GUIDELINES FOR SUBMITTING RESEARCH PROPOSALS TO THE KWAZULU-NATAL DEPARTMENT OF HEALTH FOR APPROVAL

PART A:
GUIDELINES: SUBMITTING OBSERVATIONAL STUDIES

PART B:
GUIDELINES: SUBMITTING CLINICAL TRIALS
FACILITY & COMMUNITY BASED TRIALS

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Health Services Planning, Monitoring & Evaluation
KwaZulu-Natal Department of Health

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PART A

GUIDELINES: SUBMITTING OBSERVATIONAL STUDIES

1. PURPOSE

To provide a framework for the development and submission of research proposals to the Provincial Health Research and Ethics Committee (PHREC).

2. AIM

To ensure expedient review and approval of research proposals.

3. SUBMISSION OF RESEARCH PROPOSALS

Applications to PHREC to conduct observational research within Health institutions in the Province must be done ONLINE via the National Health Research Database (NHRD) website http://nhrd.hst.org.za.

This became mandatory for all Provincial Health Research Committees in 2014.

4. THE NHRD

The NHRD is a web based research management application tool that was introduced by the National Department of Health and created by the Health Systems Trust (HST) as a uniform system to coordinate research applications to conduct studies at public health facilities as prescribed by the National Health Act (61 of 2003). The NHRD is a system that facilitates the research application process, making it faster and more efficient (Health Systems Trust, 2014). Principal Investigators are required to complete the online application form.
5. REQUIRED FIELDS FOR RESEARCH APPLICATIONS

Research proposals must include the following sub-sections for processing and approval.

The following fields are also required during Step 2 of the NHRD application process.

- **Primary Investigator and Researcher Details**
  - Title, name and qualifications of the Researcher(s), as well as the name and address of the Institution or Organisation that are represented. Telephonic, mobile, fax and e-mail contact details of the Principal Investigator (PI) must also be included.

- **Title**
  - The description of what is being studied, in whom, where, and when.

- **Type of Study**
  - Academic or non-academic

- **Study Area/Field**
  - Classify the research area as either or:
    - Child Health, Clinical, Communicable Diseases, Dental Health, Geriatrics, Health Systems, HIV/AIDS, Injury/Trauma, Mental Health, Non-Communicable Diseases, Nutrition, Public Health, Quality of Care, Sexually Transmitted Diseases, Tuberculosis (TB), Women’s Health

- **Aim and Objectives**
  - Clear and concise statement of the overall purpose of the research.

- **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, randomised control trial intervention,
Data Collection Methods and Tools

- Specify data collection methods and instruments that will be used (if applicable) and include as appendices to the protocol.

Sample

- Sampling strategy and sample size.

Data Analysis Tools and Methods

- Statistical procedures, methods, management and analysis programmes.

Request for usage of Department of Health Data

- Type of data required for use in the research study.

Time Frame

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

Ethics Approval

- Clearly indicate which institution is providing ethical approval, provide the ethics reference number and date of ethical approval for the study.

  PHREC accepts provisional ethical approval.

  Full ethical approval is provided once PHREC approval has been given.

MCC Approval if this a clinical trial

- Since this is not a clinical trial, MCC approval is not required.

Funding Source

- Provider of financial support for the study

Budget

- Indicate whether the Researcher(s), Company, Institution or Organisation will be financing the research. If any of the latter, give the name of the funding agency.
Indicate the budget allocated for the research project.

**Province & Facilities**
- Select the KwaZulu-Natal Province and facilities at which the study will be conducted at (Provincial Office/District Office/Hospital/Clinic).

**Additional Facility Requirements**
- Request additional requirements at facilities

**THE NEXT STEP IN THE RESEARCH APPLICATION PROCESS IS TO UPLOAD THE NECESSARY DOCUMENTATION REQUIRED FOR THE APPROVAL OF THE RESEARCH STUDY BY THE PHREC.**

5. **MANDATORY DOCUMENTATION FOR RESEARCH APPLICATIONS**

According to the NHRD, two documents are mandatory for uploading:

5.1. **Research Proposal**

- Brief summary or abstract outlining the aim and objectives of the study, the research methodology and data analysis.
- Summary of literature relevant to the proposed research problem/problem statement.
- Clearly describe the study population that will be sampled.
- Specify the sampling strategy/formulae that will be used to sample participants and include the sample size.
- Questionnaires and Information sheets and informed consent forms required for studies involving the observation/interview of human participants must also be included in the research proposal.
5.2. Ethical Clearance Letter

- Proof of (provisional) ethical clearance from an Ethics Committee accredited with the National Health Research Ethics Council (NHREC).

