**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Annexure 1)**

##  Application Form for Full Review

**……………………………………………………………………………………**

**MPUMALANGA PROVINCIAL HEALTH RESEARCH ETHICS COMMITTEE**

**APPLICATION FOR ETHICS APPROVAL [INITIAL REVIEW]**

**SECTION 1: STUDY PURPOSE**

Not for Degree Purposes/Quality Improvement: **Yes [ ] No [ ]**

Postgraduate Degree/Diploma: **Yes [ ]  No [ ]**  (state which):

Undergraduate Degree/Diploma: **Yes [ ]  No [ ]**  (state which):

**SECTION 2: STUDY TITLE IN FULL (NO ABBREVIATIONS)**

Title of the study:

**SECTION 3: APPLICANT DETAILS**

|  |
| --- |
| **DETAILS OF THE PRIMARY INVESTIGATOR/RESEARCHER** |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **PERSAL NUMBER (EMPLOYEES)** |  |
| **PROFESSIONAL STATUS, OR STUDENT YEAR OF STUDY AND DEGREE** |  |
| **DEPARTMENT/DIVISION/RESEARCH ENTITY:** |  |
| **SITES(S) WHERE THE RESEARCH WILL BE CARRIED OUT (**Please furnish hospital/institution and department**)** |  |
| **MAIN SUPERVISOR DETAILS, IF ANY** |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **DEPARTMENT/DIVISION/RESEARCH ENTITY:** |  |
| **NAME AND DATE OF ETHICS TRAINING** |  |
| **FUNDING DETAILS** |
| **FUNDER (SPECIFY):** |  |
| **TOTAL ESTIMATED BUDGET:** |  |

**SECTION 4: RESEARCH STUDY DETAILS**

* 1. **Objectives and end points of the research** (plain language):

Primary (if applicable):

Secondary (if applicable):

Exploratory (if applicable):

Safety:

Other:

* 1. **Brief study background** (e.g., disease, procedures, medicines, etc.):

* 1. **Brief summary of the research:** (give a brief outline of the research plan such that reviewers can understand what is to be done. (*Do not say “see attached”*):
		1. **Design:**
		2. **Duration of study:**

Start Date: **(DD/MM/YYYY)**

Stop Date: **(DD/MM/YYYY)**

* + 1. **Study Participants:**
1. Where and how the participants are selected (i.e. recruitment strategies):
2. Will vulnerable participants be recruited? **Yes [ ]  No [ ]**

**If yes,** justify the selection of vulnerable participants:

1. Age range of Participants:
2. Self-reported Gender: **Male [ ]  Female [ ]  Other [ ]**
3. Number of participants to be recruited/studied:
4. Potential benefit to participants? **Yes [ ]  No [ ]**

**If yes,** explain in what way:

1. Potential risks to participants? **Yes [ ]  No [ ]**

**If yes,** explain in what way:

1. 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:

* + 1. **Please give a brief Summary of Inclusion and Exclusion Criteria (important ones only):**

**SECTION 5: RESEARCH STUDY TYPE**

* 1. **Select study type (check/tick all that applicable):**

**[ ]** Retrospective Record Review

 What is the initial date for the records? **(DD/MM/YYYY)**

 What is the final date for the records? **(DD/MM/YYYY)**

**[ ]** Prospective Record review

 What is the initial date for the patient records? **(DD/MM/YYYY)**

 What is the final date for the patient records? **(DD/MM/YYYY)**

**[ ]** Secondary Data Analysis of Previously Approved Study

**[ ]** Qualitative

**[ ]** Quantitative

**[ ]** Cross-sectional

**[ ]** Observational/Epidemiological

**[ ]** Lab Based

**[ ]** AI/Computer Based

**[ ]** Health Economics

**[ ]** Clinical Trial **(please give Phase, e.g. I, II, III or IV):**

**[ ]** Other **(please give brief details)**:

* 1. **Will this study involve the use of a Biobank?** **Yes [ ]  No [ ]**

Please note: If this study collects human tissue as a component of the primary study, it is not considered to be biobanking. Note: Biobank Ethics applications are dealt with by the Biobanks Ethics Committees and the application may not be considered by MPHREC.

