Ethics Clearance Procedures for Medical Research

Research integrity including ethical research is governed within the University by the Research Integrity policy (see www.wits.ac.za under Research Resources). The Human Research Ethics Committee, Medical (HREC-M) is an independent committee created under the auspices of the Research Integrity policy with the purpose to assess research studies against accepted national and international ethical standards.

Ethics clearance is required for all medical and health related research involving humans, whether it is conducted by Wits students, Wits staff or Wits affiliated staff in the name of Wits University or using Wits resources or property. Medical and health science research includes all research related to therapeutic or diagnostic work involving patients who may be ill or healthy; research that involves human tissue, genetic material, fluids or organs; research involving human cadavers and research involving questionnaires related to therapeutic or diagnostic work, or examination of patient medical records.

No medical or health related research may begin before ethics clearance has been granted. No retrospective approvals for research already done are ever granted.

Process to Request Ethical Clearance

Principle Investigators (PIs) seeking ethical approval for their research studies should request a clearance certificate by submitting their full applications via this website http://www.witsethics.co.za/login.aspx

Meetings of the HREC-M are held monthly, other than in December, in the last week of the month. Applications must reach the ethics secretariat typically before the 5th of the month to be included in the agenda for that month. Applications received after that date will be added to the agenda for the next month’s meeting. The turn-around time for receipt of the clearance certificate is 28 working days post the meeting, assuming that the proposed research meets all the requirements under South African law to be regarded as ethical. If amendments to study designs are required, the PI will be informed by email of the required changes within 28 days of the HREC-M meeting. PIs have up to three months to submit these amendments and any outstanding documents.

Special Cases

There are some circumstances in which the usual full application and approval method, described above, can be simplified. They include (1) case studies, (2) sub-studies and (3) in-study changes or amendments and (4) waivers; and are described below. In all these cases the online system cannot currently be used and so 2 hard copies of the submission must be physically handed into the Ethics Secretariat on the 3rd floor of the PVT Building, corner of York and Carse O’Gowrie Roads in Parktown. This submission should include a brief covering letter.
addressed to the Chair of the HREC-M, Dr Clem Penny. The details of the content of this letter are described below under each special case.

The turn-around time between physical submission and communicated result for these special cases should not exceed 14 days.

1. Case Studies

**Definition:** Case studies include oral or poster presentations at conferences or write-ups for publication, on condition that there are not more than 5 case studies presented at one time (greater numbers will require a full application).

**Process:** Submit 2 copies of the completed application form¹ and a covering letter. The covering letter must indicate where the case studies will be presented and or the details of the publication.

**Cautionary notes:**

- The application must record clearly that no identifying details will be used in the case studies particularly when using photographs.
- If a patient in a case study is lost to follow up, there is no need for consent, but if the patient in the case study is still accessing medical care, then signed (written) informed consent is required.
- More than 5 cases will require a full online ethics application.

2. Sub-studies that are Part of an Already Approved Project

**Definition:** Sub-studies are parts of larger studies that are already cleared as ethical, where:

- No new data will be collected;
- No new specimens will be collected;
- There will be no new interactions with the original study participants

**Process:** Submit 2 copies of the completed application form¹ and a covering letter. The letter and application form must be signed by the sub-study leader – often a postgraduate student – and the PI of the bigger study. The letter must clearly state how the sub-study fits into the larger already approved study.

3. In-Study Changes or Amendments to Studies

**Definition:** In-study changes arise when the research requires that a minor change is made to the approved study design (or protocol). These changes should not lead to an entirely new study. Where the changes are significant enough to constitute an entirely new study,

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¹ [https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/](https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/) (HREC (Medical) option, under “Downloads,” HREC (M) Application Form 2021)
then the PI will have to begin the ethical clearance process from the beginning as described above.

**Process:** Submit 2 copies of a covering letter that summarizes the envisaged changes and signed by the PI.

**Cautionary notes:** It is vital that all such changes are recorded and approved by the HREC (Medical) office prior to continuing the study. [It remains the responsibility of the PI to record these changes before they arise.]

### 4. Waivers from Ethics Approval

In some cases waivers from ethical clearance can be granted.

**Note Well:** If an application for a waiver is not supported, a full application will be required.

Waivers from ethics approval may be granted for *in vitro* laboratory studies, where the Head of Department (HoD) or designated deputy indicates that the study will make use of cell lines, bacterial cultures, or similar and categorically confirms that no humans, human data or human genetic material or tissues will be used in the study.

These studies have varying procedures based on their circumstances.

#### 4.1. *In vitro* laboratory studies for non-degree purposes

**Process:** Submit 2 copies of the completed waiver application form[^3] and a letter confirming that the study is for non-degree purposes signed by the PI and the HoD must be submitted.

**Cautionary notes:** The confirmation of the HoD is vital.

#### 4.2. *In vitro* laboratory studies for MSc or PhD students and not part of a project that already has ethics approval

**Process:** Submit 2 copies of the completed waiver application form[^3] and a letter confirming the degree in question signed by the student, by the student’s supervisor and by the HoD

**Cautionary notes:** The confirmation of the HoD is vital.

[^3]: [https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/](https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/)
4.3. *In vitro* laboratory studies for MSc or PhD students within a bigger study for which an ethics waiver has already been obtained by the PI

**Process:** Submit 2 copies of the completed waiver application form and a covering letter explaining the study and signed by the student, by the student’s supervisor, by the PI of the bigger study (who has the ethics clearance) and by the HoD must be submitted.

**Cautionary notes:** The confirmation of the HoD is vital.

4.4. *In vitro* laboratory studies for MSc or PhD students within a bigger study for which an ethics waiver has already been obtained by the PI and which has stored human specimens

**Process:** Submit 2 copies of the completed waiver application form⁴, 2 study protocols¹ and a covering letter explaining the study and signed by the student, by the student’s supervisor, by the PI of the bigger study (who has the ethics clearance) and by the HoD.

**Cautionary notes:** The motivation letter must indicate what human specimens are stored (with human participant consent) and must confirm that no new specimens will be collected.

An ethics waiver may also be granted when the data to be used is already in the public domain. This is most commonly in the form of a literature search, or by interrogating databases open to the general public; no gatekeeper permission should be required.