health
Department:
Health
PROVINCE OF KWAZULU-NATAL

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

Prepared by:

Health Research & Knowledge Management

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 KwaZulu-Natal (KZN) Provincial Health Research and Ethics Committee (PHREC) of the Department of Health (DoH).

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 https://nhrd.health.gov.za.

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.

4.1. The first step is to register on the site with a username and password.

4.2. You have the following options when logged in: “Submit New Proposal”, “Manage Proposals”, etc.

4.3. Ensure that you choose the option **“Request Access to a Provincial facility”**.

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 the NHRD application process.

SECTION:	FIELD:
5.1. Researchers:	
5.1.1. 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.
5.1.2. Additional Researchers	▪ Names of additional researchers can be added.
5.2. Title, Field of Study, Aims & Objectives	
5.2.1. Title	▪ Title of proposal describing what is being studied, in whom, where, and when.
5.2.2. COVID-19 related study	▪ Indicate if the study is a COVID- 19 related study.
5.2.3. Type of Study	▪ Indicate if the study is Academic or non-academic.
5.2.4. Health Category	▪ Classify the research area according to health categories in the drop down list. Multiple options can be selected by checking the checkbox. *Ensure that the first choice is the most relevant to your study*

SECTION:	FIELD:
5.2.5. Aim and Objectives	▪ Clear and concise statement of the overall purpose of the research.
5.3. Province & Facilities	
5.3.1. Province	▪ Select the KwaZulu-Natal Province
5.3.2. Facilities	▪ Facilities at which the study will be conducted at (Provincial Office/District Office/Hospital/Clinic).
5.4. Research Activity & Study Design	
5.4.1. Data Collection Methods and Tools	▪ Specify data collection methods and instruments that will be used (if applicable) from the drop down list. Multiple selections can be made.
5.4.2. Research Activity	▪ Select a single research activity that describes your study.
5.4.3. Study Design	▪ Answer the questions on the page in order for the appropriate categorisation of your study design.
5.4.4. Position Interview Requests	▪ Indicate if you require to interview a specific person within the Department of Health.
5.5. Sample/Field Work Strategy	
5.5.1. Sample	▪ Specify sampling strategy and sample size.
5.5.2. Request for usage of Department of Health Data/Information	▪ Indicate if request for DHIS data is required
5.5.3. Specify the request	▪ Type of data required for use in the research study.
5.6. Project Time Frame	
5.6.1. Project Start Date	▪ Indicate the anticipated start date
5.6.2. Estimated Project End Date	▪ Indicate the anticipated end date
5.7. Ethics Time Frame	

SECTION:	FIELD:
5.7.1. Ethics Approval	▪ Indicate which institution is providing ethical approval. **PHREC accepts provisional ethical approval.**
5.7.2. Ethics Approval Number	▪ Provide the ethics reference number
5.7.3. Date of Ethical Approval	▪ Dates of ethical approval start date and end date
5.7.4. If clinical trial, MCC (SAHPRA) Approved	▪ **Since this is not a clinical trial, no SAHPRA approval is required**
5.7.5. National Clinical Trial Registry Number	▪ **Since this is not a clinical trial, no National Clinical Registry Number is required**
5.8. Funding Source & Budget	
5.8.1. Funding Source	▪ Please select the type of donor(s) providing financial support or whether the Researcher(s), Company, Institution or Organisation will be financing the research
5.8.2. Budget	▪ Indicate the amount
5.9. Additional Facility Requirements	
5.9.1. Additional Facility Requirements	▪ Indicate whether you have additional requirements at facilities, implications and the impact
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	
5.10. Support Documents	According to the NHRD, the following are mandatory documents that are required. This is also a requirement for KZN PHREC.
5.10.1. Mandatory Documents	▪ The NHRD has mandatory documents that should be uploaded by selecting the relevant file on your computer.

