health
Department:
Health
PROVINCE OF KWAZULU-NATAL

APPLICATION TO CONDUCT A CLINICAL TRIAL

Please ensure all fields are completed. Please ensure all documentation is attached.

Completed forms together with relevant documents must be submitted with the research application on the NHRD website: http://nhrd.hst.org.za

SECTION A : GENERAL INFORMATION		
1.	Principal Investigator Information:	
	1.1. Name and Surname	
	1.2. Designation	
	1.3. Address	
	1.4. Telephone No	
	1.5. Fax No	
	1.6. Mobile No	
	1.7. Organisation(s) and Affiliation(s)	
	1.8. Registration (Professional Council)	
	1.9. Relationship with Funder	
2.	Is this application on behalf of a company? ☐ Yes ☐ No *If **YES**, please complete questions 3 & 4.* *If **NO,** please complete question 5.*	
3.	Details of applicant (company) wishing to conduct the Clinical Trial:	
	3.1. Name	
	3.2. Physical Address	

	3.3. Postal Address	
	3.4. Email Address	
	3.5. Web Address (if applicable)	
	3.6. Telephone No. (Business)	
	3.7. Telephone No. (Home)	
	3.8. Fax No.	
4.	Details of person representing the applicant *(where the applicant is a Company)*	
	4.1. Name	
	4.2. Qualifications	
	4.3. Designation	
	4.4. Physical Address	
	4.5. Postal Address	
	4.6. Email address	
	4.7. Telephone No. (Business)	
	4.8. Telephone No. (Home)	
	4.9. Fax No.	
5.	Who is funding this clinical trial? Please provide the details	
	5.1. Name of Funder	
	5.2. Duration of the funding	
	5.3. Is there insurance for trial participants? ☐ Yes ☐ No *Please provide proof (Relevant Company Insurance and Number)*	

SECTION B : STUDY INFORMATION		
1.	**PROTOCOL TITLE**	
1.1.	**PROTOCOL & VERSION NUMBER**	
1.2.	**SA CLINICAL TRIAL REGISTER NUMBER (Provide reason for non-registration)**	
2.	**OBJECTIVES/S OF THE TRIAL**	
3.	**POTENTIAL BENEFITS AND RELEVANCE OF THE TRIAL TO THE DEPARTMENT OF HEALTH**	
4.	**METHODOLOGY**	
	4.1. Study design:	
	4.2. Please indicate the type of trial the study is: ☐ Facility based trial ☐ Community based trial	
	4.3. Please indicate where the trial will be conducted (community area, name of public health facilities) List the community of facilities below (Please attach a separate addendum if the space provided is small):	
	4.4. Please indicate where participants will be recruited from: ☐ KZN DoH Health facilities ☐ Community	

List the facilities below (Please attach a separate addendum if the space provided is small):

4.5. Please attach a letter of **motivation** for choosing the above study and or recruitment site (s), and **letters of support** from the sites listed below

4.6. If the recruitment site is different form where the study will be conducted, please specify:

1. How are participants going to be transported from the recruitment site to the study site?

2. Will the participants be insured should there be any adverse events or road accidents whilst they are transported? Yes☐ No ☐

3. Has the KZN-DoH been indemnified against these adverse events or road accidents in 4.5. (iv) above? Yes☐ No ☐

4. How will participants be reimbursed should they provide their own transport to the trial site?

4.7. Number of patients to be enrolled in the trial	*Indicate the total number as well as the number for each arm*
4.8. Duration of the trial	

4.7. Has a previous trial using this intervention been conducted? ☐ Yes ☐ No

4.8. If yes, Provide details of the previous trial(s) and motivate why this intervention is still being studied.

5.	**STANDARD OF CARE FOR TRIAL PARTICIPANTS IN FACILITY BASED TRIALS** For trials conducted within KZN Department of Health facilities, the KZN Department of Health will consider providing the standard of care to the participants participating in a clinical trial depending on the responses to the points below.
	5.1. Is the standard of care for trial participants different or above that of the standard of care provided by the KZN Department of Health? ☐ Yes ☐ No
	5.2. Please provide details of the standard of care for participants in this trial
	5.3. Who will provide the standard of care to trial participants?
	5.4. At which facilities will the standard of care for participants be given? 5.4.1. 5.4.2. 5.4.3. 5.4.4. 5.4.5.
	5.5. Will the participants be provided with non-drug treatment? ☐ Yes ☐ No *If yes, please explain*
	5.6. Please indicate who will provide the non-drug treatment, if applicable
6.	**STUDY TREATMENT INFORMATION**
	6.1. Will the applicant be responsible for providing **(free of charge)** the treatment intervention? ☐ Yes ☐ No
	6.2. Please indicate whether the intervention is a: ☐ Clinical Drug ☐ Medical Device ☐ Other Intervention

