**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)**

**CASE REPORT APPLICATION FORM 2025**

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| **When is a case report application appropriate?** It is appropriate for studies in a which a patient has displayed an unusual condition, before or after treatment. One primary reason to write up such a report is to alert peers to situations in which the standard diagnosis and treatment may be inappropriate. Usually, a case report involves a single patient. When the number goes beyond three, the HREC (Medical) Office should be consulted as to the appropriate type of ethics application. Case Report applications may be submitted via 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, 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**, and the 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:**

**1.1** Is this a New Submission? **Yes [ ]  No [ ]**

**1.2** Is this a Resubmission? **Yes [ ]  No [ ]**

 **If yes**, please give previous HREC number(s):

**SECTION 2 – CASE REPORT TITLE**:

|  |
| --- |
| **Case Report Title**:  |

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

**3.1 PRINCIPAL INVESTIGATOR –** (Please repeat the 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-INVESTIGATORS –** (Please repeat the 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 DETAILS** (Please repeat the 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: DESCRIPTION OF CASE REPORT**

## 4.1 Brief summary of the case report: (Do not say “see attached”)

**SECTION 5: REQUIRED DOCUMENTATION**

## 5.1 Is consent needed for this case report? If so, provide participant information leaflet

##  and informed consent form, if applicable.

##  Mark the appropriate box using an “X”

 **Yes [ ]  No [ ]**

(For guidance go to <http://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> and chose HREC (Med), see “Downloads”.

**Note**

* If informed consent is to be oral, or if informed consent is not considered necessary, a written motivation and justification should be attached.
* If informed consent cannot be obtained because the patient is lost to follow-up, or has died, details should accompany this application. Note that proxy consent from next of kin is usually the first alternative when the patient has died.

**SECTION 6: PARTICIPANT DETAILS**

## 6.1 How many patients / participants are involved in the study?

 Number:

**Note**

* The number must not exceed 3.

## 6.2 Age of participants

 What is/are the age(s)?

 **Note**

* If the participant(s) is/are <18 years (minors), then evidence of parental/legal consent is required.
* If the participant(s) is/are in the age range from 7 to 17 years, an age-appropriate Participant Information Sheet and Assent Form must be attached.

## 6.3 Sex of the study participant(s)

## Check the appropriate box(s) using an “X”

Male: **[ ]** Female: **[ ]** Other: **[ ]**

**SECTION 7: RISKS OF CASE REPORT STUDY PROCEDURES**

## 7.1 Is there a risk of patient / participant or family harm or distress? Check the appropriate box using an “X”

Yes [ ]  No [ ]

If “Yes”, please describe and attach a distress protocol.

**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?

* Access to the raw data?
* Who will have access to the raw data?

## 8.3 Dissemination of results and findings. \*

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

## 8.4 Attach current ethics training certificates (must be <3 years old)

 This is required by the NHREC. See Appendix for more information and guidance.

**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).

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.

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| --- |
| **Repeat Case Report 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) IF APPLICABLE -** 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 this 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:** |  |

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

**APPENDIX 1 - SUBMISSION REQUIREMENTS FOR A CASE REPORT:**

**1. REQUIRED UPFRONT FOR A CASE REPORT APPLICATION TO BE ACCEPTED:**

 **ANY INADEQUATE SUBMISSION WILL BE REJECTED**

Standard attachments in a case study:

1. Ethics training certificates (see below).

2. Data extraction sheet (no identifiers)

3. Participant Information Leaflet

4. Informed Consent Form

5. Distress protocol (if required)

6. Hospital CEO/District Manager/Provincial approval

Ethics training (Not >3 years old)

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 must complete Modules 1, 2 and 3, which costs nothing and will generate a certificate. Please attach copies.

**APPENDIX 2 - 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 2700/1234/2656/72816 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 3 – Participant Information Leaflet and Informed Consent Form (PIL/ICON):**

1. The **Wits HREC (Medical)** and **The National Health Research Ethics Council (NHREC)** requires a Participant Information Leaflet and Informed Consent Form written in language understandable to the participant (or parent/legal guardian) detailing what the participant will be told. This should include the following:
	1. Please ensure to INVITE the participant to take part in the study; please include a greeting and introduce yourself.
	2. Participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
	3. The participant may withdraw consent for the study at any time without penalty or loss of benefits.
	4. A brief description of the research, its duration, procedures, study intention, participation and what the participant may expect and/or be expected to do.
	5. Any foreseeable risks, discomforts, adverse effects or potential benefits.
	6. A separate PIL/ICON for human biospecimens taken for future testing unrelated to the study.
2. Minors over 7 years of age need to sign an Assent Form together with Parents/Legal Guardian Consent.

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

* Application Form, June 2025.