ANNEXURE

A

Application Form

PMREC
APPLICATION FOF

LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

POLOKWANE MANKWENG RESEARCH ETHICS COMMITTEE

APPLICATION FORM

SECTION 1

A. **PARTICULARS OF APPLICANT/CHIEF RESEARCHER**

First Name: ……Surname:……. …. Title: ,,,,,,,,,,

Degree(specify if applicable)_____

Department(if applicable)……..……

Tel: ……..

B. **DETAILS OF RESEARCH PROJECT**
(Tick appropriate block(s) with a 'x'

1.a	New project	☐	or : Continuation of project	☐
1.b	Independent research:	☐	or : Contract research:	☐
1.c	Post-graduate research:	☐	or : Undergraduate research :	☐

2.a. Title of project:

2. b. Co-workers (Not for post-graduate research)

Name	Department/Institution	Signature

2. c. Supervisor (In the case of post-graduate research)

Name	Department/Institution	Signature

2. d. Research Co-ordinator (In the case of independent or contract research)

Name	Department/Institution	Signature

2. e. Co-supervisor (In the case of post-graduate research)

Name	Department/Institution	Signature

2. f. Hospital Executive Clinical Director

Name	Department/Institution	Signature

C. **SPECIAL REQUIREMENTS**

Will the research involve the following:

	Yes	No		Yes	No
Experimental animals			Approval from Animal ethics Committee attached (separate application form required)		
Special apparatus			Is it available at PMHC?		
			If no, attach a statement of requirements		
Radio isotopes			Completed radio Isotopes form attached (Appendix 4)		
Special laboratory facilities			Is it available at PMHC? If no, attach a statement of requirements		
Electron microscopy			Completed Electron microscope form attached (Appendix 3)		
Health care services			Signature of health care manager attached		

Statistical analysis			Has a statistician been consulted? If yes, attach form. (Appendix 2) If no, explain.		

D. **ETHICAL ISSUES**

1. *Indemnity*

If another hospital (human, dental or veterinary) will be involved, please attach the written approval of the Superintendent. Should the use of the additional (more specialized than normal clinical practice) service laboratories be required, attached a letter of consent of the hospital Clinical Manager that this is in order.

2. *Consent*

Will patients/human volunteers form part of the experiment/trial/survey? If so, kindly modify the attached form, specifically for your project. (Appendix 1)

E. BUDGET

Who will finance this project? (Tick appropriate block with a "x")

Parent Institution		Health Department		Self		Other (specify)	

Please indicate the institutions where application has been made for financial support or where it is intended to apply for financial support.

MRC		NRF		CSD		Other (specify)	

NB: Approval of the research project does **NOT** imply that the requested funds will be made available to the applicant.

SECTION 2

THE FOLLOWING SECTIONS MUST ALL BE COMPLETED

Please tick all relevant boxes.

3.1 PURPOSE OF THE RESEARCH:

Postgraduate: degree/diploma (state which) ☐

Undergraduate: degree/diploma (state which) ☐

Not for degree purposes (State purpose hereunder) ☐

_____

3.2 OBJECTIVES OF THE RESEARCH (please list):

Please do not refer to an attached list – expand the space below to include the information required:

3.3 SUMMARY OF THE RESEARCH (give a brief outline of the research plan):

Please do not refer to an attachment – expand the space below to include the information required:

3.4 What are the Investigator's anticipated ethical concerns with the project?

3.5 What capacity building is planned for Limpopo Province/South Africa in this study?

SECTION 3

4. REQUIREMENTS

4.1 If this project involves studies with drugs at this Institution, approval must first be obtained from the Hospital Management.

Has approval been granted?
(Note : Approved request should have a signature of Management under Section 1 above)

Yes ☐ No ☐
(If not, this application cannot be considered)

4.2 In terms of radiation aspects of radiological investigations or use of isotopes related to the trial:

4.2.1 Please confirm if the radiological investigations or use of isotopes required in the study are in line with accepted standards of care for the patient's condition?

a. Yes ☐ No ☐

b. If Yes, please provide a written letter from a non-study related Clinician that is able to confirm this

4.2.2 If No, please advise if the study has already been approved in Europe; and/or US and/or Japan:

a. For studies already approved in Europe please list the European countries in which the study has been approved and when:

b. For studies not yet approved in Europe but approved in the US and/or Japan please provide the details of the expert review body (or bodies) and a list of their members that considered and approved the radiation risk benefit of the imaging required in the protocol:

4.2.3 If the study has not yet been approved in any of the above jurisdictions written approval must be obtained from the Department of Radiology at Pietersburg Hospital. For patients these are radiation dosages over and above those for standard diagnostics / therapy

Is this attached? If not, the application cannot be considered.

