



HEALTH

KwaZulu-Natal

Health Research & Knowledge Management

PART A: Guidelines: Submitting a Research Proposal

PART B: Guidelines: Obtaining Authority to Undertake a Clinical Trial in Provincial Health Facilities

Prepared by:

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

PART A

GUIDELINES: SUBMITTING A RESEARCH PROPOSAL

1. PURPOSE

Provide a framework for the development and submission of Health Research Proposals.

2. AIM

Ensure expedient review and approval of research proposals.

3. GUIDELINES FOR THE DEVELOPMENT OF RESEARCH PROPOSALS

Research proposals must include the following sub-sections to ensure expedient processing and approval:

- 3.1 Title and Authors** → ▪ Title, name and qualifications of the Researcher(s), as well as the name and address of the Institution or Organisation that are represented. Telephonic, fax and e-mail contact details of the Principal Investigator (PI) must also be included.
- 3.2 Summary or Abstract** → ▪ Brief summary or abstract outlining the aim and objectives of the study, the research methodology and data analysis.
- 3.3 Introduction** → ▪ Summary of literature relevant to the proposed research problem/ problem statement.
- 3.4 Motivation** → ▪ Outline of the relevance and benefits of the proposed research on Public Health.
- 3.5 Aim or Purpose** → ▪ The aim or purpose must be clear and feasible.
- 3.6 Objectives** → ▪ Objectives must be specific, achievable, realistic and time-bound and clearly describe the specific deliverables of the proposed study.
- 3.7 Research Area** → ▪ Classify the research area e.g. TB, HIV and AIDS, etc. or other specific research areas.

3.8 Research Methods

- 3.8.1 Study Design** → ▪ Specify the study design e.g. descriptive, analytical, intervention, etc.
- 3.8.2 Study Population** → ▪ Clearly describe the study population that will be sampled.
- 3.8.3 Sampling** → ▪ Specify the sampling strategy/ formulae that will be used to sample participants and include the sample size.
- 3.8.4 Inclusion and Exclusion Criteria** → ▪ Clearly state inclusion & exclusion criteria that will be used.
- 3.8.5 Data Collection** → ▪ Specify data collection methods and instruments that will be used (if applicable) and include as appendices to the protocol.
- 3.8.6 Data Analysis** → ▪ Describe software and techniques that will be used for data analysis.
- 3.8.7 Pilot Study** → ▪ Indicate if a pilot study will be conducted and provide details (including the duration, sites, etc.).
- 3.8.8 Research Sites** → ▪ Identify Health Facilities where the research will be conducted i.e. specific Hospitals, Community Health Centres or Primary Health Care Clinics.
- 3.8.9 Ethical Considerations** → ▪ Proof of ethical clearance from a recognised South African Research Ethics Committee should be obtained (if applicable) and provided with the research proposal.
- This section must clearly indicate what ethical issues were considered for the study including informed consent, confidentiality, etc.
- 3.8.10 Feedback and Dissemination 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 KwaZulu-Natal Department of Health.

- 3.8.11 Budget →
 - Indicate whether the Researcher(s), Company, Institution or Organisation will be financing the research.

- 3.8.12 Human Resources →
 - Specify who will be involved in conducting the research including Research Assistants and Statisticians.

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

- 3.8.14 References 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 instruments/ tools and any other relevant documentation referred to in the research proposal.

- 3.8.15 Permission from Facilities →
 - Written permission from District and/or Facility Managers granting permission for research to be conducted in facilities must be attached to the research proposal.

4. SUBMISSION OF RESEARCH PROPOSALS

Research Proposals (including all supporting documents as mentioned in section 3) and a cover letter can be hand delivered, sent via post, courier service, e-mail or fax to the Health Research & Knowledge Management Sub-Component. The contact details are:

Postal Address:

Health Research & Knowledge Management
 Private Bag X9051
 Pietermaritzburg
 3200

Physical Address:

Health Research & Knowledge Management
Natalia Building 10 - 102 South Tower
330 Langalibalele Street
Pietermaritzburg
3201

Fax:

