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

 **FOR CLEARANCE OF RESEARCH INVOLVING THE ADDITION OF A NEW INVESTIGATOR**

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| **When is this form appropriate?** It should be completed when a Principal Investigator, who already has a current ethics clearance, wishes to add an additional member to the investigating team. This would normally be in one of two circumstances: (a) the study remains unchanged and an “extra pair of hands” is added to the team, or (b) one or more facets of the study is/are taken on by a new team member, who would often, but would not necessarily have to be, a postgraduate student; this person would be gathering new data, which is what distinguishes this exercise from a “sub-study.” (There is a separate Application Form for a sub-study). Studies satisfying criteria (a) or (b) may be submitted, by e-mail HREC-Medical.ResearchOffice@wits.ac.za , to the Medical Ethics Office at any time, i.e. they are not subject to the published monthly closing dates for full applications. |

**APPLICATIONS UNDER (a) ABOVE – SECTIONS 1,2,5 AND 6 BELOW APPLY**

**APPLICATIONS UNDER (b) ABOVE – ALL SECTIONS (1-6) BELOW APPLY**

**IMPORTANT INSTRUCTIONS:**

* Read the Appendix before completing this application form. Answer all questions, incomplete application will not be accepted. State N/A rather than leaving question blank.
* **Please check the appropriate checkbox using an ‘X’**. This application form **must be typed**, handwritten form will not be accepted.

**Note Well: No data may be collected before the issue of an applicable ethics clearance.**

**In no circumstance will ethics clearance be issued retrospectively.**

**SECTION 1 – STUDY TITLE IN FULL** (No abbreviations)**:**

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

 **Protocol Number (MYY/MM/XX):**

 **Date on Clearance Certificate:**

**SECTION 2 – INVESTIGATOR(S) DETAILS:**

**PRINCIPAL INVESTIGATOR(S) DETAILS** (i.e. the person in whose name the Clearance Certificate was issued):

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

**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) |  |

**NEW INVESTIGATOR(S) DETAILS:**

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

**The new investigator is:**

[ ]  (a) to be engaged in the main study

[ ]  (b) to be engaged in a discrete facet(s) of the main study; please state the appropriate study title (which may not necessarily be identical to the title of the main study in Section 1 above):

If the new investigator is to carry out the work for the purposes of a postgraduate degree, please state what degree he/she is registered for:

In the case of (a) or (b) as above, please attach evidence of ethics training, not >3 years old.

[ ]  Attached

In the case of (b) above, when the new investigator is studying for a postgraduate degree, please also attach a copy of final approval of the protocol title from the Faculty Office (not from the Protocol Review Committee).

[ ]  Not for degree purposes

[ ]  Attached

In the case of (b) above, please provide a brief overview of the study, to cover primary, secondary and other objectives, design and methodology - (please do not cut and paste from the Protocol:

|  |
| --- |
| Overview/Abstract: |

**SECTION 3 – not required in the case of an additional investigator on the main study - Section 2 (a) above:**

Qualitative studies

If the study involves interaction with human participants, are there approved Participant Information and Informed Consent Documents already in place under the main study?

If not, please attach the new versions (No consent required on a self-administered questionnaire).

[ ] Covered under the main study

[ ] Attached

Quantitative studies

If the study involves data collection, are the approved data collection sheets already in place under the main study? If not, please attach the new versions.

[ ] Covered under the main study

[ ] Attached

**SECTION 4 –** **not required in the case of an additional investigator on the main study – Section 2 (a) above**

Facility approvals

If study sites not covered under the main study are to be included, please attach the relevant permissions, *e.g.* Hospital CEO, School Principal, other site managers, etc. Please list the relevant permissions:

[ ]  Covered under the main study

[ ]  Listed below and aattached

**SECTION 5**

Any other information which may help the Medical Ethics Office to evaluate this application, may be provided here:

**SECTION 6: INFORMATION, DECLARATION AND SIGNATURES (To be kept on separate page) \***

**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 in the Appendix to this Application Form.

I have read and understood the terms and conditions in the Appendix 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:** |  |

 **NEW INVESTIGATOR:**

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

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| **PLEASE DO NOT SUBMIT THE APPENDICES WITH YOUR APPLICATION FORM, IT IS FOR YOUR INFORMATION.** |

**APPENDIX 1 - STANDARD ATTACHMENTS REQUIRED WITH THIS APPLICATION:**

1. Ethics training certificates (see below)
2. Data extraction sheet (no identifiers)
3. Study protocol (if Section 2 (b) above applies, not otherwise)
4. Faculty protocol title approval letter, if for postgraduate degree purposes
5. Participant Information and Consent Sheets, if new ones are required (Section 3 above refers)
6. New site approvals (Section 4 above applies)
7. Anything else as appropriate

**Ethics training:**

Ethics training is a compulsory requirement for consideration of this application. This applies to the additional new investigator only. If you do not already have ethics training, one easy way to get it is to go to <https://elearning.trree.org/course/index.php?categoryid=1> and complete at least the Introductory Module, which costs nothing and will generate a certificate. Please attach copies.

NHREC rules stipulate that ethics training certificates are not acceptable if they are more than three years old and that GCP Certificates are only acceptable in this context if they specify an ethics component.

**NOTES**

1. The addition of new investigators does not extend the expiry date on the Clearance Certificate issued over the main study
2. Please note that it is the responsibility of the new investigator to ensure that he/she has received the final HREC (Medical) Clearance before commending any research. This is signified by, and only by, the issuing of a Clearance Certificate, which will be headed as such.
3. If any doubt exists over any aspect of this application, please come into the Ethics Office (Phillip Tobias Building, 3rd Floor, Cnr York Road and Princess of Wales Terrace, Parktown) during normal office hours and ask the staff on duty there.
4. The University’s policy on plagiarism is set out at: [https://www.wits.ac.za/media/wits-university/library/documents/Student%20Plagiarism%20Policy%20Approved%202020-11-28%20(002).pdf](https://www.wits.ac.za/media/wits-university/library/documents/Student%20Plagiarism%20Policy%20Approved%202020-11-28%20%28002%29.pdf)

Applicants seeking ethics clearance are required to be familiar with this policy.

HREC (Medical) Committee Form Revision/Edit version Number, Application Form version 01, 11 Dec 2024.