Yes ☐ No ☐

4.3 Participant Information Sheet is attached. (For written and verbal consent)

Yes ☐ No ☐

Informed Consent Form is attached. (For written consent).

Yes ☐ No ☐

Consent will be verbal

Yes ☐ No ☐

Informed consent is not necessary. State why not.

Yes ☐ No ☐

4.4 If a Questionnaire or Interview is to be used in the research, it must be attached. Is it attached? *If not, the application cannot be considered***.**

Yes ☐ No ☐

SECTION 4

5. PARTICIPANTS FOR STUDY

5.1 If patients are being utilized as participants, state where and how the participants will be selected *(i.e. state the recruitment strategies)*

5.2. Where the participants are not patients,

They will be invited to volunteer ☐ they will be selected ☐

State how the participants will be selected , or who is invited to volunteer:

Are the participants subordinate to the person doing the recruiting?

Yes ☐ No ☐

If yes, justify the selection of subordinate participants:

5.3 Will control participants be used?

Yes☐ No☐

If yes, explain how they will be recruited –

Note : for clinical trials this refers to Control Arm

5.4 Participants records: state what records will be used and how they will be selected:

5.5 Age range of patients/participants/controls:

If under 18 years, from who will consent be obtained?

If under 18 years, is a Patient Assent Document included?

Yes ☐ No ☐

5.6 Gender **:** Male ☐ Female ☐

5.7 Number of patients _____ *Applicable to clinical trials*

Non-patient participants_____ *Not applicable to commercial clinical drug trials*

Controls _____ *Not applicable to commercial clinical drug trial*

5.8 Benefit to patient or participants: will the research benefit the patient(s) or participant(s) in any direct way. If yes, explain in what way.

Yes ☐ No ☐

Are the participants being remunerated for participating in the study?

Yes ☐ No ☐

If yes, please state what the remuneration is for and how much will be paid. _____

5.9 Disadvantages to patients/participants/controls.

Will participation or non-participation disadvantage them in any way? If yes, explain in what way:

Yes ☐ No ☐

5.10 Describe what post-trial access to test medicament (medication) there will be to participants who respond well to the test medicament shown by objective measurements.

5.11 Will participants in the control arm also receive post-trial access to test medication?

SECTION 5

UPDATED PMREC
APPLICATION FOF

6. PROCEDURES

6.1 Mark research procedure(s) that will be used:

☐ Record review (patient file)

☐ Interview form (must be attached)

☐ Questionnaire (must be attached)

☐ Examination (state below nature and frequency of examination)

☐ Drug or other substance administration (state below name(s) of drug(s)/substance(s) and dose(s) and frequency of administration)

☐ X-rays

☐ Isotope administration (state below name(s) of isotope(s) and frequency)

☐ Blood sampling; and the (frequency of blood sampling) ☐venous; ☐arterial (state below amount to be Taken)

☐ Biopsy

Please note: Should a study require a portion or slides of histological diagnostic specimens to be sent away for testing, the anatomical pathologist who has custody of the specimen block must agree to this in writing.

☐ Other procedures (explain)

Use this space to elaborate procedures marked above:

6.2 Is / are procedure/(s) routine for: Diagnosis / Management? ☐
Specific to research? ☐

6.3 Who will carry out the procedure(s)?

- (State name/(s) and position/(s) held per research unit.
- All Principal and Sub-investigators must be listed here,
- Please attach the study specific CV's And Declarations in the required format.

GCP TRAINING: Please list all Investigators GCP Training

Please indicate date and name of GCP Course attended

(Investigators meetings do not qualify as GCP training)

- Full Name:_____
- GCP CourseName: _____
- Date of GCP course:

  day/month/year: _____

  (It is a requirement that a GCP course be attended every THREE years)

ETHICS TRAINING: Please list all Investigators Ethics Training

Please indicate date and name of Ethics Training Course completed

- Full Name:_____
- Ethics Course Name: _____
- Date of Ethics course: day/month/year: _____

6.4 Who will be collecting data, blood samples etc.

6.5 Are data collectors part of the study team or service providers?

6.6 Are data collectors aware of and have they agreed to collect data / specimens?

6.7 When will the research commence in South Africa and/or internationally, and over what approximate time period will the research be conducted?

STARTDATE:_____

ENDDATE: _____

RECRUITMENT START: _____

END DATE: _____

Please include: Anticipated number of participants to be enrolled at each site.