SECTION:	FIELD:
5.10.1.1. Research Ethics Committee (REC) Approval Document	▪ Proof of ethical clearance (**full/provisional**) from an Ethics Committee accredited with the National Health Research Ethics Council (NHREC). ▪ International studies will require local (South African) ethical clearance.
5.10.2. Optional Documents	▪ **The following documents are actually MANDATORY for KZN PHREC** but can only be uploaded on this section**.**
5.10.2.1. Other	▪ **Research Proposal** ▪ **Letter(s) of Support.** Please refer to section 6 below for more information. ▪ Data Collection Tool (Info Sheets, Consent Forms, Questionnaire, , etc)
5.11. Review & Submit	
Review your data before proceeding. This will allow you to ensure that your data is complete and accurate. ▪ If you are satisfied that all information is complete, you can choose the "yes" option. ▪ You will receive an email confirming details regarding your submission ▪ You will receive a **KZ** reference number, e.g.. KZ_YYYY_MM_00 ▪ Please refer to section 7 below for more information	

6. ADDITIONAL DOCUMENTATION REQUIRED FOR RESEARCH APPLICATIONS TO THE KZN PHREC:

6.1. 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.

Letters of support from Facility Managers and/or District Managers must be obtained **PRIOR** to online submission to PHREC.

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

6.1.2. 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.

6.1.3. If the study will be conducted at four or more **Districts**, approval from the relevant Programme Manager within the KZN Department of Health is required (e.g., HIV/HAST Programme manager). Individual district support is not required.

- Once PHREC approval has been granted, arrangements with the relevant Facility/ District should be made prior to commencing the study.

- In order to obtain support from the Facility and/or District 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 such as proof from the relevant academic institution 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 template for the relevant fields that should be included).

- District Health Information System (DHIS) data. Please refer to section 8.

7. SYNOPSIS OF STUDY TEMPLATE FOR SEEKING SUPPORT FROM INSTITUTIONS

Study Institution/District	*eg Northdale Hospital*						
Name of Researcher							
Researcher's Organisation							
Researchers Contact Number	**Office**		**Cell**				
Researchers E-mail							
Study Title							
Purpose of Study							
Aim of Study							
Objectives of Study							
Planned Study Period	**Start Date**		**Completion Date**				
Planned Visit Dates to Institution	**Start Date**		**Completion Date**				
Study Design							
Study Participants	**Patients**		**Health Care Workers**				
Details of Participants	*e.g. Ante Natal Care clients presenting for the first time/ Theatre Nurses etc.*						
Planned Sample Size	*No of participants that will recruited from the relevant institution*						
Data Collection Tool (s)	*Eg. Researcher administered questionnaires*						
Ethical Clearance	**Full**		**Provisional**		**None**		
Potential Benefits and Relevance of the Study to the Institution							
Comments							

8. NOTES ON RESEARCH APPLICATIONS ON THE NHRD

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

8.2. Update and save your proposal and Click "Next".

8.3. Ensure that a minimum of three documents are uploaded with your application (proposal, ethics letter, letter of support).

8.4. Ensure all files are correctly named when uploading.

8.5. If you select "Request access to NDOH", KZN PHREC will **NOT** receive your application. Your reference number would indicate which committee you have submitted your application to.

8.6. If you do not have all the required documents, click 'NO' in Step 5.11.1, as the system will not allow you to upload the outstanding document/s once you have submitted your application.

8.7. If you click "YES" in Step 5.11.1 WITHOUT the required documents for submission, you will have to RE-DO the application once you have all the required documents.

8.8. Uploaded documents must be 4MB or less.

8.9. For all technical queries regarding the application BEFORE submission of the application, please e-mail nhrd@health.gov.za and they will assist you promptly.

8.10. For information on how to submit your application onto the NHRD website, please view the "Researcher Manual": https://nhrd.health.gov.za/Downloads/Researcher%20Manual.pdf

9. 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:

9.1. Procedure outlined above (4.1. to 5.11.2).

9.2. In this case, the **Letter of Support** will be the "Data User Agreement form" that is **signed** by Director of the Data Management and Geographical Information Services Unit of the Department of Health.

