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

**FOR AN AMENDMENT TO AN APPROVED STUDY**

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| **When is this form appropriate?** The amendment formshould be completed when the Principal Investigator is seeking approval for change(s), including the addition of a new investigator to a study which has ethics clearance and is already underway. The amendment form is not appropriate for renewal of a clearance when the previous version has expired – usually after 5 years. A completed copy of this form, with attachments, may be submitted, by e-mail **HREC-Medical.ResearchOffice@wits.ac.za****,** to the Medical Ethics Office at any time. |

**IMPORTANT INSTRUCTIONS:**

* Read all the Appendices 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.

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

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| **Study Title**:  |

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

**SECTION 2 – INVESTIGATOR(S)/ SUPERVISOR(S)/APPLICANT INFORMATION:**

**2.1 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) |  |

**2.2 CO 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) |  |

**2.3 SUPERVISOR(S) DETAILS -** (Please 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** |  |

**2.4 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) |  |

**2.5 NEW INVESTIGATOR(S) DETAILS** – (If applicable)**:**

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

**SECTION 3 - DETAILS OF ORIGINAL/APPROVED STUDY** (please avoid copying and pasting from the study protocol)**:**

**Brief Summary**

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**SECTION 4: REASON(S) FOR AMENDMENT**

In this section, please check the appropriate box, provide summary and rationale/justification.

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| **AMENDMENT DETAILS** |
| 4.1 Does the applicant wish to change the eligibility criteria for this study?**[ ]**  No**[ ]** YesIf “Yes”, provide the tracked changes protocol as well as a brief justification/rationale for these changes cross-referenced to the amended protocol text. |  |
| 4.2 Does the applicant wish to change the primary, secondary and/or other objectives of this study?**[ ]**  No**[ ]** YesIf “Yes”, provide the tracked changes protocol of these changed objectives as well as a justification/rationale for the changes (cross-referenced to the amended protocol text). |  |
| 4.3 Does the applicant wish to change the design of this study?**[ ]**  No**[ ]** YesIf “Yes”, provide the tracked changes protocol as well as a brief justification/rationale for these changes cross-referenced to the amended protocol text. |  |
| 4.4 Does the applicant wish to change the duration of this study?**[ ]**  No**[ ]** YesIf “Yes”, provide details of the justification/rationale for the changes (cross-referenced to the amended protocol text). |  |
| 4.5 Are the changes due to new safety concerns? **[ ]**  No**[ ]** YesIf yes: a. Briefly Describe:b. Steps to be taken:  |  |
| 4.6 Does the applicant wish to add additional test(s) on stored biological specimens?**[ ]**  No**[ ]** YesIf “Yes”, please select the following:a. Specimens being stored:**[ ]**  Blood**[ ]**  Sputum**[ ]**  Other tissue (describe)b. Tests to be done with justification: |  |
| 4.7 Does the proposed amendment require a new PIL/ICON form from the participant?**[ ]**  No**[ ]** YesIf “Yes”, submit the new PIL/ICON and /or ASSENT together with this application and summarise the resultant changes. |  |
| 4.8 Does the applicant wish to add a new investigator to the study?**[ ]**  No**[ ]** YesIf “Yes”, please provide details of the investigator on section 2.5 and attach ethics training certificate(s). |  |
| 4.9 Does the applicant wish to add a new study site to the study?**[ ]**  No**[ ]** YesIf “Yes”, please provide details of the new site and attach relevant permissions. |  |
| 4.10 Does the applicant wish to add other changes not covered above?**[ ]**  No**[ ]** YesIf “Yes”, please include a brief description of the amendment and justification. |  |
| 4.11 Are there any other changes affected by this amendment?**[ ]**  No**[ ]** YesIf yes, provide a summary of the tracked changes as well as a motivation and scientific rationale for these changes. |  |

**SECTION 5: 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 Appendix 3 to this Application Form.

I have read and understood the terms and conditions in Appendix 3 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).

|  |
| --- |
| **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 –** PLEASENOTE: HOD 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:** |  |

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

**APPENDIX 1 - SUBMISSION REQUIREMENTS:**

**1. REQUIRED UPFRONT FOR AN AMENDMENT APPLICATION TO BE ACCEPTED:**

 **ANY INADEQUATE SUBMISSION WILL BE REJECTED**

1. Completed and signed **Amendment Form**.
2. Copy of ethics clearance certificate (not more than 5 years old)
3. Revised study protocol, or equivalent (show mark-up), if appropriate
4. Revised (show mark-up) or new Information and Consent Sheets, if appropriate
5. New site approvals – CEO or equivalent, if appropriate
6. Any other form of endorsement
7. Faculty approval of changed study title, if appropriate
8. Any other relevant documents, e.g. statutory changes, report on serious adverse events, cautionary letter from appropriate authorities, etc

**Ethics training (<3 years)**

Ethics training is a compulsory requirement for consideration of this application. This applies to the applicant, any co-applicants and the supervisor(s), where there is one (or more). 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 Modules 1, 2 and 3, which costs nothing and will generate a certificate. Please attach copies.

**NB: NOTE: STUDY SITES WITH INSUFFICIENT DOCUMENTATION MAY BE REJECTED WITHOUT AFFECTING THE APPROVALS OF OTHER SITES**.

**APPENDIX 2 – LIST OF POSSIBLE APPROVALS AND DOCUMENTS (if applicable):**

1. **SAHPRA.**
2. **University Protocol Review Committee or Postgrad Approval Letter.**
3. **University Registrar/School authority.**
4. **Research Ethics Training Certificate for all Investigators and Supervisors (not more than three years old) and GCP Training Certificate** (if applicable).
5. **Gatekeeper or database keeper permission for secondary data analysis** (plus a list of the data to be recorded must accompany this application; omit all identifiers on the data collection sheet – name, address, contact details, date of birth, etc.; use a study number to identify individuals where necessary).
6. **South African National Clinical Trials Registry (SANCTR).**
7. **National Health Research Database (NHRD) registration.**
8. **NHLS approval for access to Bio samples: AARMS registration.**
9. **Hospital CEO or Representative e.g., Chair of Hospital Research Committee.**
10. **HoD.**
11. **District Manager.**
12. **Provincial or National Department of Health**
13. **Other Independent Ethics Committees/Institutional Review Board (IRBs) – inside and outside South Africa.**
14. **International Healthcare Authorities.**
15. **School principals.**
16. **Other.**

**WITS PLAGIARISM POLICY:**

1. The University’s policy on plagiarism is set out at: <https://intranet.wits.ac.za/exec/registrar/Policies/Policy%20%20Plagiarism.pdf#search=plagiarism>
2. Applicants seeking ethics clearance are required to be familiar with this policy.

# HREC (Medical) Committee Form Revision/Edit version Number

* Application Form, June 2025.