+27 33 394 3782

E-mail Address:

hrkm@kznhealth.gov.za

5. THE REVIEW PROCESS

- 5.1. The research proposal, allocated to one of the Principal Technical Advisors in the Health Research & Knowledge Management Sub-Component, will be assigned a unique identifier number after which the Principal Investigator is notified of receipt of proposal and the unique identifier number.
- 5.2. The proposal is reviewed (in the presence of all the required documentation) by the assigned Principal Technical Advisor and Manager in the Sub-Component.
- 5.3. If the proposal is recommended by the Manager, it is submitted to the General Manager: Health Services Planning Monitoring and Evaluation for recommendation and submission to the Provincial Health Research Committee for approval.
- 5.4. If the Health Research Committee approves the research, a letter of approval is submitted to the Principal Investigator either by fax or e-mail.
- 5.5. The Principal Investigator is required to make the necessary arrangements with the relevant Health Facilities after written approval of the research is received. The research can now commence.
- 5.6. If approval is not granted the Principal Investigator will be informed in writing.
- 5.7. The approval process takes approximately two weeks after receipt of the complete proposal package.

6. INTERIM PROGRESS REPORTS AND FINAL REPORT

- 6.1. Researchers are required to provide feedback on research once it commences.
- 6.2. If the duration of the research is less than six months, one interim report must be submitted to Health Research and Knowledge Management (Section 4: Contact Details) followed by the final research report once the research is completed.
- 6.3. If the duration of the research is greater than six months, bi-annual reports must be submitted to Health Research & Knowledge Management followed by the final research report once the research is completed.
- 6.4. Research results and recommendations must be formally presented to Departmental stakeholders including Management, Health Research & Knowledge Management and relevant District/ Facility stakeholders. It is preferred that feedback is given at District level to ensure representation of all stakeholders.
- 6.5. Arrangements for dissemination of results can be made in consultation with the Principal Technical Advisor: Health Research & Knowledge Management responsible for processing the specific research.

PART B

GUIDELINES: OBTAINING AUTHORITY TO UNDERTAKE A CLINICAL TRIAL IN PROVINCIAL HEALTH FACILITIES

- Applicant →
- Pharmaceutical Company or their agent; OR
 - Individual Clinician; OR
 - NU Health (Pty) (Ltd) - facilitates research at the University of KwaZulu-Natal (UKZN) College of Health Sciences.
- Health Facility →
- A Provincial Health Facility managed by the KwaZulu-Natal Department of Health.
- MCC →
- Medicines Control Council.
- Ethics Committee →
- Ethics Committee of the College of Health Sciences, UKZN; OR
 - Other recognised South African Ethics Committees.
- KwaZulu-Natal Department of Health →
- Health Research and Knowledge Management Sub-Component.
 - Pharmaceutical System Development.
 - Provincial Health Research Committee.

1. ROLES AND RESPONSIBILITIES

- Health Research and Knowledge Management →
- Ensure that all administrative aspects of research applications have been complied with.
 - Recommendation and submission of the research proposal to the Provincial Health Research Committee for recommendation and submission to the Head of Department for final approval.
- Pharmaceutical System Development →
- Conduct the technical evaluation of Clinical Drug Trial applications **before** submission of the proposal to Health Research and Knowledge Management for processing.

Provincial Health Research Committee	→	<ul style="list-style-type: none"> ▪ Assessment and final recommendation of the research proposal before submission to the Head of Department: KwaZulu-Natal Department of health for final approval.
Head of Department, KwaZulu-Natal Department of Health	→	<ul style="list-style-type: none"> ▪ Approval of Clinical Trial to be conducted in Provincial Health Facilities.
Medicines Control Council	→	<ul style="list-style-type: none"> ▪ Attends to compliance with regulatory matters.
NU Health	→	<ul style="list-style-type: none"> ▪ Facilitate the application and approval process of studies that involve the College of Health Sciences at UKZN, before submission to Pharmaceutical System Development and Health Research and Knowledge Management.
Ethics Committee	→	<ul style="list-style-type: none"> ▪ The Ethics Committee of the Medical Faculty gives ethical approval for studies undertaken by UKZN staff. ▪ A recognised South African Ethics Committee gives ethical approval in the case of other investigators.

2. SUBMISSION OF THE CLINICAL TRIAL PROTOCOL

2.1 The applicant must complete the prescribed application forms (Annexure 1) and submit it together with the protocol and other relevant documents to Pharmaceutical Systems Development: KwaZulu-Natal Department of Health for technical evaluation **prior** to submitting the complete proposal to Health Research & Knowledge Management.

