

## HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

### STANDARD OPERATION PROCEDURE

#### RESEARCH ETHICS TRAINING

**SOP-HREC-013 (VERSION 3)**

**REVISED AND UPDATED: JULY 2026**

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| <b>SUBJECT</b>                                   | Policy regarding Research Ethics Training Compliance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>DIVISION / SCOPE:</b>                         | University of the Witwatersrand, Human Research Ethics Committee (Medical)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>REVISION:</b>                                 | Ethics Secretariat                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>PURPOSE:</b>                                  | This statement aims to provide policy and guidelines regarding the approval of Researchers involved in research conducted in Wits affiliated Research Entities/Departments and/or Private/External Research Sites (within Gauteng), requiring Wits HREC (Medical) approval. This is based on the requirements for <b>Research Ethics Training</b> from the National Health Research Ethics Council (NHREC) <b>South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2 (NdoH 2024, 3<sup>rd</sup> ed.(v3.2))</b> , which is a national requirement for all health-related research across South Africa |
| <b>PREVIOUS VERSIONS / (REASON FOR REVISION)</b> | SOP-HREC-013v2<br>Updated NDoH 2024 guideline version                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>CONTENT:</b>                                  | <b>INDEX</b> <ol style="list-style-type: none"> <li>1. Policy Statement</li> <li>2. Requirements for Training in Research Ethics</li> <li>3. Formal assessment of the knowledge of Researchers</li> <li>4. Who requires Research Ethics Training</li> <li>5. Definitions and Abbreviations</li> <li>6. References</li> </ol>                                                                                                                                                                                                                                                                                                                                             |
| <b>APPROVALS:</b>                                | Signature of Chair / Co-Chair:<br><br>Date: 2026/07/23                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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#### 1. POLICY STATEMENT

As per the National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition, Version 3.2, Research Ethics Training is a compulsory requirement for consideration of a research application nationally (**in addition** to Good Clinical Practice (2020) Training which is only needed for clinical research). Researchers have to provide proof of Research Ethics Training in their HREC (M) [IEC] applications – without this, the application cannot be approved.

As per the guidelines, Section 2.3.8: **Researcher competence and expertise**

Researchers must be suitably qualified and technically competent (suitably trained and supervised, in the case of student researchers - see also 5.4.2.2) to carry out the proposed research. The principal investigator (PI) has primary responsibility to ensure the safety and wellbeing of participants, the scientific integrity of the protocol, research data management, and responsible implementation of that protocol. For international multi-site research, at least one PI must be physically present in South Africa.

Competence is demonstrated mainly by academic qualifications, credentials, scientific and technical competence, as evidenced in previous publications, testimonials and/or research experience. Competence includes research competence, which is assessed in terms of education, knowledge, certification, and experience. In addition, **researchers must produce evidence of appropriate Research Ethics Training, renewed every three years.**

#### 2. Requirements for Training in Research Ethics

- The Wits HREC (Medical) will accept both online and face-to-face Research Ethics Training.
- Research Ethics Training Courses must include health research ethics and research-related legislation.
- The South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2 (NDoH 2024, 3<sup>rd</sup> ed. (v3.2)) should be referenced in the training material.
- Current Research Ethics Training certificates that do not reference NDoH 2024 guidelines will be **accepted until expiry**, after which refresher training must include reference to the NDoH 2024 guidelines.
- New Research Ethics Training to be undertaken must reference the NDoH 2024 guidelines.

##### Online training opportunities

The Wits HREC (Medical) will accept TRREE training provided that the South African Regulatory Framework Modules 1, 2 and 3 are completed. These three modules together will be viewed as valid ethics training.

- Module 1 – Introduction to Research Ethics
- Module 2 - Research Ethics Evaluation
- Module 3 – Informed Consent

Please Note:

- TRREE Ethics Training Module 1 completed before the 30th of September 2025 will be valid as is, until expiry, after which Modules 2 and 3 must be done.
- TRREE Ethics Training Module 1 completed after 1st of October 2025 will be required to also complete Modules 2 and 3 to be valid.

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Other online ethics training incorporating NDoH 2024 e.g. Academic Advance Ethics Training, will also be accepted.

#### 3. **Formal assessment of the knowledge of individuals completing Research Ethics courses**

For Applications submitted to the Wits HREC (Medical), valid Research Ethics Training Certificates are to be attached to CV's. This applies to Principal and Co/Sub-Investigators on new studies submitted for review, as well as **additional Investigators** added onto already approved/ongoing studies.

#### 4. **Who requires Research Ethics Training**

As per the National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition:

As per the guidelines, Section 5.4 "**Education and Training in Research Ethics**"

It is expected that all **REC members, REC administrators, researchers, and students** who will undertake research with human participants, or that involves use of animals, will ensure they complete theoretical research ethics training to ensure they are familiar with expectations, especially those set out in NDoH 2024 3rd ed., SANS 10386:2021 and, for clinical trials, SA GCP 2020. The expectation is that researchers, and especially students, should complete the institutional required research ethics training before conducting research. Researchers are expected to ensure they have the appropriate knowledge, skills, expertise, competence, including discipline-appropriate scientific background and research ethics training to conduct studies involving human participants.

##### **Who requires Research Ethics Training:**

- Career and Contract Researchers (Principal and Co/Sub-Investigators)
- Any Research undertaken for degree or non-degree purposes
- **All Supervisors** of all undergraduate and post-graduate students
- Members and Advisors of the University of the Witwatersrand, Human Research Ethics Committee (Medical)

*If you have already done ethics training in the last three years, as part of research methodology or academic course, please include your certificate or letter of completion.*

#### 5. **Definitions and Abbreviations**

|       |                                         |
|-------|-----------------------------------------|
| HREC  | Human Research Ethics Committee         |
| NDOH  | National Department of Health           |
| NHREC | National Health Research Ethics Council |
| WITS  | University of the Witwatersrand         |

#### 6. **References**

- ♦ National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2
- ♦ Follow the link: <https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/> - select 'Human Research Ethics Committee (Medical); Grant and commercially funded research applications, select bullet point "Click here for NDoH 2024"