- International studies will require local (South African) ethical clearance.

**ADDITIONAL DOCUMENTATION REQUIRED FOR RESEARCH APPLICATIONS TO THE KZN PHREC:**

5.3. Letters of Support

- Researchers are required to obtain a letter of support from the Facility Manager and/or District Manager for their research to be conducted in the relevant facility.

- If research will be conducted at three or fewer facilities, individual facility support is required.

- If the study will be conducted at four or more facilities in a particular District, the Researcher will require a letter of support from the relevant District Manager. Individual facility support will not be required.

- If the study will be conducted at four or more Districts, approval from relevant Programme Manager within the KZN Department of Health is required. Individual district support is not required. Please note that once approval has been granted, arrangements with the relevant District should be made prior to commencing the study.

- Letters of support from Facility, District and/or programme managers must be obtained **PRIOR** to online submission to PHREC.

- In order to obtain support from the Facility, District and/or programme managers, researchers must submit to them: the final research proposal, provisional/final ethics approval letter, patient information sheet, consent form, data collection tools and any other relevant documents pertaining to their research study.

- In addition to the above documents, researchers must also provide the Facility and/or District Managers with a synopsis of their proposed research, highlighting the research activities that will take place in the facility or district (please refer to below table for the relevant fields that should be included as a template).
# SYNOPSIS OF STUDY TEMPLATE

<table>
<thead>
<tr>
<th>Study Institution/District</th>
<th>Institution Researcher wishes to conduct the study at: eg Northdale Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Researcher</td>
<td></td>
</tr>
<tr>
<td>Researcher’s Organisation</td>
<td></td>
</tr>
<tr>
<td>Researchers Contact Number</td>
<td>Office</td>
</tr>
<tr>
<td></td>
<td>Cell</td>
</tr>
<tr>
<td>Researchers E-mail</td>
<td></td>
</tr>
<tr>
<td>Study Title</td>
<td></td>
</tr>
<tr>
<td>Purpose of Study</td>
<td></td>
</tr>
<tr>
<td>Aim of Study</td>
<td></td>
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<tr>
<td>Objectives of Study</td>
<td></td>
</tr>
<tr>
<td>Planned Study Period</td>
<td>Start Date</td>
</tr>
<tr>
<td></td>
<td>Completion Date</td>
</tr>
<tr>
<td>Planned Visit Dates to Institution</td>
<td>Start Date</td>
</tr>
<tr>
<td></td>
<td>Completion Date</td>
</tr>
<tr>
<td>Study Design</td>
<td></td>
</tr>
<tr>
<td>Study Participants</td>
<td>Patients</td>
</tr>
<tr>
<td></td>
<td>Health Care Workers</td>
</tr>
<tr>
<td>Details of Participants</td>
<td>e.g. Ante Natal Care clients presenting for the first time/ Theatre Nurses etc.</td>
</tr>
<tr>
<td>Planned Sample Size</td>
<td>No of participants that will recruited from the relevant institution</td>
</tr>
<tr>
<td>Data Collection Tool(s)</td>
<td>Eg. Researcher administered questionnaires</td>
</tr>
<tr>
<td>Ethical Clearance</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Provisional</td>
</tr>
<tr>
<td>Potential Benefits and Relevance of the Study to the Institution</td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
</tr>
</tbody>
</table>
6. PHREC GUIDELINES FOR SUBMISSION OF RESEARCH APPLICATION ON THE NHRD

*Please ensure that details entered on the NHRD are as accurate as possible.*

i. If you are using the NHRD for the first time you will be required to register to obtain a login username and password.

ii. **Step 1:** Select “Request Access to a Provincial Facility”.

iii. **Step 2:** Provide details for your application by completing the fields on the form. Click “Update & Save Proposal” as you complete the fields.

iv. **Step 3:** Upload support documents (step 10 of the NHRD process).

   The mandatory documents can be uploaded by clicking “Select File”. Required documents (Point 5 above) can be selected by clicking on “Optional Documents” and selecting files. You can save all the required documents as one ZIP file and select the Zip file under “optional documents”. Ensure all files are correctly named. Update and save your proposal and Click “Next”.

v. **Step 4:** You can review your application details in Step 11 of the NHRD process.