The application must include the following:

2.1.1 A complete Trial Protocol using the Guidelines for Research Proposals (*Part A, Section 3 - Guidelines for Submitting a Research Proposal*).

2.1.2 Application Form (*Annexure 1: Application to Conduct a Clinical Drug Trial*) completed in full and signed by all the relevant persons.

2.1.3 Summary of Details Form (*Annexure 2: Summary of Clinical Drug Trial Details Required By the KwaZulu-Natal Department of Health*).

- 2.1.3. Proof of adequate insurance (carried by the applicant) to cover unforeseen adverse events during the trial must be submitted with the application.
- 2.1.4 Signed MCC approval for the trial if the product(s) involved in the trial is not registered with the MCC.
- NOTE:** The name of the Principal Investigator must appear on this document.
- 2.1.5. Signed ethical approval for the trial from a recognised South African Ethics Committee.
- 2.1.6 Approval from the Hospital Manager(s) of institution(s) where the trial will be conducted.
- NOTE:** If the trial is to be conducted at more than one Health Institution, an application form must be completed for each Institution and approval obtained for each individual institution. Institutions reserve the right to conduct their own technical evaluation of the trial before consent is given for the trial to be conducted in their institution.
- NOTE:** All applications must be submitted on the original form. Faxes or photocopies of signatures will not be accepted.
- 2.2 All studies that involve the College of Health Sciences at UKZN must submit proposals via NU Health before submission to Pharmaceutical Systems Development. Other Investigators must submit proposals directly to Pharmaceutical Systems Development.
- 2.3 Pharmaceutical System Development will, after technical evaluation and approval of the trial proposal, submit the complete proposal to Health Research & Knowledge Management for further management and processing.
- 2.4 The proposal (with all the supporting documents) and a cover letter can be hand delivered, sent via post, courier service, e-mail or fax to Pharmaceutical System Development. The contact details are:

Postal Address:

Pharmaceutical Systems Development
Private Bag X9051
Pietermaritzburg
3200

Physical Address:

Pharmaceutical Systems Development
Capital Towers Building 10 - 12
121 Chief Albert Luthuli Street
Pietermaritzburg
3201

Fax:

+27 33 846 7280

E-mail Address:

peter.avery@kznhealth.gov.za

3. COST

The applicant or company undertaking a trial does so at no expense to the KwaZulu-Natal Department of Health. The company/ firm/ organisation must:

- 3.1 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. If laboratory investigations are not done privately, the applicant, investigator, Head of Chemical Pathology and Head of Laboratory Services must reach agreement regarding the costs involved.
- 3.2 Patients that are entered into trials are considered paying patients and in-patient and out-patient fees must therefore be levied. This payment includes payment for out-patient visits, in-patient costs where the patient may be admitted, diagnostic procedures such as x-rays, scans, etc. These fees will be calculated from the official Fees Manual.
- 3.3 Specific costs for each trial will be calculated and negotiated once the trial protocol has been received.
- 3.4 If the trialists are to be compensated in any way, full details of the compensation must be declared to the KwaZulu-Natal Department of Health before authority will be granted to proceed with the trial. The applicant must in this case confirm that payment will be made to a recognised research fund, preferably the UKZN Research Fund which is administered by the Dean of the Faculty of Medicine.
- 3.5 Costs due to Hospital(s) for use of facilities during the trial will be calculated by the Hospital (in consultation with Pharmaceutical System Development if necessary) from the current Fees Manual and an invoice submitted to the applicant.

- 3.6 The costs must be paid directly to the hospital by the applicant. Confirmation of this invoice/ payment must form part of the application documentation.
- 3.7 Details of other funding must be disclosed. 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.

