**Full Application Form 2025**

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL) – FULL APPLICATION FORM 2025**

**For PhD, MSc, MPH, other Higher Degrees, and Undergraduate Degrees, and other Investigator Initiated Research**

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

**UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG.**

**For PhD, MSc, MPH, other Higher Degrees, and Undergraduate Degrees, and other Investigator Initiated Research.**

**\*Not** for Case Reports, Sub-studies, Retrospective Record Reviews and Waivers.

**IMPORTANT INSTRUCTIONS:**

* Read all the checklist and guidelines 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/>.

**SECTION 1 – STUDY DETAILS:**

**1.1 Purpose of the Research:**

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

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

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 give initial HREC number):

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

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

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

**3.1 PRINCIPAL INVESTIGATOR(S):**

Please list all the PIs involved in the study.

|  |  |
| --- | --- |
| **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 SUPERVISOR(S) DETAILS:**

Please list all the supervisors involved in the study.

|  |  |
| --- | --- |
| **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) |  |

**3.3 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):

Other:

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

**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:**

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 and Exclusion Criteria (important ones only):**
    2. **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. Biological Sex: **Male  Female  Other** (If other, please clarify)
3. Number of participants to be recruited/studied:
4. 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 TIE Model \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SECTION 5:**

**5.1 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)**:

**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**

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

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

* Please specify roles and responsibilities:

**7.2 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, the frequency of blood sampling and disposal):

**Biopsy(s)**

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

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

**Yes  No**

**7.4 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**

**7.5 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

Other **(specify)**:

**7.6 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:**

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

**8.2 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 9 – APPROVAL REQUIREMENTS:**

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

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

**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):

University Registrar/School authority:

HoD permission:

Hospital CEO (if applicable):

District Manager (if applicable):

Provincial:

National:

International (in case of studies outside South Africa)

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:

**SECTION 10 – GENERAL:**

**10.1 Confidentiality:**

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

**confidentiality Yes  No**

**If yes,** please describe below:

**10.2 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.

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

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

i. Will the data collected be coded, deidentified, anonymised, 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 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.*

**10.5** 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.

**10.6** 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?

**10.7** 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/>.

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

**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 the HREC (Medical).

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

**PRINCIPAL INVESTIGATOR(S):**

|  |  |
| --- | --- |
| *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):**

|  |  |
| --- | --- |
| *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:**

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