   Peruse through the fields that were completed in the form in Step 2.

vi. **Step 5:** Submit Application For Approval if you are satisfied that your research application is complete.

   If you would like to submit your application, click “Yes”.

   The next screen that will appear is “Congratulations, you have successfully submitted your research proposal” followed by a confirmation email.

   When you see this message, your application will be sent to the Secretariat, HRKM for review and approval.

   If you only want to save what you have done so far and you are not ready to submit as yet, you can select “No”.

vii. The researcher will receive a reference number e.g. KZ_2015RP00_000
PLEASE NOTE:

- If you **DO NOT** click ‘YES’ in Step 5, the Health Research & Knowledge Management (HRKM) Unit does **NOT** receive the application even though you receive a reference number from the NHRD website.

- **IF YOU DO NOT HAVE ALL THREE REQUIRED DOCUMENTS, CLICK ‘NO’ in Step 5**, as the system will not allow you to upload the outstanding document/s once you have submitted your application.

- If you click “YES” in Step 5 **WITHOUT** the required documents for submission, you will have to RE-DO the application once you have all the required documents.

- Uploaded documents must be 4MB or less.

- For all technical queries regarding the application BEFORE submission of the application, please e-mail support@neoterra.zendesk.com and they will assist you promptly.


7. USAGE OF DISTRICT HEALTH INFORMATION SYSTEMS (DHIS) DATA

If the Principal Investigator (PI) will be using data from the District Health Information System (DHIS), the following process should be followed:

i. Obtain PHREC approval as per outlined procedure above (*without any letter of support*).

ii. Subsequent to PHREC approval, the PI is then required to seek permission from the Department of Health’s Data Management and Geographical Information Services Unit. The PI may contact the Unit’s Director: Mrs Nirvasha Narayan (nirvasha.narayan@kznhealth.gov.za).

iii. The PI will be required to complete the “Data User Agreement Form” provided by the Data Management and Geographical Information Services Unit.

iv. The Principal Investigator will be provided access to data once Data Management and Geographical Information Services Unit have approved the request.
8. **THE REVIEW PROCESS**

7.1. PHREC will only receive the application with the required documents once the NHRD application has been successfully submitted.

7.2. The research proposal is allocated to one of the Deputy Directors of the Health Research and Knowledge Management Unit.

7.3. The proposal is reviewed in the presence of the mandatory and required documentation by the assigned Deputy Directors.

7.4. If the proposal is recommended for approval, it is submitted to the PHREC Chairperson.

7.5. If the PHREC Chairperson approves the research, a letter of approval will be sent to the Principal Investigator via the NHRD website. Applicants are advised to keep checking the status of their application by logging onto the NHRD website.

7.6. The Principal Investigator will receive an automatic email notification once the study has been granted approval.

7.7. The Principal Investigator will be required to login with his/her username and password onto the NHRD website to download the study approval letter.

7.8. The Principal Investigator is then required to make the necessary arrangements with the relevant Health Facilities before commencing the study.

7.9. The review process for observational studies takes approximately three weeks after receipt of the application via the NHRD in the presence of the mandatory and required documentation.

7.10. If the study is not approved, the Principal Investigator will be informed with the reasons for non-approval via “Comments” on the NHRD website.

7.11. Appeals against the non-approval of studies can be directed to the Chairperson of the PHREC Committee.
9. INTERIM PROGRESS REPORTS AND FINAL REPORT

8.1. Researchers are required to provide feedback on research once it commences.

8.1.1. If the duration of the research is a year or less, one interim report must be submitted, within a month of completion, to Health Research and Knowledge Management (Refer to Section 9 for Contact Details) followed by the final research report once the research is published.

8.1.2. If the duration of the research is greater than a year, annual reports must be submitted to Health Research & Knowledge Management (Refer to Section 9 for Contact Details) followed by the final research report once the research is published.

8.2. The Department of Health encourages researchers to present their research results and recommendations to Departmental stakeholders including Management, Health Research & Knowledge Management and relevant District/ Facilities where the study was conducted in order to add value to health care services.

8.3. Arrangements for dissemination of results must be made in consultation with the Deputy Directors: Health Research & Knowledge Management.

