**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**

**FULL APPLICATION FORM 2025**

**FULL APPLICATION TO THE HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)**

**UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG.**

NOT FOR CASE REPORTS, SUB-STUDIES, RETROSPECTIVE RECORD REVIEWS, DE-IDENTIFIED HUMAN BIOSPECIMENS, SECONDARY DATA ANALYSES AND WAIVERS.

* NOT FOR COMMERCIAL AND GRANT FUNDED STUDIES WHICH MUST GO TO WITS HEALTH CONSORTIUM (WHC).

**IMPORTANT INSTRUCTIONS:**

* Please read the checklist and guideline document before completing this application form.
* Answer all the questions, incomplete application will not be accepted. State N/A rather than leaving the question blank.
* **Please check the appropriate checkbox using an ‘X’**. This application form **must be typed**; handwritten form will not be accepted.
* A completed copy of this form, with supporting documents, must be submitted online via the Ethics Management System (EMS) <https://www.witsethics.co.za/Login.aspx>. Please see the submission dates published on the Ethics Website <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>.
* **Note Well: No data may be collected before the issue of an ethics clearance. In no circumstance will ethics clearance be issued retrospectively.**

**SECTION 1 – STUDY DETAILS:**

**1.1 Purpose of the Research:**

Postgraduate Degree/Diploma: **Yes  No**  (If yes, state which qualification):

Undergraduate Degree/Diploma: **Yes  No**  (If yes, state which qualification):

Not for Degree Purposes: **Yes  No**

**1.2** Is this a New Submission? **Yes  No**

**1.3** Is this a Resubmission? **Yes  No**

**If yes**, please previous HREC number(s):

**SECTION 2 – STUDY TITLE IN FULL** (No abbreviations)**:**

|  |
| --- |
| **Study Title**: |

**SECTION 3 – INVESTIGATOR(S)/ SUPERVISOR(S)/APPLICANT INFORMATION:**

**3.1 PRINCIPAL INVESTIGATOR(S) DETAILS –** (Please repeat this box for any additional PIs):

|  |  |
| --- | --- |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **WITS STAFF/STUDENT NUMBER** |  |
| **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**)** |  |
| **NAME AND DATE OF ETHICS TRAINING**  (please include/attach certificate) |  |

**3.2 CO OR SUB INVESTIGATOR(S) –** (Please repeat this box for any additional co-investigators):

|  |  |
| --- | --- |
| **TITLE** (Prof/Dr/Mr/Mrs/Miss/Ms/Other): |  |
| **FIRST NAME** |  |
| **SURNAME** |  |
| **TELEPHONE**/**CELL NO** |  |
| **E-MAIL** |  |
| **WITS STAFF/STUDENT NUMBER** |  |
| **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**)** |  |
| **NAME AND DATE OF ETHICS TRAINING**  (please include/attach certificate) |  |

**3.3 SUPERVISOR(S) DETAILS:**

Please list all the supervisors involved in the study – repeat this box for all supervisors.

|  |  |
| --- | --- |
| **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**  (please include/attach certificate) |  |
| **PERCENTAGE OF SUPERVISION** |  |

**3.5 APPLICANT DETAILS** (if applicable – applying on behalf of PI/Investigators):

|  |  |
| --- | --- |
| **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**  (please include/attach certificate) |  |

**SECTION 4: STUDY DETAILS** (please avoid copying and pasting from the study protocol)**:**

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

Primary (if applicable):

Secondary (if applicable):

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

(One paragraph)

**4.3 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. **Study Design and Methodology:**

Summary:

* + 1. **Duration of study activities:**

Start Date: **(DD/MM/YYYY)** \*must be after HREC (Medical) meeting/approval.

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

* + 1. **Please give a brief Summary of Inclusion Criteria (important ones only):**
    2. **Please give a brief Summary of Exclusion Criteria (important ones only):**
    3. **Study Participants (If applicable):**

1. Where and how the participants are selected (i.e. recruitment strategies):
2. Age range of Participants:
3. Biological Sex: **Male  Female  Other** (If other, please clarify)
4. Number of participants to be recruited/studied: **Total:**

**Per Site:**

**SECTION 5: STUDY PROCEDURES**

**5.1 Select study type(s) (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

In-vivo Lab Based

In-vitro Lab Based

AI/Computer Based

Health Economics

Environmental

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

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

**SECTION 6 – BIOBANKING (If applicable):**

**Will this study involve the use of a Biobank?** **Yes  No**

If yes, please refer to the HREC (Medical) checklist and guidelines for more information.

Please note: If this study collects human tissue as a component of the primary study, it is not considered to be biobanking.

**SECTION 7 - Participant Information Leaflet and Informed Consent Form (PIL/ICON (If applicable)**

(see guidance at <http://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, choose HREC (Med), select “Downloads”)

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

**Yes  No  N/A**

**7.2 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**

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

**7.3 Who will carry out study procedures: Outside vendor or PI/Sub-I/Co-I?**

* Please specify roles and responsibilities:

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

**Record review (patient file)**

**Interview / Questionnaire form (must be attached):**

**Delphi**

**Self-Administered Questionnaire (SAQ)**

**Focus Group Discussion (FGD)**

**One on one interview**

**Other** (Please, specify):

**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):

**Biopsy(s) including blood**

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

**7.5**  Will vulnerable participants be recruited? **Yes  No**  **N/A**

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

**7.6 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** Please attach if applicable.

**7.7 If a questionnaire or interview is to be used in this research, how have literacy and language diversity aspects been considered?**