4. THE REVIEW PROCESS

- 4.1 Pharmaceutical Systems Development will record the trial in a register and conduct the technical evaluation of the trial proposal. If satisfied that the trial complies with all the legal requirements the complete proposal is submitted to Health Research and Knowledge Management for further processing.
- 4.2 Health Research & Knowledge Management assign the trial a unique identifier number and notify the Principal Investigator of receipt and the unique identifier number of the trial proposal.
- 4.3 The proposal is reviewed (in the presence of all the required documentation) by the assigned Principal Technical Advisor and Manager in the Sub-Component. Research Committees (based at Hospitals) may be consulted for technical support.
- 4.4 If the proposal is recommended by the Health Research and Knowledge Management Manager it is submitted through the General Manager: Health Services Planning Monitoring and Evaluation to the Provincial Health Research Committee for recommendation and submission to the Head of Department: KwaZulu-Natal Department of Health.
- 4.5 The Head of Department: KwaZulu-Natal Department of Health must approve all trials to be conducted in health facilities.
- 4.6 If the trial is approved, a letter of approval is submitted to the Principal Investigator either by fax or e-mail.
- 4.7 The Principal Investigator is required to make the necessary arrangements as stipulated in the notification letter. The research can now commence.
- 4.8 If approval is not granted the Principal Investigator will be informed in writing.
- 4.9 The approval process takes approximately two to four weeks after receipt of the complete proposal package.

5. INTERIM PROGRESS REPORTS AND FINAL REPORT

- 5.1 Researchers are required to provide feedback on research once it commences.
- 5.2 If the duration of the research is less than six months, one interim report must be submitted to Health Research and Knowledge Management (Section 4: Contact Details) followed by the final research report once the research is completed.
- 5.3 If the duration of the research is greater than six months, bi-annual reports must be submitted to Health Research & Knowledge Management followed by the final research report once the research is completed.
- 5.4 Research results and recommendations must be formally presented to Departmental stakeholders including Management, Health Research & Knowledge Management and relevant District/ Facility stakeholders. It is preferred that feedback is given at District level to ensure representation of all stakeholders.
- 5.5 Arrangements for dissemination of results can be made in consultation with the Principal Technical Advisor: Health Research & Knowledge Management responsible for processing the specific research.
- 5.6 On completion of the study, reconciliation is done to determine the number of patients recruited into the study agrees with the number of patients for which payment has been made.



ANNEXURE 1

KWAZULU-NATAL - DEPARTMENT OF HEALTH APPLICATION TO CONDUCT A CLINICAL DRUG TRIAL

A. GENERAL INFORMATION

1. Name and address of applicant (company or individual) wishing to conduct the Clinical Drug Trial:

2. Person representing the applicant (where applicant is a Company):

2.1 Name:

2.2 Qualifications:

2.3 Designation:

2.4 Address:

2.5 Telephone No. (Business):

2.6 Fax No.:

2.7 Telephone No. (Home):

3. Investigator's Information:

3.1 Name:

3.2 Designation:

3.3 Address:

3.4 Telephone No:

3.5 Fax No:

3.6 Cell No :

B. STUDY INFORMATION

1. Objective(s) of the trial:

2. Method:

2.1 Study design:

2.2 Patient No's.:

2.3 Duration:

2.4 Has a previous trial been conducted? If yes, where? Provide details of the trial.

2.5 Is the Protocol suggested a modification of any previously followed protocols?

Yes No

2.6 Will the applicant be responsible for providing (free of charge) all materials and/ or equipment required for this trial?

Yes No

2.7 If yes to 2.6 above, state the name and address of Institution/Company that will be responsible for providing materials and/or equipment for the above mentioned trial.

3. Relevant Company Insurance and Number

4. Summary of Information on Test Product with reference to the included Protocol

- 4.1 Approved Name: Page:
- 4.2 Chemical Formula: Page:
- 4.3 Dosage form and strength: Page:
- 4.4 Mode of Action: Page:
- 4.5 Mode of Administration: Page:
- 4.6 Dosage: Page:
- 4.7 Duration of Treatment: Page:
- 4.8 Storage instructions or any special precautionary measures to be taken and by whom: Page:
- 4.9 How much test material will be supplied? (State quantity in words and figures).
- a. Test compound:
 - b. Comparator:
 - c. Placebo:
- 4.10 If more material for this trial is required, are you prepared to provide this free of charge?
- Yes No
- 4.11 Scientific information attached as appendices (if applicable)
- a. Pre-clinical data Page:
 - b. Clinical data Page:
- 4.12 Status of registration in other countries (if not registered in RSA):

5. Special Investigations:

5.1 What laboratory investigations will be required?

5.2 What equipment will be required?

5.3 What arrangements have been made for investigations and with whom?

C. DECLARATION

1. Declaration by Applicant (company)

I/We _____ agree to conduct the above said trial under conditions as stated in this application form.