8.4. One hard copy as well as a soft (electronic) copy of the research report must be submitted to Health Research & Knowledge Management.

8.5. The hard copy is placed in the Departmental library and soft copies are distributed to the relevant provincial Programme Managers.

8.6. Soft copies, with the permission of the Principal Investigator, are added to the Department’s webpage: http://www.kznhealth.gov.za/hrkm.htm.
10. **HRKM CONTACT DETAILS**

**Postal Address:**

Health Research & Knowledge Management  
Private Bag X9051  
Pietermaritzburg, 3200

**Physical Address:**

Department of Health: KZN  
Health Research & Knowledge Management  
Natalia Building 10 - 102 South Tower  
330 Langalibalele Street  
Pietermaritzburg, 3201

**E-mail Address:**

hrkm@kznhealth.gov.za
PART B

GUIDELINES: SUBMITTING CLINICAL TRIALS
(FACILITY & COMMUNITY BASED TRIALS)

1. DEFINITIONS

Applicant

- Pharmaceutical Company or their agent; OR
- Research organisation; OR
- Academic institution; OR
- Individual Clinician
- Other

Funder

- The individual or entity funding the clinical trial

Health Facility

- A Health Facility managed by the KwaZulu-Natal Department of Health.

Facility Based Trial

- The application of an intervention e.g. treatment of trial participants, which takes place in a public health facility.
  Recruitment of participants may take place either within or outside of public health facilities.

Community Based Trial

- The application of an intervention e.g. treatment of participants, which takes place outside of a health facility.
  Recruitment of participants may take place either within or outside of health facilities.

MCC

- Medicines Control Council.
Ethics Committee

- Any South African Research Ethics Committee that is accredited with the National Health Research Ethics Council.

Provincial Health Research and Ethics Committee (PHREC)

- Provincial level committee tasked with co-ordinating the review of health research proposals, and the stewardship of health research, in each province.

Health Research and Knowledge Management

- Provides secretariat services to the Provincial Health and Research Ethics Committee (PHREC).
- Co-ordinates the approval of health research in the Province.

Pharmaceutical Services

- Manages and coordinates the implementation of national pharmaceutical policy and legal framework;
- Monitoring of the provision of pharmaceutical services; selection; procurement; storage; distribution and use of (essential) medicines in the public sector.
- Facilitates the implementation of The Essential Drugs/Medicines Programme (EDP) of South Africa
2. ROLES AND RESPONSIBILITIES

Health Research and Knowledge Management
- Ensure that all administrative aspects of research applications have been complied with.
- Review the research proposal; where relevant distribute the protocol and summary to the relevant Programme/Component or reviewer within the Department. Receive input from these Programmes/Components and make recommendations to the Chairperson of the Provincial Research and Ethics Committee (PHREC) and obtain final approval from the Head of Health, Department of Health. Inform applicant of outcome of the review.

Pharmaceutical Services
- Conduct part of the technical evaluation of Clinical Trial applications and submit recommendations to the Health Research and Knowledge Management Unit for processing.

Clinical Program Managers and Departmental Clinicians
- Conduct part of the technical evaluation of Clinical Facility/Community Based Trial applications and submit recommendations to Health Research and Knowledge Management for processing.

National Health Laboratory Services (NHLS)
- Provide technical expertise on the use and costs of their services if these will be used during the Clinical Trials/Community Based Trials.

Finance Component, DOH
- Provide technical expertise on the plan for financial reimbursement of the Department of Health where relevant.
Provincial Health Research and Ethics Committee (PHREC)  
- Review research proposals submitted; approve if all requirements are met, disapprove if they are not; provide timely and relevant feedback to researchers on decision.

Head of Health, KwaZulu-Natal Department of Health  
- Final approval of the Clinical Trials based on recommendations.
- Adjudicate appeals for Clinical Trials/Community Based Trials or other research proposals that were not approved by the Department.

Medicines Control Council  
- Attends to compliance with regulatory matters.

Ethics Committee  
- Reviews the ethical and scientific rigor of health research on animals and on human participants being conducted in South Africa.
- Ensures that the rights, safety and wellbeing of study participants are protected.

3. SUBMISSION OF THE CLINICAL TRIAL/COMMUNITY BASED TRIAL PROTOCOL

Applications to the Provincial Health Research and Ethics Committee (PHREC) to conduct clinical trial research or community based trials in the Province must be done ONLINE via the National Health Research Database (NHRD) website [http://nhrd.hst.org.za](http://nhrd.hst.org.za). This became mandatory for all Provincial Health Research Committees in 2014.