9.3. The PI may obtain the form by emailing: Data.Management@kznhealth.gov.za

9.4. The signed form should be uploaded on the NHRD as part of the online application.

9.5. Once the PI receives approval from the KZN PHREC, the approval letter and the signed Data User Agreement form should be submitted to the Director: Data Management, at which point the required data will be extracted and released.

10. THE REVIEW PROCESS

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

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

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

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

10.5. 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.

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

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

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

10.9. 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.

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

10.11. Appeals against the non-approval of studies can be directed to the Chairperson of the PHREC Committee.

11. INTERIM PROGRESS REPORTS AND FINAL REPORT

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

11.1.1. 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 followed by the final research report once the research is published (Refer to Section 11 for Contact Details).

11.1.2. If the duration of the research is greater than a year, annual reports must be submitted to Health Research & Knowledge Management followed by the final research report once the research is published (Refer to Section 11 for Contact Details).

11.2. Applicants must ensure that their study application is "concluded" on the NHRD once the study has been completed and a report/dissertation/publication is uploaded on the relevant application

11.3. 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.

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

11.5. A soft (electronic) copy of the research report must be submitted to Health Research & Knowledge Management.

11.6. Soft copies, with the **permission** of the Principal Investigator, are added to the Department's webpage: http://www.kznhealth.gov.za/hrkm.htm.

11.7. If permission is provided by the PI, the abstract is placed in the monthly Research Bulletin which is circulated throughout the Department.

12. 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 TRIAL STUDIES)

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 health facilities.
Community Based Trial	▪ The application of an intervention e.g. treatment of participants, which takes place outside of a health facility. Provincial approval is only necessary if participants are recruited from or referred to provincial health facilities at any stage before, during or after the trial.

South African Health Products Regulatory Authority (SAHPRA) Certification	▪ Replaces Medicines Control Council (SAHPRA).
Ethics Committee	▪ Any South African Research Ethics Committee that is accredited with the National Health Research Ethics Council (NHREC).
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-ordination of 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 Trial/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	▪ Final approval of the Clinical Trials based on recommendations.
KwaZulu-Natal Department of Health	▪ Adjudicate appeals for Clinical Trials/Community Based Trials or other research proposals that were not approved by the Department.
SAHPRA	▪ 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 https://nhrd.health.gov.za .

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.

4.1. The first step is to register on the site with a username and password.

4.2. You have the following options when logged in: “Submit New Proposal”, “Manage Proposals”, etc.

4.3. Ensure that you choose the option **“Request Access to a Provincial facility”**.

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 the NHRD application process.

SECTION:	FIELD:
5.1. Researchers:	
5.1.1. 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.
5.1.2. Additional Researchers	▪ Names of additional researchers can be added.
5.2. Title, Field of Study, Aims & Objectives	
5.2.1. Title	▪ Title of proposal describing what is being studied, in whom, where, and when.
5.2.2. COVID-19 related study	▪ Indicate if the study is a COVID- 19 related study.
5.2.3. Type of Study	▪ Indicate if the study is Academic or non-academic.
5.2.4. Health Category	▪ Classify the research area according to health categories in the drop down list. Multiple options can be selected by checking the checkbox. *Ensure that the first choice is the most relevant to your study*
5.2.5. Aim and Objectives	▪ Clear and concise statement of the overall purpose of the research.

SECTION:	FIELD:
5.3. Province & Facilities	
5.3.1. Province	▪ Select the KwaZulu-Natal Province
5.3.2. Facilities	▪ Facilities at which the study will be conducted at (Provincial Office/District Office/Hospital/Clinic).
5.4. Research Activity & Study Design	
5.4.1. Data Collection Methods and Tools	▪ Specify data collection methods and instruments that will be used (if applicable) from the drop down list. Multiple selections can be made.
5.4.2. Research Activity	▪ Select a single research activity that describes your study.
5.4.3. Study Design	▪ Answer the questions on the page in order for the appropriate categorisation of your study design.
5.4.4. Position Interview Requests	▪ Indicate if you require to interview a specific person within the Department of Health.
5.5. Sample/Field Work Strategy	
5.5.1. Sample	▪ Specify sampling strategy and sample size.
5.5.2. Request for usage of Department of Health Data/Information	▪ Indicate if request for DHIS data is required
5.5.3. Specify the request	▪ Type of data required for use in the research study.
5.6. Project Time Frame	
5.6.1. Project Start Date	▪ Indicate the anticipated start date
5.6.2. Estimated Project End Date	▪ Indicate the anticipated end date
5.7. Ethics Time Frame	