**SECTION 6: PARTICIPANT INFORMATION LEAFLET AND INFORMED CONSENT FORM**

* 1. **Has Participant Information Leaflet and Informed Consent Form (****PIL/ICON) been attached?**

 **Yes [ ]  No [ ]**

 **If yes,** please provide details of how have literacy and language diversity aspects been considered in the PIL/ICON:

* 1. **In case of minors aged 7-17, has an Assent Form been attached?**

 Assent Form for 7–12-year-olds: **Yes [ ]  No [ ]**

 Assent Form for 12 - 17-year-olds: **Yes [ ]  No [ ]**

 Not Applicable **[ ]**

* 1. **Mark research procedure(s) that will be used:**

**[ ]  Record review (patient file)**

**[ ]  Interview / Questionnaire form (must be attached)**

**[ ]  Clinical Examination (state below nature and frequency of examination)**

**[ ]  Medicine/medical devices/kits (state below names(s), dose(s), and frequency of administration (if applicable)**

* Please provide Professional Information or Package Insert (PI):

**[ ]**  **Blood sampling; [ ]** **venous; [ ] arterial**

* (state below amount to be taken and the frequency of blood sampling):

**[ ]  Biopsy(s)**

**[ ]  Any other invasive procedures (e.g. endoscopy)**

* 1. **Will a questionnaire or interview be used in the research for data collection? It must be attached. (If not, this application cannot be considered).**

 **Yes [ ]  No [ ]  Not applicable [ ]**

 Is this attached? **Yes [ ]  No [ ]  Not applicable [ ]**

**Type of questionnaire (check/tick all that applicable):**

[ ]  Self-Administered Questionnaire (SAQ)

[ ]  One-On-One Interview

[ ]  Focus Group Discussion (FDG)

[ ]  Delphi Study

[ ]  Quality of Life

[ ]  Other **(specify)**:

* 1. **If a questionnaire or interview is to be used in this research, how have literacy and language diversity aspects been considered?**
	2. **Who will carry out procedures: Outside vendor or PI/Sub-I/Co-I?**
* Please specify roles and responsibilities:
	1. **Please include potential risks of the procedures:**
	2. **Radiological Investigations or Treatments:**
		1. **Will there be any form of radiation being used in the study for diagnostic / monitoring / or therapeutic purposes? Yes [ ]  No [ ]**

**If yes,** please answer the following questions:

* + 1. **What form of radiation will this be?**

**[ ]** Radioisotopes

[ ]  Plain Xray’s

[ ]  CT scanning

[ ]  PET/CT

[ ]  Other **(provide details of this)**:

* + 1. **Which radiological investigations are considered to be standard clinical care?**
		2. **Which radiological investigations are considered to be for research purposes only? Please justify.**

**SECTION 7: RISKS OF THE STUDY PROCEDURE(S)**

* 1. **Please consult the risk table at** [https://www.mpuhealth.gov.za/MPHREC documents/](https://www.mpuhealth.gov.za/MPHREC%20documents/) chose **and indicate the level of risk to:**

**Patients/Participants:**

None/Minimal **[ ]**  Low/Medium **[ ]** High/Very High **[ ]**

**Research team members:**

None/Minimal **[ ]**  Low/Medium **[ ]** High/Very High **[ ]**

**All other persons:**

None/Minimal **[ ]**  Low/Medium **[ ]** High/Very High **[ ]**

* 1. **Please indicate whether the patients/participants will be exposed to any levels of:**
1. **Adverse effects Yes[ ]  No[ ]  N/A[ ]**

**If yes,** please indicate which:

[ ]  Investigational Products (IP) used

[ ]  Standard of care

[ ]  Supportive care

1. **Physical discomfort/pain Yes [ ]  No [ ]**

**If yes,** please elucidate:

Is there a **distress protocol?** **Yes [ ]  No [ ]**

1. **Psychological stress Yes [ ]  No [ ]**

Is there a **distress protocol?** **Yes [ ]  No [ ]**

1. **Breach of confidentiality Yes [ ]  No [ ]**
2. **Potential stigmatization and or profiling Yes [ ]  No [ ]**
* If you have checked any of the above, **please provide details**:

**SECTION 8: APPROVAL REQUIREMENTS**

* 1. **Please provide evidence of capacity building at the site(s)** (if applicable)**:**
	2. **If this study involves health products, then SAHPRA approval is required.**

Has this application been made?  **Yes [ ]  No [ ]**

 **If yes,** provide details**:**

* 1. **Has permission of other relevant authority/ies been applied for? Yes****[ ]  No****[ ]  N/A****[ ]**

**[ ]** State name of authority/ies (If applicable):

**[ ]** HoD permission:

**[ ]** Hospital CEO (if applicable):

**[ ]** District Manager (if applicable):

**[ ]** Provincial:

**[ ]** National:

**[ ]** International (in case of studies outside South Africa)

**[ ]** Other (provide details):

* 1. **Has this study been submitted to other Ethics Committees/Institutional Review Board (IRBs),**

 **inside or outside South Africa? Yes[ ]  No[ ]  N/A[ ]**

 **If yes,** where has it been submitted, and what is the status of the application?

* Where:
* Status:

**SECTION 9: ADDITIONAL INFORMATION**

* 1. **Confidentiality:**

**Will the patients/participants be exposed to any levels of Breach of**

**confidentiality Yes [ ]  No [ ]**

**i. In respect of the type of research methodology?**

(As an example, a focus group can offer no guarantee of confidentiality)

 **If yes,** please describe how this will be managed or mitigated.

**ii. Has Mandatory Reporting requirements been considered and detailed as to the process if research involves minors, with due consideration of reporting timelines?**

* 1. **Please explain how confidentiality will be maintained so that participants are not identifiable to persons not involved in the research:**

For example:

i. Will the data collected be coded, anonymized, or pseudo-anonymised?

ii. Who will have access to identifiable data?

iii. Does your protocol/proposal make mention of how this process will be dealt with and details this in respect of POPIA’s provisions?

iv. Has a POPIA statement been included in the Informed Consent Form?

 As a minimum, the following statement should be included:

*In accordance with the provisions of the****Protection of Personal Information Act 4 of 2013*** *(as amended), I hereby consent:*

* + - *To my personal information (hereinafter 'data') being collected, processed, shared and stored in accordance with the research protocol/proposal as approved by the mphrec;*
		- *To my anonymised data being shared, processed, and transferred by third parties and between third parties, and where relevant beyond the jurisdictional borders of South Africa;*
		- *To all findings and results flowing from my anonymised data being broadly shared and published at the conclusion of the research.*

v. Does the sharing of data require the drafting and completion of a Data Transfer Agreement or a Cross Border Data Transfer Agreement? **Yes [ ]  No [ ]**

 **If so (Yes),** this will be required to the submitted to the MPHREC for approval.

vi. Have you adequately dealt with this in your Information Sheet to participants? Do they have sufficient information or detail to understand what they are consenting to in terms of the collection, processing, and storage of their data and what the risks are of a breach?

vii. Do you have a process in place to report a breach should this occur?

* 1. **Any other information, which may be of value to the ethics committee should be provided here:**

**SECTION 10: DECLARATION AND CHECKLIST**

* 1. **Declaration**

|  |
| --- |
| 1. **DECLARATION (Please tick as applicable)**
 |
| **[ ]**  | I/We certify that the information provided in this application is complete and correct. |
| **[ ]**  | I/We confirm that all investigators have approved the submitted version of proposal/related documents. |
| **[ ]**  | I/We confirm that this study will be conducted in accordance with the latest National Health Guidelines for Research (2024) and other applicable regulations and guidelines of research Human Participants. |
| **[ ]**  | I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted. |
| **[ ]**  | I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol**.**  |
| **[ ]**  | I/We declare that the expenditure in case of injury related to the study will be taken care of. |
| **[ ]**  | I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports and a final report and also participate in any audit of the study if needed.  |
| **[ ]**  | I/We confirm that we will maintain accurate and complete records of all aspects of the study. |
| **[ ]**  | I/We will protect the privacy of participants and assure confidentiality of data and biological samples. |
| **[ ]**  | I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study. |
| **[ ]**  | I/We have the following conflict of interest (PI/Co-I):1. ……………………………………………………………………………………………………………………………………………………………………………………………
2. …………………………………………………………………………………………………………………………………………………………………………………………….
 |
| **[ ]**  | I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable. |
| Name of PI/Researcher: ………………..................................................................................Signature: ........................………………………………..................................... Name of Co-PI: ....................................................................……………............ Signature: ........................………………………………..................................... Name of Supervisor if any: ............................................................................................ Signature: ........................………………………………..................................... |
| * 1. **CHECKLIST**
 |
| **s. No.** | **Items** | **Yes** | **No** | **NA** | **Enclosure****No** | **MPHREC Remarks****(If applicable)** |
| **ADMINISTRATIVE REQUIREMENTS** |
|  | Cover letter  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 2 | Brief CV of the Primary Investigator | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 3 | Approval of scientific committee | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 4 | EC clearance of other centers | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 5 | Agreement between collaborating partners | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 6 | Insurance policy/certificate  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 7 | Evidence of external laboratory credentials in case of an externally outsourced laboratory study certification | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 8 | Copy of contract or agreement signed with the sponsor or donor agency | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| **PROPOSAL RELATED REQUIREMENTS**  |
| 1 | Copy of the detailed protocol | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 2 | Investigators Brochure (If applicable for drug/biologicals/device trials)  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 3 | Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 4 | Assent form for minors (7-17 years) (English and Translated) | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 5 | Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated) | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 6 | Advertisement/material to recruit participants (fliers, posters etc) | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| **ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY** |
| 1 |  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 2 |  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| 3 |  | **[ ]**  | **[ ]**  | **[ ]**  |  |  |
| ***For multicentre research.*** ***MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry’s Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre***  |