**ELECTRONIC APPLICATIONS VIA E-MAIL ARE NO LONGER ACCEPTED**

4. THE NHRD

The NHRD is a web based research management application tool that was introduced by the National Department of Health and created by the Health Systems Trust (HST) as a uniform system to coordinate research applications to conduct studies at public health facilities as prescribed by the National Health Act (61 of 2003). The NHRD is a system that facilitates the research application process, making it faster and more efficient (Health Systems Trust, 2014). Principal Investigators are required to complete the online application form.
5. REQUIRED FIELDS FOR TRIAL APPLICATIONS ON THE NHRD

Research proposals must include the following sub-sections to ensure expedient processing and approval. The following fields are also required during the NHRD application process:

- **Title, name and qualifications of the Researcher(s), as well as the name and address of the Institution or Organisation that are represented. Telephonic, mobile, fax and e-mail contact details of the Principal Investigator (PI) must also be included.**

- **The description of what is being studied, in whom, where, and when.**

- **Academic or Non-academic**

- **Classify the research area as either or:**
  - Child Health, Clinical, Communicable Diseases, Dental Health, Geriatrics, Health Systems, HIV/AIDS, Injury/Trauma, Mental Health, Non-Communicable Diseases, Nutrition, Public Health, Quality of Care, Sexually Transmitted Diseases, Tuberculosis (TB), Women’s Health

- **Clear and concise statement of the overall purpose of the research.**

- **Specify the study design e.g. case control, case series, cohort, cross-sectional, descriptive, exploratory, longitudinal, meta-analysis, observational, quasi-experimental, randomised control trial intervention, retrospective, systematic review, etc.**
Data Collection Methods and Tools ▪ Specify data collection methods and instruments that will be used (if applicable) and include as appendices to the protocol.

Sampling ▪ Sampling strategy and sample size.

Data Analysis Tools and Methods ▪ Statistical procedures, methods, management and analysis programmes.

Request for use of Department of Health Data ▪ Type of data required for use in the research study.

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

Ethics Approval ▪ Clearly indicate which institution is providing ethical approval, provide the ethics reference number and date of ethical approval for the study.

▪ PHREC accepts provisional ethical approval.

Full ethical approval is provided once PHREC approval has been given.

MCC Approval for a Clinical Trial ▪ Indicate whether MCC approval has been given for the clinical trial

National Clinical Trial Registry ▪ Complete the number

Number

Funding Source ▪ Provider of financial support for the study

Budget ▪ Indicate whether the Researcher(s), Company, Institution or Organisation will be financing the research. If any of
the latter, give the name of the funding agency.

- Indicate the budget allocated for the research project.

**Province & Facilities**
- Select the KwaZulu-Natal Province and facilities at which the study will be conducted at (Provincial Office/District Office/Hospital/Clinic).

**Additional Facility Requirements**
- Request additional requirements at facilities

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**THE NEXT STEP IN THE RESEARCH APPLICATION PROCESS IS TO UPLOAD THE NECESSARY DOCUMENTATION REQUIRED FOR THE APPROVAL OF THE RESEARCH STUDY BY THE PHREC.**

5. **MANDATORY DOCUMENTATION FOR TRIAL APPLICATIONS**

According to the NHRD, two documents are mandatory for uploading:

5.1. **Research Proposal**

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

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

- Clearly describe the study population that will be sampled.

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

- Information sheets and informed consent forms required for studies involving the observation/interview of human participants must also be included in the research proposal.
5.2. Ethical Clearance Letter

- Proof of provisional ethical clearance from a South African Research Ethics Committee accredited with the National Health Research Ethics Council (NHREC) must be submitted with the application.

**NOTE:** Final approval from the Head of Department will only be given once the trial has received full ethical approval.

ADDITIONAL DOCUMENTATION REQUIRED FOR TRIAL APPLICATIONS TO THE PHREC:

5.3. Letters of Support

*Facility Based Trials*

Support from the Hospital Manager(s) of institution(s) where the trial will be conducted is required.