	6.3. Please describe the treatment being tested in this trial	
	6.4. Please describe the mechanism of action of the treatment being tested	
	6.5. What is the duration of intervention/treatment?	
	6.6. If the treatment is a **drug**, please complete the section below.	
	6.7.1. Approved Drug Name	
	6.7.2. Chemical Formula	
	6.7.3. Dosage Form and Strength	
	6.7.4. Mode of Action	
	6.7.5. Mode of Administration	
	6.7.6. Dosage	
	6.7.7. Duration of treatment	
	6.7.8. Storage instructions	
	6.7.9. Are there any special precautionary measures to be taken and by whom?	
	6.7.10. Who will be responsible for dispensing of the trial drugs?	
	6.7.11. If the clinical trial will have its own dispensing staff, is there a Research Pharmacy License? ☐ Yes ☐ No *If **yes**, please provide proof.*	
	6.7.12. How much test material will be supplied? (State quantity in words and figures)	

Test Compound	
Comparator	
Placebo	

6.7.13. If more material for this trial is required, will the company funding this trial provide this free of charge? ☐ Yes ☐ No

6.7.14. Scientific information attached as appendices *(if applicable)*

6.7.14.1.	Pre-Clinical Data	☐ Included ☐ Not included
6.7.14.2.	Clinical Data	☐ Included ☐ Not included

6.7.15. Status of registration in other countries *(if **not** registered in RSA)*
☐ Included ☐ Not included

6.7.2. If the treatment is a **medical device**, please complete the section below

6.7.2.1. Name of medical device

6.7.2.2. Brand name of medical device

6.7.2.3. Who is the manufacturer of the device?

6.7.2.4. Is the device licensed? ☐ Yes ☐ No
*If **yes**, please explain the type of license obtained.*

6.7.2.5. Model /Series/System (if applicable)

6.7.2.6. Class of the medical device:

☐ Class A: Low risk

☐ Class B: Low moderate risk

☐ Class C: Moderate high risk

☐ Class D: High risk (related to patient and public health)

6.7.2.7. Reason for above classification of Medical Device

	6.7.2.8. Mode of Action
	6.7.2.9. Mode of Administration
	6.7.2.10. Dosage
	6.7.2.11. Duration of treatment
	6.7.2.12. Storage instructions
7.	**POST-TRIAL CARE AND HAND-OVER**
	7.1. If the trial intervention is shown to benefit trial participants, who will provide access to the drug/intervention to participants after the trial?
	7.2. For how long will post trial care for trial participants be provided?
	7.3. When and how will trial participants be handed over to the KZN Department of Health after the completion of the trial?
	7.4. To which public health facilities will trial participants be transferred? 7.4.1. 7.4.2. 7.4.3. 7.4.4.
8.	**TRIAL MATERIALS AND EQUIPMENT**
	8.1. Please describe investigations and laboratory tests (e.g. sputum, blood tests) that will be used for the trial as outlined in the sections below.
	8.1.1. What laboratory investigations will be required, and how often will these tests be done? Please indicate how these deviate from the routine tests performed in standard patient treatment.

	8.1.2. Which laboratory (ies) will perform these investigations?
	8.1.3. Who will reimburse the laboratory (ies) for the tests?
	8.1.4. What other trial investigations and tests will be required in the trial?
	8.1.5. How do these deviate from the routine tests performed in standard patient treatment?
	8.1.6. Who will be responsible for the costs of these investigations and tests?
	8.1.7. If additional specimens are required for investigations over and above those required for standard of care by the KZN Department of Health, who will collect those specimens?
9.	**ADDITIONAL MATERIALS AND EQUIPMENT**
	9.1. Are there any other additional materials and equipment over and above for standard of care required for the clinical trial? ☐ Yes ☐ No *If yes, please describe.*
	9.2. Who will be responsible for providing these materials and equipment?
10.	**UTILISATION OF PUBLIC SECTOR FACILITIES**
	10.1. Hospitals
	10.1.1. Will patients be hospitalised in public hospitals for the trial? ☐ Yes ☐ No
	10.1.2. If so, list the total number of bed days required over and above the standard of care
	10.1.3. The trialist is responsible for extra bed occupancy over and above the standard of care. Hence, the trialist is required to reimburse the KZN Department of Health for the rate specified for private patients in the current Patients Fees Manual. Estimate the amount owing to the KZN Department based on this rate. R_____