SECTION:	FIELD:
5.7.1. Ethics Approval	▪ Indicate which institution is providing ethical approval. **PHREC accepts provisional ethical approval.** ▪ **PHREC Application for a clinical trial study can be made concurrently with Ethics application** ▪ **Full ethical approval is provided once PHREC approval has been given.**
5.7.2. Ethics Approval Number	▪ Provide the ethics reference number
5.7.3. Date of Ethical Approval	▪ Dates of ethical approval start date and end date
5.7.4. If clinical trial, MCC (SAHPRA) Approved	▪ **Since this is a clinical trial, SAHPRA approval is required**
5.7.5. National Clinical Trial Registry Number	▪ **Since this is a clinical trial, National Clinical Registry Number is required**
5.8. Funding Source & Budget	
5.8.1. Funding Source	▪ Please select the type of donor(s) providing financial support or whether the Researcher(s), Company, Institution or Organisation will be financing the research
5.8.2. Budget	▪ Indicate the amount
5.9. Additional Facility Requirements	
5.9.1. Additional Facility Requirements	▪ Indicate whether you have additional requirements at facilities, implications and the impact
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	
5.10. Support Documents	According to the NHRD, the following are mandatory documents that are required. This is also a requirement for KZN PHREC.

SECTION:	FIELD:
5.10.1. Mandatory Documents	▪ The NHRD has mandatory documents that should be uploaded by selecting the relevant file on your computer.
5.10.1.1. Research Ethics Committee (REC) Approval Document	▪ Proof of ethical clearance (**full/provisional**) from an Ethics Committee accredited with the National Health Research Ethics Council (NHREC). ▪ International studies will require local (South African) ethical clearance.
5.10.2. Optional Documents	▪ **The following documents are actually MANDATORY for KZN PHREC** but can only be uploaded on this section**.**
5.10.2.1. Other	▪ **Research Proposal** ▪ **Letter(s) of Support.** Please refer to section 6 below for more information. ▪ Clinical Trial Application Form ▪ Checklist for Trial Applications ▪ Proof of Insurance ▪ Dispensing License or Pharmacy Registration ▪ SAPHRA Approval ▪ Data Collection Tool (Info Sheets, Consent Forms, Questionnaire, , etc)
5.11. Review & Submit	
Review your data before proceeding. This will allow you to ensure that your data is complete and accurate. ▪ If you are satisfied that all information is complete, you can choose the "yes" option. ▪ You will receive an email confirming details regarding your submission ▪ You will receive a **KZ** reference number, e.g.. KZ_YYYY_MM_00 ▪ Please refer to section 7 below for more information	

6. ADDITIONAL DOCUMENTATION REQUIRED FOR RESEARCH APPLICATIONS TO THE KZN PHREC:

6.1. 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.

Letters of support from Facility Managers and/or District Managers must be obtained **PRIOR** to online submission to PHREC.

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.
  - 6.1.1. If research will be conducted at three or fewer facilities, individual facility support is required.
  - 6.1.2. 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.
  - 6.1.3. If the study will be conducted at four or more **Districts**, approval from the relevant Programme Manager within the KZN Department of Health is required (e.g., HIV/HAST Programme manager). Individual district support is not required.
- Once PHREC approval has been granted, arrangements with the relevant Facility/ District should be made prior to commencing the study.
- In order to obtain support from the Facility and/or District 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 template for the relevant fields that should be included).

- 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.