SECTION 6

7. RISKS OF THE PROCEDURE(S) participants/controls will suffer:

☐ No risk ☐ Discomfort

A. Routine diagnosis and standard of care
B. Over and above those for routine diagnosis and treatment

☐ Pain ☐ Possible complications

☐ Side effects from agents used

If you have checked any of the above except "No risk" provide details here:

SECTION 7

8. GENERAL

8.1. Has permission of relevant authority/ies been obtained?
Yes ☐ No ☐ N/A ☐

State name of authority/ies:

8.2 Has this study been submitted to other Ethics Committees?

Yes ☐ No ☐ N/A ☐

If yes, what is the status of the application?

8.3 Confidentiality:

Please explain how confidentiality will be maintained so that participants / controls are not identifiable to persons not involved in the research by answering the questions below:

i. Data de-identification?
ii. Data access / protection (data security)?
iii. Period of data storage?
iv. Period of sample storage?
v. Destruction of data/samples
vi. Sample transfer (Material Transfer Agreements)?
vii. Data transfer (Data Transfer Agreements)?

8.4 Results: to whom will result be made available?

8.5 Finances: There will be financial costs to:

Patient/Participants	Yes ☐	No ☐
Hospital/institution	Yes ☐	No ☐
Other	Yes ☐	No ☐

Explain any box marked 'Yes'

8.6 How will the research be funded?

Please complete details of Funder/Donor/Sponsor Pharmaceutical Company - (Full name and address)

8.7 Any other information, which may be of value to the Committee, should be provided here:

8.8 Select DAIDS Risk/Benefit Category (If NIH Sponsored):

Subpart D – Additional Protections for Children Involved as Participants in Research:

X	Category	Description
☐	45 CFR 46.404	Research not involving greater than minimal risk.
☐	45 CFR 46.405	Research involving greater than minimal risk but presenting the prospect direct benefit to the individual subjects.
☐	45 CFR 46.406	Research involving greater than minimal risk and Presenting no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
☐	45 CFR 46.407	Research not otherwise approvable which presents an Opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
☐	45 CFR 46.408	Requirements for permission by parents or guardians and for assent by children.
☐	45 CFR 46.409	Wards

The Ethics Assessors will select a DAIDS Risk/Benefit Category for NIH Sponsored studies that include minors.

APPLICANT'S INFORMATION AND SIGNATURE:

Note: THE PRINCIPAL INVESTIGATOR IS THE APPLICANT

Name: *Please Print Name*	
Department:	
Telephone No:	
Date	
Signature:	

WHO WILL SUPERVISE THE PROJECT? May not be applicable to commercial clinical trials / drug trials / device trials– please insert N/A – if not applicable)

Name: *Please Print Name*	
Department:	
Telephone No:	
Date	
Signature:	

HEAD OF DEPARTMENT / UNIT OF INSTITUTION IN WHICH STUDY WILL BE CONDUCTED

Name: *Please Print Name*	
Signature:	
Date:	
Head of Dept / Unit of Institution where the Study will be conducted:	
Tel No:	
Fax No:	
Email:	

NAME, CONTACT DETAILS AND SIGNATURE OF COMPANY REPRESENTATIVE / RESEARCH COORDINATOR:

Name: *Please Print Name*	
Signature:	
Date:	
Company:	
Tel No:	
Fax No:	
Email:	

DECLARATION BY RESEARCHER(S)

Should this project be approved, I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research. I/we guarantee to ensure compliance with these approved conditions. Furthermore, I/we undertake **not** to change the procedure as detailed in the protocol but will submit a further application to the Research Committee if changes become necessary

SIGNATURE: _____ DATE: _____
CHIEF RESEARCHER:

SIGNATURE: _____DATE:_____
HEAD OF DEPARTMENT
(not for independent research)

PLEASE NOTE:

1 Please indicate clearly, where correspondence should be sent.

2 Whether written or verbal consent is to be obtained, the HREC requires a Participant Information Sheet written in language understandable to the participant (or guardian) detailing what the participant will be told.

This should include the following:

- Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled:
- The participant may discontinue participation at any time without penalty or loss of benefits:
- A brief description of the research, its duration, procedures and what the participant may expect and/or be expected to do:
- Any foreseeable risks, discomforts, side effects or benefits, including those for placebo:
- Disclosure of alternatives available to the participant. If risks are involved:
- A professional contact name and 24 hour telephone number:
- Explanation whether medical treatment will be provided in the case of a complication developing:
- Compensation for trial related injuries will be in accordance with the ABPI guidelines:
- A separate Patient Information and Informed Consent sheet for blood / tissue samples taken for future testing.

The Participant Information Sheet may be incorporated into the consent form, or the consent form may be submitted separately:

- Please ensure to INVITE the participant to take part in the study; please

include a greeting and introduce yourself.