	10.1.4. The trialist should ensure that the time spent in hospital over and above the standard of care is explained, understood and agreed to by each participant. Indicate the page on the consent form on which this is explained. Page no _____
	10.2. Clinics/Community Health Centres/Hospital Outpatient Departments
	10.2.1. Will the trial participants be treated at a public sector clinic/community health centre or the outpatients department of a public sector hospital during this trial? ☐ Yes ☐ No
	10.2.2. If so, indicate the number of visits per facility that will be required, over and above the standard of care
	10.2.3. The trialist should reimburse the KZN Department of Health for visits over and above the standard of care, at the rate specified for private patients in the current Patients Fees Manual. Estimate the amount owing to the KZN Department of Health based on this rate. R _____
	10.3. Will the trial participants be compensated for transport costs? ☐ Yes ☐ No
	10.4. If yes, what amount will be paid per visit to the trial site? R _____

SECTION C: APPROVALS

1.	Has this study obtained SAHPRA authorisation? ☐ Yes ☐ No
2.	If yes, what is the SAHPRA registration number? _____ *Please attach a copy of the authorisation* **NOTE**: On request, the *KZN Department of Health will review the trial whilst awaiting SAHPRA approval but will **ONLY** approve the clinical trial once it has received SAHPRA approval.*
3.	Research Pharmacy Dispensing License (*Please attach copy*) ☐ Yes ☐ No ☐ N/A
4.	Ethical Approval for the trial: ☐ Yes ☐ No *If **YES**, attach a copy of the approval.*

5.	**DEPARTMENTAL SUPPORT FOR THE TRIAL** For facility based trials, letter(s) of support are required from the management of the specified Institution (Hospital Manager/Operational Manager/District Manager/Programme Manager according to the Guidelines for submitting research proposals for approval) for the conduct of the above mentioned trial in the specified Institution. (*Please attach copies with the application)* For community based trials, letters of support are required from District or Programme managers (*Please attach copies with the application)*	
	FINAL APPROVAL FOR THE TRIAL Upon recommendation of the trial by the Chairperson of the Provincial Health Research & Ethics Committee (PHREC), final Approval for the trial to proceed will be given by the Head of Health, KwaZulu-Natal Department of Health.	
	SECTION D: DECLARATION BY PRINCIPAL INVESTIGATOR(S)	PI Initial
1.	I hereby agree to conduct the trial as specified in this application form, the appended protocol and the KZN Department of Health guidelines.	
2.	I agree to conduct this trial at no expense whatsoever to the KZN Department of Health.	
3.	For patients treated in public health facilities, I agree that any additional costs over and above the standard of care will be incurred by the trialist and will be calculated with the assistance of the Finance Component of the KZN Department of Health and reimbursed in full to the KZN Department of Health.	
4.	I accept full responsibility for any/ all possible harmful effects caused by my/ our product or intervention and in this respect exonerate the KZN Department of Health from all liability and damages legally, financially, or otherwise.	
5.	Should it be deemed necessary to stop the trial, I shall inform the Data Safety Monitoring Board and the PHREC Chairperson within 2 weeks of stopping the trial.	
6.	I agree 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.	
7.	I agree to obtain written consent from the PHREC Chairperson, should I wish to deviate from the submitted protocol.	
8.	I undertake to discuss matters arising from the trial with the KZN Department of Health if relevant.	
9.	I agree to render a progress report every annually and the full report of my findings at the end of this trial to the PHREC Chairperson	
10.	I undertake to ensure that information regarding participants' management and treatment in the trial is available on their KZN Department of Health patient-held cards.	

11.	I undertake to ensure the smooth transition of trial participants from the trial to the care of the KZN Department of Health, and to discuss this transition with the relevant facilities prior to and during the transition period.	
12.	I agree to obtain informed consent from legally competent participants who will be participating in the clinical trial.	
13.	If the participant is a child, I agree to obtain consent from parents/guardians of children participating in the trial, from the relevant authorities as per Section 71 of the National Health Act, as well as assent from the children themselves.	
14.	I undertake to facilitate the post-trial access of participants to trial treatments, should these be found to be beneficial.	
15.	I agree to inform the PHREC Chairperson of any publications arising from the clinical trial and will provide the publication to the PHREC Chairperson.	
16.	I further understand that the Department of Health having allowed this trial to be conducted, places itself under no obligation whatsoever, and that the Department may, through the PHREC Chairperson, terminate this trial at any point if patient care or rights are compromised.	

SIGNATURES:

Name of Principal Investigator:

_____

Signature of Principal Investigator:

_____

Date: _____

Name of Managing Director of firm asking for this trial (if applicable):

_____

Signature of Managing Director of firm asking for this trial (if applicable):

_____

Date: _____

Witness 1	**Witness 2**
Name: _____	**Name:** _____
Signature: _____	**Signature:** _____