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

**FOR CLEARANCE OF RESEARCH INVOLVING DE-IDENTIFIED HUMAN BIOSPECIMENS**

|  |
| --- |
| **When is a De-identified Human Biospecimens study application appropriate?** It is appropriate for studies based on the use of human de-identified materials, such as surplus blood stocks, urine, liver samples, brain cells, saliva, teeth, etc., which would otherwise normally be discarded by medical facilities. Where the research is to be conducted on commercially available cell lines and other materials not directly derived from humans, a waiver may be applied for, using the appropriate form (not this one). De-identified Human Material Study applications 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.
* **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. **Purpose of the Research:**

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

Undergraduate Degree/Diploma: **Yes [ ]  No [ ]**  (If yes, state 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 give 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 box for 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-INVESTIGATOR(S) DETAILS -** Please repeat box for 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 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** |  |

**3.4 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) |  |

**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.):

**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. **Study Participants:**
1. Where and how the materials are selected:
2. Number of participants to be studied:

**SECTION 5: HUMAN BIOSPECIMENS**

**Please answer all the following questions clearly but succinctly.**

**5.1 Describe the nature of the human biospecimens which will be studied, e.g., blood, urine, tissue, etc.**

**5.2 Who will provide the human biospecimens, i.e., name the institution, or organisation.**

**5.3 How did the providers (described in 5.2) come by the biospecimens?**

**5.4 In cases where the biospecimens come from a living human host, did the host provide informed consent/assent to research on the sample(s)?**

**5.5 If the source of the sample(s) is a deceased person, was informed consent obtained from an immediate family member, or other suitable proxy? If so, from whom?**

**5.6 How and where is the study biospecimens to be stored?**

**5.7 When and how will the study biospecimens be disposed of?**

**SECTION 6: GENERAL INFORMATION**

## 6.1 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.

## 6.2 Access to the raw data

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

## 6.3 Access to the results

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

## 6.4 Dissemination of results

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

**SECTION 7: INFORMATION, DECLARATION AND SIGNATURES (To be kept on separate page)**

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

In appending my signature below, I confirm that 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).

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:** |  |

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

**APPENDIX 1: GUIDING INFORMATION FOR DE-IDENTIFIED HUMAN BIOSPECIMENS STUDY**

Standard attachments in a lab study:

1. Ethics training certificates (see below)
2. Study protocol
3. Faculty protocol approval letter, where the study is for the purposes of a postgraduate degree
4. Data extraction sheet (no identifiers)
5. Hospital CEO approval, or equivalent
6. Institutional Biosafety Committee (IBC) clearance of the laboratory to be used
7. Anything else as appropriate

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 M odules 1,2 and 3 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.

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

**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 Authority (for studies outside South Africa).**
15. **School principals.**
16. **Others.**

**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 HUMAN BIOSPECIMENS:**

The policy of the ethics committee is:

* If, human biospecimens 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/assent 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; as per PIL/ICON and Wits HREC (Medical)
* 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.

# HREC (Medical) Committee Form

* De-identified Human Biospecimens Study Application Form, June 2025.