PMREC requests that the participant be invited – (using a friendly tone):

3 **THE INFORMED CONSENT** Form should include a clear statement that the participant is consenting to involvement in research, and not to treatment, which will not necessarily provide personal benefit. Any personal benefit should be mentioned when this is possible. In a trial containing a placebo, the participant must be made aware that, although the potential risks and benefits of all the substances under trial have been explained, none of the active substances may be administered and it will not be possible for the researcher to reveal whether an active substance or placebo is being administered. An important piece of information is that the participant is free to withdraw from the trial at any time without prejudicing any treatment that is required for existing or future medical conditions. If this is not made clear, the researcher risks the accusation that consent was obtained by subtle coercion (that is, the possibility of prejudice against the participant as a current or future patient).

4. STORAGE OF BLOOD AND/OR TISSUES SAMPLES:

The ethical issues surrounding the storage of blood and/or tissue samples internationally and in South Africa

"If, blood specimens are to be stored for future analysis and it is planned that such analysis will be done outside Wits then the blood must be stored at Wits with release of sub-samples only once projects have been approved by the local Research Ethics Committee applicable to where the research will be done as well as by the Wits Human Research Ethics Committee: (Medical)."

5. SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY (SANCTR)

The South African Cochrane Centre (SACC), in partnership with the National Department of Health (DoH) and the Cochrane Infectious Disease Group, has established a South African registry for all clinical trials conducted in South Africa

The South African National Clinical Trials Registry (SANCTR) is a South African initiative to support clinical trial registration within the Republic of South Africa. The SANCTR is an official registry and member of the World Health Organization (WHO) Network of Primary Registers. The SANCTR provides data to the central WHO International Clinical Trials Registry Platform (ICTRP) through the regional register - PACTR, so that trials registered in the SANCTR are represented in global searches (WHO ICTRP search portal URL: http://apps.who.int/trialsearch)

Please note that there is a new South African National Clinical Trials Registry (SANCTR) database, and that the South African Medical Research Council and the NHREC system/platform is no longer in use. Going forward the only point of trial data entry is the new SANCTR database on this url: https://sanctr.samrc.ac.za/. Please follow this link for information on how to register.

APPENDIX 1

PMREC CONSENT FORM

Statement concerning participation in a Research study

Name of Study :

I have read the information on the aims and objectives of the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Study is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Study has been approved by Pietersburg Mankweng Hospital Complex Ethics Committee. I am fully aware that the results of this Study will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Study

....
Name of patient/volunteer Signature of patient or guardian.

....
Place. Date. Witness

Statement by the Researcher

- I provided verbal and/or written* information regarding this Trial / Study / Project*
- I agree to answer any future questions concerning the Trial / Study / Project* as best as I am able.
- I will adhere to the approved protocol.

....……
Name of Researcher Signature Date Place

*Delete whatever is not applicable.

APPENDIX 2

STATISTICAL ANALYSES

The Chairperson,
Pietersburg Mankweng Hospital Complex Ethics Committee,
Faculty of _____
Box _____
UNIVERSITY OF LIMPOPO
PMHC

Dear Sir/Madam

STATISTICAL ANALYSES

I have studied the research protocol of _____

titled: _____

and I agree/do not agree * to assist with the statistical analyses.

Yours sincerely,

_____
Signature: Statistician

_____
Name in block letters

_____
Date

* Please delete which is not applicable. If you do not agree to assist with the statistical analyses, please provide reasons on a separate sheet.

APPENDIX 3

ELECTRON MICROSCOPE UNIT

A. Outline requirements

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

B. Give estimation of cost (this should be discussed with the Director of the Electron Microscope Unit)

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

SIGNATURE: _____ DATE: _____

DIRECTOR: ELECTRON MICROSCOPE UNIT

APPENDIX 4

RADIO ISOTOPES

a) Will isotopes be used during the course of the experiment: _____

b) If affirmative, state the isotopes to be used _____
_____
_____

c) State the quantity of radioactive materials to be stored:
_____
_____

For what period? _____

Used at any given moment? _____

d) State the name of the registered laboratory where the work will be conducted
_____

e) Do you have previous experience in the handling of radioactive material? If affirmative, please qualify
_____
_____

f) Do the laboratory personnel have any experience in the handling of the radioactive material: Please qualify
_____

g) State the method of disposal after use
_____
_____

SIGNATURE: _____ DATE: _____

RADIATION PROTECTION OFFICER

(Approval of above-mentioned information must be obtained before submission to the Research Committee of the Faculty)

APPENDIX 5: Informed Consent

I Prof/Dr/Mr/Mrs/Miss_____will be participating in a study titled_____ at_____ (Place). The study was explained to me in the language that I am comfortable with, by Principal (Study conductors) or his or her colleague. You are not forced to be part of study if you don't want. We would like to assure you that you are free to opt out of the study any time. You will still continue to take your medications or get help from_____ _____ (Name of the Institution).