**NOTE:** Only the Hospital CEO is authorised to give authorization to conduct the Trial.

- If any person other than the Hospital CEO has been delegated to give authorization to conduct trials, the Hospital CEO must write a letter confirming the person as his/her delegate.
- If the trial is to be conducted at less than four facilities in a particular District, a letter of support must be obtained from each individual institution.
- If there are four or more facilities involved in the Trial, approval must be sought from the relevant District Health Manager. Individual facility support is not required.
- If the study will be conducted at four or more Districts, approval from the relevant programme manager is required. Individual district support is not required. Please note that once approval has been granted, arrangements with the relevant District should be arranged prior to commencing the study.
- Institutions reserve the right to conduct their own technical evaluation of the trial before support is given for the trial to be conducted in their institution.
Community Based Trials

- Support is required from either the relevant municipality or the local area authority.

5.4. Trial Application Form
All trial applications (Clinical and Community Based) should be accompanied by a trial application form. It is available from

5.5. Checklist for Trial Applications
Include in the research application the “Checklist When Submitting Clinical Trials Form”. It is available from

5.6. Proof of Insurance
Applicants must supply proof of current insurance. This indicates that any unforeseen adverse events during the trial will be covered.

5.7. MCC Approval
- MCC approval letter for the trial if the product(s) involved in the trial is not registered with the MCC. The name of the Principal Investigator must appear on this document.

NOTE:
- Departmental review of the research application can also be done concurrently with MCC review.
- NOTE: Final approval from the Head of Health will only be given once the trial has received FULL MCC approval.
6. PHREC GUIDELINES FOR SUBMISSION OF A TRIAL RESEARCH APPLICATION

Please ensure that details entered on the NHRD are as accurate as possible.

i. If you are using the NHRD for the first time you will be required to register to obtain a Login username and password.

ii. Step 1: Select “Request Access to a Provincial Facility”.

iii. Step 2: Provide details for your application by completing the fields on the form. Click “Update & Save Proposal” as you complete the fields.

iv. Step 3: Upload support documents (step 10 of the NHRD process).

The mandatory documents can be uploaded by clicking “Select File”. Required documents (Point 5 above) can be selected by clicking on “Optional Documents” and selecting files. You can save all the required documents as one ZIP file and select the zip file under “optional documents”. Ensure all files are correctly named. Update and save your proposal and click “Next”.

v. Step 4: You can review your application details in Step 11 of the NHRD process.

Peruse through the fields that were completed in the form in Step 2.

vi. Step 5: Submit Application For Approval if you are satisfied that your research application is complete.

If you would like to submit your application, click “Yes”. The next screen that will appear is “Congratulations, you have successfully submitted your research proposal” followed by a confirmation email.

When you see this message, your application will be sent to the Secretariat, HRKM for review and approval.

If you only want to save what you have done so far and you are not ready to submit as yet, you can select “No”.

vii. The researcher will receive a reference number e.g. KZ_2015RP00_000
PLEASE NOTE:

- **IF YOU DO NOT** CLICK ‘YES’ in **Step 5**, the Health Research & Knowledge Management (HRKM) Unit does **NOT** receive the application even though you receive a reference number from the NHRD website.
- **IF YOU DO NOT HAVE ALL THREE REQUIRED DOCUMENTS**, CLICK ‘NO’ in **Step 5**, as the system will not allow you to upload the outstanding document/s once you have submitted your application.
- If you click “YES” in **Step 5** WITHOUT the required documents for submission, you will have to RE-DO the application once you have all the required documents.
- Uploaded documents must be 4MB or less.
- For all technical queries regarding the application BEFORE submission of the application, please e-mail support@neoterra.zendesk.com and they will assist you promptly.

7. **COST**

The Finance Unit of the Department of Health will give billing and costing advice when necessary to the Health Research and Knowledge Management Unit, the District and the Facility. The applicant or company undertaking a trial does so at no expense to the KwaZulu-Natal Department of Health. The company/ firm/ organisation must:

7.1 Supply all test materials or other material that may be used in comparative studies and bear the cost of all necessary investigations. This includes all scans and radiological examinations.

7.2 If additional laboratory investigations over and above the standard of care are required, company/ firm/ organisation must be responsible for the fees. If the laboratory investigations are not done privately, the applicant, investigator, and Head of Laboratory Services in the KZN Department of Health must reach agreement regarding payment of the costs involved.

