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

**FOR DEGREE AND OTHER INVESTIGATOR INITIATED RETROSPECTIVE RECORD REVIEW BASED RESEARCH**

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| --- |
| When is a retrospective data review application appropriate? It is appropriate for studies based entirely on the review of data already collected, usually but not necessarily, on hospital patients. If the study includes any prospective data collection, by whatever means, a full application is required. The normal online application process applies to prospective reviews. Retrospective data reviews 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. |

**IMPORTANT INSTRUCTIONS:**

* Read all the Appendices before completing this application form. Answer all questions (Y/N), 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 DETAILS:**

* 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) DETAILS:**

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

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

**SECTION 5: Timescales for Retrospective Review Procedures\***

**Note**: Please do not confuse research procedures with clinical procedures.

## 5.1 What is the initial date for the patient records? \*

 Date: (DD/MM/YYYY)

## 5.2 What is the final date for the patient records? \*

 Date: (DD/MM/YYYY)

**SECTION 6: Study Population \***

## 6.1 Patient records

If patients/patient records, or the records of any other group, are being studied, state where and how they are selected. \*

## 6.2 What is the age range of the participants in the study?

## 6.3 Sex of study participants?

**[ ]** Male only: \* **[ ]** Female only: \* **[ ]** Both: \*

## 6.4 Number of study patients/participants?

Number of patients/participants? \*

**SECTION 7: Procedures \***

**Note**: In Section 7 the word “Procedures” refers to the study, and not clinical procedures.

## 7.1 Indicate which research procedure(s) will be used (mark all that are appropriate). \*

**[ ]** Record review:

**[ ]** Radiographs:

**[ ]** Other sorts of records:

Please describe these records below:

**SECTION 8: General Information\***

## 8.1 Has permission been obtained from relevant authority(ies) *e.g.,* Hospital CEO, Head of Department, NHLS, etc., to carry out the study? Mark the appropriate box using an “X” \*

**Yes [ ]  No [ ]**

If “Yes”, please state name of authority(ies)and provide written proof of approval. Note: evidence of application serves no purpose, it is the response which is required.

## 8.2 How will confidentiality be maintained so that participants are not identifiable to persons not involved in the research? \*

## 8.3 Access to the raw data \*

Who will have access to the raw data and how will it be de-identified?

## 8.4 Access to the results \*

To whom will the results be made available, e.g., participants, supervisor, hospital management, etc.?

## 8.5 Dissemination of results \*

How will the results and findings be disseminated? (E.g., peer reviewed journal article, conference proceeding, departmental seminar, etc.)

## 8.6 Other helpful information.

Provide additional information that may be used by the HREC (Med) to evaluate this case report application.

## 8.7 Ethics training. \*

Please see the Guiding Information in the Appendix related to ethics training.

Note: It is essential to attach evidence of suitable training.

**SECTION 9: 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 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:** |  |

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

**APPENDIX 1: GUIDING INFORMATION FOR RETROSPECTIVE RECORD REVIEW BASED RESEARCH**

**Note Well: no data may be collected before the issue of an ethics clearance. In no circumstance will ethics clearance be issued retrospectively.**

**SUBMISSION REQUIREMENTS:**

**REQUIRED UPFRONT FOR THE APPLICATION TO BE ACCEPTED:**

 **ANY INADEQUATE SUBMISSION WILL BE REJECTED**

1. Completed and signed Retrospective Record Review **Application Form**.
* All sections must be completed correctly.
* Realistic duration of study (section 4.3.2) – usually start date should be 6 weeks or more after scheduled HREC (Medical) meeting date.
* Section 9 must be signed by PI, Supervisor(s) and Academic HoD.
* Degree and non-degree studies must be signed by PI and HoD other than PI, if PI is HoD. This includes Wits affiliates i.e. academic staff, entities, public government institution and NGOs affiliated with Wits.
1. Clean **Research/Study Proposal**. Compulsory for all applications/submissions (non-degree, undergraduate and postgraduate degree).
2. **Ethics training certificates** for all investigators and supervisors (not >3 years old); GCP training is not sufficient.
3. Data extraction sheet (no identifiers)

Ethics Training

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 <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.

**2. Required before final approval (ethics clearance):**

Documents to be submitted together with amendments after receiving outcome of ethics application. Submit together with ethics corrections.

1. Relevant permission from study site/s (e.g. hospital CEO, etc) and other entities.
2. SAHPRA approval (if health product - including medicine, medical devices, or kits).
3. Faculty protocol approval letter, where the study is for the purposes of a postgraduate degree
4. Data Transfer Agreement/Material Transfer Agreement (DTA/MTA) if data or samples are to be taken outside of Wits for analysis.
5. An Independent Ethics Committee (IEC) certificate(s) for an area outside WITS’ jurisdiction - must be NHREC accredited if in South Africa. Country IEC or an Institutional Review Board (IRB) if international collaboration.

**3. Can be post-clearance:**

1. Registrar’s approval, where University of the Witwatersrand students are concerned.

**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.**
10. **HoD.**
11. **District Manager.**
12. **Provincial or National Department of Health**
13. **Other Independent Ethics Committees/Institutional Review Board (IRBs).**

**APPENDIX 3 - RESPONSIBILITIES:**

1. Please note that it is the responsibility of the Principal Investigator and the Supervisor (if applicable) in an application 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.
2. Please indicate clearly, where correspondence should be sent; failure to do this may cause delays. Please provide the PI and the supervisor’s email address (where applicable) for sending copies of correspondence.
3. Please provide a protocol detailing the background to the research, the design of the investigation and all procedures, is submitted with the application.
4. Researchers with syndicates in the Wits Health Consortium – please read the home page at [www.witshealth.co.za](http://www.witshealth.co.za) regarding the requirement that the syndicate must be based in a Wits academic department, or recognised research entity.
5. For any assistance, please contact the WRO Ethics Secretariat to the Human Research Ethics Committee (Medical) at 011 717 2700/1234/2656 or email: Hrec-Medical.ResearchOffice@wits.ac.za
6. No data may be collected before ethics clearance certificate is issued by the HREC (Medical). In no circumstance will retrospective clearance be given.

**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.

**APPENDIX 4 - STORAGE OF BLOOD AND/OR TISSUE SAMPLES:**

The policy of the ethics committee is:

* If, blood or tissue specimens are to be stored for future analysis and/or it is planned that analysis may be done outside Wits, then the specimens must be stored at Wits with release of sub-samples only once projects have been approved by the local Research Ethics Committee applicable to where the research will be done, as well as by the Wits Human Research Ethics Committee: (Medical);
* A separate information sheet and consent form for this is required. Please see the Standard Operating procedure at [www.witshealth.co.za/Services/Research-Ethics](http://www.witshealth.co.za/Services/Research-Ethics)
* For information on Biobanks and the Biobank Ethics Committee within the Wits Human Research Ethics Committee, please go to <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/>, choose HREC (Med), see “Downloads”, see “Biobanks Ethics Committee”
* Only approved analyses may be done;
* Specimens may not be shared with anyone, unless approved by the Wits Human Research Ethics Committee (Medical); usually, an inter-institutional Materials Transfer Agreement (MTA) will be pre-requisite.

**APPENDIX 5:**

1. **THE NATIONAL HEALTH RESEARCH DATABASE (NHRD) REGISTRATION:**

This is essential for Provinces to be aware of, and evaluate studies being done in their hospital’s districts or clinics, etc.

# HREC (Medical) Committee Form

* Application Form version 03, 11 Dec 2024.