HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATION PROCEDURE

RESEARCH ETHICS TRAINING

SOP-HREC-013 *(VERSION 1)* **REVISED AND UPDATED: JANUARY 2025**

SUBJECT	**Policy regarding Research Ethics Training Compliance**
DIVISION / SCOPE:	**University of the Witwatersrand, Human Research Ethics Committee (Medical)**
REVISION:	Ethics Secretariat
PURPOSE:	This statement aims to provide policy regarding approval of researchers involved in research conducted in Wits affiliated Research Entities/Departments and/or Private/External Research Sites (within Gauteng), requiring Wits HREC Medial approval, as well as NHREC requirement for **Research Ethics Training**, which is a national requirement for all health-related research across South Africa
PREVIOUS VERSIONS / (*REASON FOR REVISION*)	**Revised**
CONTENT:	**INDEX** **1. POLICY STATEMENT** **1.1 Training in Research Ethics** **1.2 Formal assessment of the knowledge of Researchers** **1.3 Who requires Research Ethics Training** **2. DEFINITIONS AND ABBREVIATION** **3. REFERENCES**
APPROVALS:	**Signature of Chair / Co-Chair:** Paul Ruff **Date:** 2025/01/13

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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, Research Ethics Training is a compulsory requirement for consideration of a research application nationally (**in addition** to Good Clinical Practice Training for Clinical Trials). 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 in South Africa.

"Competence is demonstrated mainly by academic qualifications, credentials, scientific and technical competence, as evidenced in previous publications or testimonials. 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 within the previous three years**."

1.1 Training in Research Ethics

1.1.1 Online training opportunities

Online training in research ethics which will be accepted by the Wits HREC (Medical)

1.1.2 Face to face Research Ethics Training Courses

Research Ethics Training Courses must include health research ethics and research-related legislation. Various face to face research ethics training courses are available.

1.2 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.

1.3 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.

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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.

2. Definitions and Abbreviations

HREC	Human Research Ethics Committee
NHREC	National Health Research Ethics Council
WITS	University of the Witwatersrand

3. References

- National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition
- Follow the link: https://www.witshealth.co.za/Services/Research-Ethics/Application-Forms - click on item 22
- See example of a free online ethics training course recommended by the Wits HREC:
  TRREE: https://elearning.trree.org/course/index.php?categoryid=1
  - Module 1 – Introduction to Research Ethics
  - Module 3.1 – Informed Consent