7.3 Should Department of Health resources be used during the conduct of the trial, the principal investigator will be required to calculate the costs of these resources with the assistance of the Finance component of the KZN DOH, and reimburse the Department of Health in full.
These include the payment of costs for out-patient visits, in-patient costs where the patient may be admitted, diagnostic procedures such as x-rays, scans, etc.

7.4 Specific costs for each trial will be calculated and negotiated once the trial protocol has been received.

7.5 A full time employee of the KZN Department of Health may **NOT** receive any remuneration for conducting or assisting with the conduct of any trial. Any gifts or support received by such employees by the funders or organisers of a trial must be declared to the direct line manager of the affected employee in the Department as well as to the Manager: Health Research and Knowledge Management.

7.6 If a full time employee of the KZN Department of Health is conducting or assisting with the trial, the Hospital CEO must declare in the Clinical Trial Application form s/he approves this.

7.7 If funding or equipment is to be donated to the institution, the necessary written approval to accept such donation must be obtained by the Hospital.

8. **THE REVIEW PROCESS**

8.1 PHREC will only receive the application with the required documents once the application has been submitted onto the NHRD website.

8.2 The research proposal is allocated to one of the Deputy Directors of the Health Research and Knowledge Management Unit

8.3 The proposal is reviewed in the presence of the mandatory and required documentation by the assigned Deputy Directors.

8.4 Once the trial is reviewed by the Health Research & Knowledge Management Unit, it is subjected to technical review by two other reviewers. The reviewers assigned are: the Department’s Pharmaceutical Services, clinicians or Clinical Programme Managers. Internal and external reviewers may also be asked to provide technical assessments.

8.5 Reviewers will submit their evaluation form to the Health Research and Knowledge Management Unit within six weeks of receipt of the evaluation request from the Health Research and Knowledge Management Unit.
8.6 If additional information or documentation is required for the technical evaluation, the Health Research and Knowledge Management Unit will contact the Applicant and request the required information.

8.7 If any concerns are raised during the review process, the Applicant will be requested to address these either via e-mail, or in a face-to-face meeting with the relevant reviewer.

8.8 Once the various reviewers have made their recommendations regarding the trial, the Health Research & Knowledge Management will submit the application to the Chairperson of the Provincial Health Research and Ethics Committee for approval.

8.9 Final approval for the trial study will be given by the Head of Health, KwaZulu-Natal Department of Health.

8.10 If the Head of Health approves the research, a letter of approval will be sent to the Principal Investigator via the NHRD website. Applicants are advised to keep checking the status of their application by logging onto the NHRD website.

8.11 The Principal Investigator will receive an automatic email notification once your study has been granted approval.

8.12 The Principal Investigator will login with his/her username and password onto the NHRD website and download the study approval letter.

8.13 The Principal Investigator is then required to make the necessary arrangements with the relevant Health Facilities before commencing the study.

8.14 For trials, the approval process takes approximately three months after receipt of the required documents.

8.15 If the study is not approved, the Principal Investigator will be informed with the reasons for non-approval via “Comments” on the NHRD website.

8.16 The Applicant may appeal to the Chairperson of the PHREC to review this non-approval of the trial.
9. INTERIM PROGRESS REPORTS AND FINAL REPORT

9.1 Researchers are required to provide feedback on research once it commences.

9.2 Annual reports must be submitted to Health Research & Knowledge Management followed by the final research report once the research is completed.

9.3 Should it be deemed necessary to stop the trial, the Applicant must comply with all procedures as required by the approving ethics committee, as well as inform the facility or district management and the Chairperson of PHREC in writing within two weeks of stopping the trial, giving the reasons for doing so.

9.4 The Applicant is required to forward all Data Safety and Monitoring Board Reports to the Health Research and Knowledge Management Unit, KZN Department of Health within a week of their receipt.

9.5 On completion of the trial, research results and recommendations must be formally presented to the Provincial Department of Health and relevant District/ Facilities where the study was conducted.

9.6 Arrangements for dissemination of results can be made in consultation with the Deputy Director: Health Research & Knowledge Management.

9.7 One hard copy as well as soft copies of the research report must be submitted to the Health Research & Knowledge Management Unit. The hard copy is placed in the Departmental library and soft copies are distributed to the relevant Programme Managers. Soft copies of the research report will be added to the Department’s webpage with the permission of the Applicant. Contact details of HRKM can be found in Section 11.
11. HRKM CONTACT DETAILS

Postal Address:

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3200

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