Principal Investigator_____Signature_____
Witness 1_____Signature_____
Witness 2_____Signature_____

APPENDIX 6: Assent

I the guardian/Caregiver/Parent of_____
(Name of the Child). I am aware that my child
_____ (Name of the child) is under age (< 18 years) according to law. I have read the information leaflet of the study titled_____
and understood it, as explained by the study conductor (Principal Investigator) or his associated (colleagues). Hence, I am giving you the permission for my child to be part of the study.

Principal Investigator_____Signature_____
Witness 1_____Signature_____
Witness 2_____Signature_____

APPENDIX 7: Adverse Event Reporting Form

This form must be completed and returned to the Polokwane Mankweng Research Ethics Committee (PMREC) Administrator, Mr MA Poopedi as soon as possible but within 7 days for serious adverse events, and within 15 days for other adverse and unexpected events. One form is to be completed per participant, even if several participants are involved in a similar adverse event.

STUDY INFORMATION:

STUDY NAME:

DESCRIPTION OF THE INTERVENTION:

PMREC Research Ethics Committee Number:

1. CLINIC AND PARTICIPANT INFORMATION:

CLINIC NAME:
PARTICIPANT ID:
PARTICIPANT AGE:
PARTICIPANT GENDER:

2. ADVERSE EVENT:

2.1 AE REPORT TYPE: Initial ☐ Follow-Up: ☐

2.2 DATE OF ADVERSE EVENT: / / (DD/MM/YY)

2.3 ADVERSE EVENT REPORTED TO RESEARCHERS BY:

☐ Study participant returning to the site

☐ By other means, specify:

2. 1 COMPONENT OF STUDY, PARTICIPANT INVOLVED IN:	
1 ☐ Baseline	3. ☐ Six months
2 ☐ Six weeks	4. ☐ Other, specify:

2. 2 ADVERSE EVENT SEVERITY:	
1 ☐ Mild	3 ☐ Severe
2 ☐ Moderate	4 ☐ Fatal

2. 3 ADVERSE EVENT DESCRIPTION:
PROVIDE A BRIEF DESCRIPTION OF INJURY/ADVERSE EVENT INCLUDING ANY ACTION TAKEN BY THE STUDY TEAM TO DATE ON BEHALF OF THE PARTICIPANT.

2.4 IS THE ADVERSE EVENT SERIOUS?*	1. ☐ Yes 2. ☐ No

*SERIOUS ADVERSE EVENTS ARE CONSIDERED FATAL OR LIFE THREATENING THAT REQUIRE HOSPITALIZATION OR PROLONG EXISTING HOSPITALIZATION, OR RESULT IN PERSISTENT OR SIGNIFICANT DISABILITY

2.5 CLASSIFICATION OF ADVERSE EVENT	☐ Results in death ☐ Is life-threatening ☐ Requires inpatient hospitalization or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Any other experience that suggests a significant hazard, contraindication, side-effect, or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above ☐ Events changes the risk/benefit ratio of the study

2.6 AT THE TIME OF THIS REPORT, THE ADVERSE EVENT IS:	
1. ☐ Resolved	(No additional follow-up necessary)
2. ☐ Unresolved	(Additional follow-up necessary)

3. RESEARCH STAFF ASSESSMENT OF ADVERSE EVENT

3.1 IN YOUR JUDGEMENT, IS THE ADVERSE EVENT RELATED, POSSIBLE RELATED, UNKOWN, OR NOT RELATED TO THE PROTOCOL?	
1 ☐	Related
2 ☐	Possibly Related
3 ☐	Unknown
4 ☐	Not related

4. VERIFICATION

STAFF MEMBER:

COMPLETED BY (PLEASE PRINT OR TYPE):

FIRST NAME: LAST NAME:

DESIGNATION/ROLE ON RESEARCH PROJECT:

STAFF MEMBER SIGNATURE:

DATE: / / (DD/MM/YY)

PRINCIPAL INVESTIGATOR (PLEASE PRINT OR TYPE):

I have reviewed this AE Form for this participant and attest that the information recorded is accurate and complete.

INVESTIGATOR'S FIRST NAME:
INVESTIGATOR'S LAST NAME:

INVESTIGATOR SIGNATURE:

DATE: / / (DD/MM/YY)