6.2. Trial Application Form

All trial applications (Clinical and Community Based) should be accompanied by a trial application form. It is available from (http://www.kznhealth.gov.za/research/clinical-trial-application-2020.pdf).

6.3. Checklist for Trial Applications

Include in the research application the "Checklist When Submitting Clinical Trials Form". It is available from (http://www.kznhealth.gov.za/research/Checklist_submitting_clinical_trial_studies_2015.pdf).

6.4. Proof of Insurance

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

6.5. Dispensing License or Pharmacy Registration

When the intervention involves administering drug(s) to participants, the person dispensing the drug(s) should be in possession of a Dispensing License or Pharmacy Registration with the Health Profession Council of South Africa (HPCSA).

6.6. SAHPRA Approval

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

6.7. NOTE:

- Departmental review of the clinical trial research application can be done **concurrently** with ethical review and SAPHRA review.
- FINAL approval from the Head of Health will only be given once the trial has received **FULL** Ethics & SAHPRA approval.

Community Based Trials

- Provincial approval is only necessary if participants are recruited from or referred to provincial health facilities at any stage before, during or after the trial. Support is required from the relevant health authority (Provincial/Municipal).

7. NOTES ON RESEARCH APPLICATIONS ON THE NHRD

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

7.2. Update and save your proposal and Click "Next".

7.3. Ensure that a minimum of seven documents are required for your clinical trial application (proposal, ethics letter, letter of support, SAHPRA, Insurance Certificate, Clinical Trial Application Form, checklist when submitting a clinical trial application).

7.4. Ensure all files are correctly named when uploading.

7.5. If you select "Request access to NDOH", KZN PHREC will **NOT** receive your application. Your reference number would indicate which committee you have submitted your application to.

7.6. If you do not have all the required documents, click 'NO' in Step 5.11.1, as the system will not allow you to upload the outstanding document/s once you have submitted your application.

7.7. If you click "YES" in Step 5.11.1 WITHOUT the required documents for submission, you will have to RE-DO the application once you have all the required documents.

7.8. Uploaded documents must be 4MB or less.

7.9. For all technical queries regarding the application BEFORE submission of the application, please e-mail nhrd@health.gov.za and they will assist you promptly.

7.10. For information on how to submit your application onto the NHRD website, please view the "Researcher Manual": https://nhrd.health.gov.za/Downloads/Researcher%20Manual.pdf

8. 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:

8.1 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.

8.2 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.

8.3 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.

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

8.5 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.

8.6 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.

8.7 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.

9. THE REVIEW PROCESS

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

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

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

9.4. Once the trial is reviewed by the Health Research & Knowledge Management Unit, it is subjected to technical review by two other reviewers.

9.5. 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.

9.6. 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.

9.7. **COVID-19 CLINICAL TRIALS**: COVID-19 clinical trial applications undergo expedited review. Technical review (9.4, 9.5 & 9.6) is omitted. The Chairperson of PHREC approves COVID-19 clinical trial applications.

9.8. 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.

9.9. 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.

9.10. 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.

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

9.12. 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

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

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

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

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

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

9.18. The Applicant may appeal to the Chairperson of the PHREC to review this non-approval of the trial.

10. INTERIM PROGRESS REPORTS AND FINAL REPORT

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

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

10.3. 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.

10.4. 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.

10.5. Applicants must ensure that their study application is "concluded" on the NHRD once the study has been completed and a report/dissertation/publication is uploaded on the relevant application.

10.6. Research results and recommendations must be formally presented to the Provincial Department of Health and relevant District/ Facilities where the study was conducted.

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

10.8. Soft (electronic) copies of the research report must be submitted to the Health Research & Knowledge Management Unit. Soft copies are distributed to the relevant Programme Managers with the permission of the researcher.

10.9. Soft copies of the research report will be added to the Department's webpage with the **permission** of the Applicant: http://www.kznhealth.gov.za/hrkm.htm

10.10. If permission is provided by the PI, the abstract is placed in the monthly Research Bulletin which is circulated throughout the Department.

11. HRKM CONTACT DETAILS

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