I/We also agree to conduct this trial at no expense whatsoever to the KwaZulu-Natal Department of Health and to accept full responsibility for any/ all possible harmful effects caused by my/our product and in this respect exonerating the KwaZulu-Natal Department of Health, from all liability and damages legally, financially, or otherwise, except for negligence on the part of the doctor or employee of the Department in administering the said product to the patient(s) concerned. Should it be deemed necessary to deviate from the protocol or stop the trial, then I shall inform the Head of Department: KwaZulu-Natal Department of Health.

I/We further agree to make available, without delay, all the results of this trial to the Head of Department: KwaZulu-Natal Department of Health.

I/We further understand that the Department of Health having allowed this trial to be conducted, places itself under no obligation whatsoever, and the final choice of the Institution for this trial is left to the Head of Department: KwaZulu-Natal Department of Health.

Signature of Applicant: _____ Date: _____

Signature of Managing Director
of firm asking for this trial: _____ Date: _____

Witnesses:

1. _____ Date: _____

2. _____ Date: _____

If **not** a Company, state designation:

Signature of Medical Director/Monitor/CRA of Applicant:

Signature: _____

Date: _____

Witnesses:

1. _____

Date: _____

2. _____

Date: _____

D. APPROVALS

1. MCC authorisation given?

Yes No
Not required Pending

1.1 If yes, supply the number and attach a copy of the authorisation.

1.2 If the product has been registered, supply the Registration Number:

Comments (if appropriate)

2. Ethical Approval for the trial:

Yes No Pending

If yes to 2, attach a copy of the approval

Comments:

3. Approval of Hospital Manager/Medical Manager of the specified Institution for the stipulated trialist(s) to conduct the abovementioned Clinical Trial in the specified Institution.

Comments:

Signature: _____

Name: _____

Designation: _____

Date: _____

E. INVESTIGATOR RESPONSIBILITIES

1. Declaration by Investigator:

- i) I hereby agree to conduct the Clinical Trial as specified in the Protocol and to obtain in writing the necessary authorisation from the relevant Ethical or Clinical bodies (if not already done) before final submission of Protocol for approval.
- ii) I undertake to discuss the funding of the trial with the KwaZulu-Natal Department of Health, if relevant.
- iii) I agree to obtain informed consent from patients who are legally competent in all cases.
- iv) I agree to obtain consent from the firm, Hospital Management and the Head of Department: KwaZulu-Natal Department of Health should I wish to deviate from the Protocol.
- v) I agree to render a full report of my findings at the end of this trial and to render a progress report periodically as instructed to the Head of Department: KwaZulu-Natal Department of Health.
- vi) I agree not to publish any report relevant to the trial without the permission of the Head of Department: KwaZulu-Natal Department of Health and the sponsor.

Signature: _____

Name: _____

Designation: _____

Date: _____

**F. FINAL APPROVAL
HEAD OF DEPARTMENT: KWAZULU-NATAL DEPARTMENT OF HEALTH**

APPROVED / NOT APPROVED

Comments:

Signature: _____

Name: _____

Designation: _____

Date: _____

ANNEXURE 2

SUMMARY OF CLINICAL DRUG TRIAL DETAILS REQUIRED BY THE KWAZULU-NATAL DEPARTMENT OF HEALTH

Completion of the following details is essential for the speedy approval of the Clinical Drug Trial.

1. ITEM	
2. STUDY PROTOCOL NUMBER	
3. NUMBER OF PATIENTS TO BE RECRUITED AT THIS SITE	
4. NUMBER OF OUTPATIENT VISITS PER PATIENT	
5. DIAGNOSTIC INVESTIGATIONS	
6. NUMBER OF ECG's PER PATIENT	
7. NUMBER OF X-RAYS PER PATIENT	
8. NUMBER OF CT SCANS PER PATIENT	
9. NUMBER OF MRI SCANS PER PATIENT	
10. OTHER	
11. LABORATORY INVESTIGATIONS	PRIVATE HOSPITAL
12. MCC REGISTRATION NUMBER	
13. IF NOT REGISTERED – MCC AUTHORITY NUMBER	26/8/1/2/1 ()
14. ETHICS COMMITTEE APPROVAL	PENDING / SUBMITTED TO THIS OFFICE