**7.7 Radiological Investigations or Treatments:**

**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:

**What form of radiation will this be?**

Radioisotopes

Plain Xray’s

CT scanning

PET/CT

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

**Which radiological investigations are considered to be standard clinical care?**

**Which radiological investigations are considered to be for research purposes only? Please justify.**

1. Number of scans or interventions above Standard of Care:
2. Frequency of scans of the same:
3. Dose of radiation per scan or intervention:

**SECTION 8: RISKS OF THE STUDY PROCEDURE(S):**

**8.1 Please consult the risk table (Appendix 10) and indicate the level of risk to:**

**Patients/Participants: (as applicable)**

None/Minimal  Low/Medium High/Very High

**Research team members: (as applicable)**

None/Minimal  Low/Medium High/Very High

**All other persons: (as applicable)**

None/Minimal  Low/Medium High/Very High

**8.2 Please indicate whether the patients/participants will be exposed to any adverse effects (Please describe):**

1. **Physical Adverse effects Yes No N/A**

**If yes,** please indicate which:

Investigational Products (IP) used

Standard of care

Supportive care

Other (Specify):

1. **Psychological effects Yes  No  N/A**

If yes, is there a **distress protocol?** **Yes  No**

1. **Breach of confidentiality Yes  No  N/A**

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

1. Will the data collected be coded, deidentified, anonymised, or pseudo-anonymised?
2. Who will have access to identifiable data?
3. Does your protocol/proposal make mention of how this process will be dealt with and details this in respect of POPIA’s provisions?
4. 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 Wits HREC (Medical);*
    - *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.*

1. **Potential stigmatization and or profiling Yes  No  N/A**

If you have checked any of the above, **please provide details**:

**SECTION 9 – APPROVAL REQUIREMENTS:**

**9.1 If this study involves health products, then SAHPRA approval/notification is required.**

Has this application been made?  **Yes  No  N/A**

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

**9.2 Has permission of other relevant authority/ies been applied for? Yes** **No** **N/A**

State name of authority/ies (If applicable):

Postgraduate/Faculty approval letter

Undergraduate approval letter e.g. UUME approval letter of the protocol

University Registrar/School authority:

HoD permission:

Hospital CEO (if applicable):

District Manager (if applicable):

Provincial:

National:

International (in case of studies outside South Africa)

National Health Laboratory Service (NHLS) AARMS

National Nuclear Regulator (NNR)

Other (provide details):

**9.3 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:
  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:

Please refer to SAHPRAs Time, Inconveniece, Expense (TIE) Model \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*Please note that remuneration/reimbursement is to cover participant TIE and is not a payment or incentive.

**SECTION 10 – DATA AND MATERIAL TRANSFER AGREEMENTS:**

**10.1 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 HREC for approval.

**10.2** **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?

**10.3** **Do you have a process in place to report a breach should this occur?**

Please refer to the breach form <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>.

**SECTION 11 – INFORMATION, DECLARATION AND SIGNATURES:**

**Investigator(s) Name and Surname:**

In appending my signature below, I confirm that I am aware of and agree to abide by the University’s policy on plagiarism, as referenced (link provided) at in the Appendix 3 (WITS Plagiarism Policy) to this Application Form.

I have read and understood the terms and conditions in Appendix 3 section 1 of the HREC (Medical) Application Form. I acknowledge that it is my responsibility to ensure that I have received final HREC (Medical) clearance before commencing any research.

I declare that I have not and will not collect data or do secondary data analysis, or any other form of research involving human participants, prior to obtaining a Clearance Certificate from HREC (Medical).

I acknowledge that the University of the Witwatersrand and the University of the Witwatersrand, Human Research Ethics Committee (Medical) must be acknowledged on all publications emanating from this approval.

|  |
| --- |
| **Repeat Study Title here:** |

**PRINCIPAL INVESTIGATOR(S) –** Please repeat box for additional PIs**:**

|  |  |
| --- | --- |
| *Name:*  *Please Print Title, Name and Surname* |  |
| *Department:* |  |
| **Email:** |  |
| **Date:** |  |
| **Signature:** |  |

**CO-INVESTIGATOR(S) -** Please repeat box for additional co-investigators**:**

|  |  |
| --- | --- |
| *Name:*  *Please Print Title, Name and Surname* |  |
| *Department:* |  |
| **Email:** |  |
| **Date:** |  |
| **Signature:** |  |

**APPLICANT (where applicable -** applying on behalf of PI/Investigators**):**

|  |  |
| --- | --- |
| *Name:*  *Please Print Title, Name and Surname* |  |
| *Department:* |  |
| **Email::** |  |
| **Date** |  |
| **Signature:** |  |

**SUPERVISOR(S) (where applicable) -** Please repeat box for additional supervisors**:**

|  |  |
| --- | --- |
| *Name:*  *Please Print Title, Name and Surname* |  |
| *Department:* |  |
| **Email:** |  |
| **Date** |  |
| **Signature:** |  |

**HEAD OF DEPARTMENT / UNIT OF INSTITUTION / RESEARCH ENTITY IN WHICH STUDY WILL BE CONDUCTED –** PLEASE NOTE: HEAD OF DEPARTMENT MUST NOT SIGN IF THEY ARE A PRINCIPAL INVESTIGATOR / CO-INVESTIGATOR / SUPERVISOR ON THE STUDY:

|  |  |
| --- | --- |
| **Name:**  *Please Print Title, Name and Surname* |  |
| **Head of Dept / Unit of Institution / Research Entity where study will be conducted:** |  |
| **Date:** |  |
| **Signature:** |  |