2. Full research proposal
3. Participants information sheet
4. Participants consent form (if applicable)
5. Curriculum vitae (PI and Co-investigator if applicable)
6. Data collection tool(s)
   1. **Logistics for Submission of the Research Proposal**

The application must be submitted to the PHREC ***six weeks*** before the meeting (see dates for the meeting in annexure B), through the Research and Development Directorate. Application can be done via postal services, e-mail or hand delivered to the Research and Development Directorate (see detailed addresses in annexure A).

* 1. **PHREC Ethics Review Process**

1. Once the application has been received, the research secretariat will assign a reference number to that application.
2. The research secretariat will send an e-mail to the applicant as acknowledgement of the receipt of his/her application, and study the study provide the reference number, and also indicate on when the PHREC will convene for a meeting to review all received proposals.
3. The secretariat assesses and verify if all the required documents are included

During the meeting, the PHREC will thoroughly review each proposal and take one of the following decision:

1. ***Approved:*** the secretariat will prepare the approval letter for signature by the PHREC chairperson, and send it to the applicant via e-mail.
2. ***Revert back for changes***: the secretariat will prepare the letter, indicating points/areas for changes/amendment for signature by the PHREC chairperson, and send it to the applicant via e-mail.
3. ***Declined:*** the secretariat will prepare the letter with reasons for signature by the PHREC chairperson, and send it to the applicant.

***Note: This process takes a period of three months, as the committee’s meetings are held only once every quarter.***

* 1. **Interim Progress Report and the Final Report**

1. For studies that will be completed within a period not exceeding one year:

* A six-month interim report is required
* A final report is required once the study has been completed

1. For studies that the study period exceeds one year:

* One-year progress report is required
* Researchers must also request extension from the PHREC to continue the study for another

***At the completion of the study, a final report must be submitted to the Research and Development Directorate (details in annexure A).***

* 1. **Appeal Processes**

If the application is declined, the researcher has the right to lodge appeal to the PHREC in writing through the secretariat, using the contact details in annexure A.

# **ANNEXTURE A**

***E-mail of the research coordinator***

[BMashute@ncpg.gov.za](mailto:BMashute@ncpg.gov.za)

***Postal address:***

Northern Cape Department of Health

Research and Development Directorate

Private Bag X 5049

Kimberley 8300

***Physical address:***

144 Du Toit Span Road

Executive Offices

Kimberley Hospital Complex

HOD’s Office, Room 7

Belgravia, Kimberley

8301

# **ANNEXTURE B**

**Dates of the PHREC meeting in 2018**

|  |  |
| --- | --- |
|  | **Tentative Dates** |
| Quarter 1 | 06 June 2018 |
| Quarter 2 | 15 August 2018 |
| Quarter 3 | 14 November 2018 |
| Quarter 4 | 06 February 2019 |

# **ANNEXURE C**

**The research proposal must include the following sub-sections to ensure expedient processing and approval:**

**Title and Authors:**

Title, name and qualifications of the researcher(s), as well as the name and address of the institutions or organization that is represented. Telephonic, fax and e-mail contact details of the Principal Investigator (PI) must also be included.

**Summary or Abstract**

A brief summary or abstract outlining the aim and objectives of the study, research methodology and data analysis.

**Introduction**

Summary of literature relevant to the proposed research problem/problem statement

**Motivation**

Outline the relevance and benefits of the proposed research study on Public Health

**Aims or Purpose**

The aim or purpose must be clear and feasible

**Objectives**

Objectives must be specific, achievable, realistic and time-bound and clearly describe the specific deliverables of the proposed study.

**Research Area**

Classify the research area e.g. child health, clinical, communicable disease, dental health, geriatrics, health systems, HIV and Aids, injury/trauma, mental health, non-communicable disease, nutrition, public health, quality of care, sexually transmitted diseases (other than HIV and Aids), tuberculosis and women’s health.

**Research Methods**

**Study Design**

Specify the study design e.g. case control, case series, cohort, cross-sectional, descriptive, exploratory, longitudinal, meta-analysis, observational, quasi-experimental, randomized control trial intervention, retrospective, systematic review, etc.

**Study Population**

Clearly describe the study population that will be sampled.

**Sampling**

Specify the sampling strategy/formulae that will be used to sample participations and include the sample size.

**Inclusion and Exclusion Criteria**

Clearly state inclusion & exclusion criteria that will be used.

**Data collection methods**

Specify data collection methods and instruments that will be used (if applicable) and include as appendices to the protocol. If applicable, include informed consent forms.

**Data Analysis**

Describe software and techniques that will be used for data analysis.

**Research Sites**

Identify Health Facilities where the research will be conducted i.e. specific Hospitals, Community Health Centres or Primary Health Care Clinics.

**Ethical Considerations**

Proof of ethical clearance from a South African Research Ethics Committee accredited with the National Health Research Council (NHREC). This section must clearly indicate what ethical issues were considered for the study including informed consent, confidentiality, etc.

**Feedback and Disseminating of Research Findings**

Clearly outline a strategy for feedback/dissemination of results and recommendations to relevant stakeholders.

Note that research reports, presentations and publications must formally acknowledge the Northern Cape Department of Health.

**Budget**

Indicate whether the Researcher(s), Company, Institution or Organization will be financing the research.

**Human Resources**

Specify who will be involved in conducting the research including Research Assistants and Statisticians.

**Time Frame**

Provide a realistic time frame for research i.e. specify the anticipated commencement and completion dates.

**Reference and Appendices**

Literature used for the development of the research proposal must be clearly referenced.

Relevant appendices must be attached to the Research Proposal including data collection instrument/tools, informed consent forms and any other relevant documentation referred to in the research proposal.

# **REFERENCES**

1. **Policy on conducting health Research: Northern Cape Department of Health**
2. **National Health Research Database (NHRD):** [**http://nhrd.hst.org.za**](http://nhrd.hst.org.za)
3. **NDoH. Ethics in Health Research Principles, Processes and Structures, 2015.** [**file:///C:/Users/Worku/AppData/Local/Packages/Microsoft.MicrosoftEdge\_8wekyb3d8bbwe/TempState/Downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf**](file:///C:/Users/Worku/AppData/Local/Packages/Microsoft.MicrosoftEdge_8wekyb3d8bbwe/TempState/Downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf)

# **FLOW CHART**

SUBMIT application to the PHRC through the NHRD

Check relevant documents & send request for gatekeeping approval

Feedback from reviewers

Comments/Questions/Concerns or Approval or Refusal

Send researcher: comments, questions or concerns

Send researcher approval letter

Send researcher refusal letter

Response to comments, questions or concerns

Send responses to the reviewers

Feedback: Approval or Refusal

Send Approval or Refusal letter to the re