A. GENERAL INFORMATION

1. Name and address of the 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: _____