**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 initial HREC number):

**SECTION 2 – CASE REPORT TITLE**:

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| **Case Report Title**:  |

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

**3.1 PRINCIPAL INVESTIGATOR(S):**

|  |  |
| --- | --- |
| **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: Only if applicable**

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

## 5.2 Attach current ethics training certificates

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

**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/guardian consent is required.
* If the participant(s) is/are in the age range from 7 to 17 years, at least one age-appropriate Information Sheet and Assent Form must be attached.

## 6.3 Gender of the study participant(s)

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

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

**SECTION 7: Risks of Case Report Study Procedures\***

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

Yes [ ]  No [ ]

If “Yes”, please 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 Other helpful information.

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

**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).

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| --- |
| **Repeat Case Report 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:** |  |

# Principal Investigator version no XX dated DD/MM/YYY

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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 Sheet

4. Participant Consent Sheet

5. Distress protocol (if required)

6. Hospital CEO approval

7. Study synopsis

8. 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 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.

National HREC rules stipulate that ethics training certificates are not acceptable if they are more than three years old and that Good Clinical Practice Certificates are only acceptable in this context if they specify an ethics component.

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

**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, including those for placebo and standard of care.
	6. Disclosure of approved alternatives available to the participant.
	7. Emergency contact name and 24-hour telephone number.
	8. Explanation that medical treatment will be provided in the case of an adverse event (especially serious adverse event).
	9. Compensation for trial related injuries will be in accordance with the ABPI 2014 guidelines.
	10. A separate PIL/ICON for blood / tissue samples taken for future testing unrelated to the study.
2. The **Informed Consent Form** should include a clear statement that the participant is consenting to involvement in research, and not to specific treatment, which will not necessarily provide personal benefit. Any potential personal benefit should be mentioned when this is possible. In a trial **involving a placebo**, the participant must be made aware that, although the potential risks and benefits of all the investigational products have been explained, none of the active investigational products may be administered and it will not be possible for the researcher to reveal whether an active investigational products or placebo is being administered. An important piece of information is that the participant is free to withdraw from the study at any time without prejudicing any treatment that is required for existing or future medical conditions.
3. 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 version 01, 11 Dec 2024.