HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

GOOD CLINICAL PRACTICE

SOP-HREC - 010*(VERSION 1)* **REVISED AND UPDATED: JANUARY 2025**

SUBJECT	**Policy of the University of the Witwatersrand, Human Research Ethics Committee (Medical) regarding Good Clinical Practice (GCP) compliance of Investigators and Essential Support Staff in Clinical Trials**
DIVISION / SCOPE:	**University of the Witwatersrand, Human Research Ethics Committee: (Medical)**
REVISION:	Ethics Secretariat
PURPOSE:	This procedure aims to provide current policy of the Wits HREC (Medical) regarding the approval of Investigators and notification of Essential Staff, involved in clinical trials conducted at Wits Affiliated Research Entities/Departments, and Private Practice/External Sites (within Gauteng), ensuring Investigators comply with Good Clinical Practice guidelines.
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	SOP-IEC-010v7 Revised and updated
	1. Policy on Good Clinical Practice 2. Wits HREC (Medical) Approval Requirements for Investigators 3. Notification of Essential Support Staff 4. SAHPRA And NHREC Requirements 5. Definitions and Abbreviations 6. References
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2025/01/13

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1. POLICY ON GOOD CLINICAL PRACTICE

As stated in the *South African Good Clinical Practice: Clinical Trial Guidelines, Third Edition (SA GCP 2020)*, clinical trials should be conducted in accordance with all the ethical principles outlined in the Declaration of Helsinki and must be consistent with GCP and other applicable regulatory requirements.

All role players involved with clinical trials should also be familiar with other national and international guidelines, including but not limited to the following current versions or their successors:

- National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd edition
- Declaration of Helsinki (2024)
- ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 (R2) 2016 (ICH GCP 2016)
- ICH Harmonised Tripartite Guideline: Clinical Investigation of Medicinal Products in the Pediatric Population E11 2000
- Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research involving Human Subjects (2016)
- CIOMS with WHO International Ethical Guidelines for Epidemiological Studies (2009)
- Clinical Trial Compensation Guidelines, Association of British of Pharmaceutical Industry (ABPI) Guidelines (2014)
- European Union requirements at http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm
- World Health Organisation WHO Technical Report Series, No. 850 Guidelines for good clinical practice (GCP) for trials on pharmaceutical products (1995)
- World Health Organisation Handbook for Good Clinical Research Practice (GCP) (2005)

Ethical principles of beneficence and non-maleficence, distributive justice (equity) and respect for persons (dignity and autonomy), discussed in detail in 2.1 of NDoH 2024, govern all clinical trials conducted in South Africa.

The term ‘clinical trial’ is inclusive. Specific types of clinical trials are not addressed separately unless a particular need is identified, i.e. ‘clinical trials’ includes trials involving complementary and alternative medicines, traditional medicines, and non-pharmacological interventions including surgical procedures, medical devices, *in-vitro* devices, cell and gene therapy, genetics and genomics, and imaging technology. Consequently, these GCP guidelines, read with NDoH 2024, provide guidance for any clinical trial involving human participants, especially those with investigational designs.

The rights, safety and well-being of trial participants are critical considerations. The Site Principal Investigator (PI) has, or the Co-Principal Investigators (Co-PI) have, primary responsibility for the safety and welfare of local participants.

The National PIs have overall responsibility to ensure that all sites maintain good clinical practice particularly in large multicentre trials.

2. WITS HREC (MEDICAL) APPROVAL REQUIREMENTS FOR INVESTIGATORS

- All Investigators must submit to the Wits HREC (Medical), evidence of current (i.e. within three years) GCP training as well as current general research ethics training.
- GCP training must be specific to South African research environment and must include South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP

2020) and South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition

- Basic SA GCP training should be done live (virtual or face-to-face) and be in alignment with the prescribed outcomes or unit standards (approximately 2 days).
- Thereafter, Refresher SA GCP training must be done three-yearly. This may be done online.
- SA GCP training should be accredited by the Health Professions Council of South Africa (HPCSA).

NOTE: Trial Investigators and Site Staff whose SA GCP training has expired for more than three months must re-do the basic SA GCP course.

Investigators should also have comprehensive training in Internationally accepted GCP principles:

- ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH – E6(R2) – Current Step 4 version dated 9 November 2016
- Declaration of Helsinki 2024
- FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards

3. NOTIFICATION OF ESSENTIAL SUPPORT STAFF

The following essential support staff who have contact with trial participants, must be submitted to the Wits HREC (Medical) for notification:

- Senior and Back-up Pharmacist(s)
- Only Study Nurses / Study Coordinators who have a direct clinical involvement with participants i.e. who are active involved in the treatment of participants e.g. administering participants treatment with the investigational product, or independently taking Informed Consent or In-depth Interviews.
- Essential Support Staff to submit a copy of their CV's, a signed Declaration by Sub-Investigator, relevant statutory body registration and GCP Training certificates.

  Note: Other support staff members who have an administrative role and who are not clinically involved with participants, would not need to be submitted to Wits HREC (Medical) for notification.

4. SAHPRA AND NHREC REQUIRMENTS

Communication to Stakeholders, from The National Health Research Ethics Council (NHREC) and The South African Health Products Regulatory Authority (SAHPRA), dated 22 April 2024 refers:

South African Health Products Regulatory Authority (SAHPRA) and National Health Research Ethics Council (NHREC) acknowledge that due to the advent of virtual meetings via Zoom, Teams, etc., the methods of GCP training should also be adapted to align with local and global practices and trends relating to the conduct of virtual trainings.

In view of the above, virtual methods will be acceptable (via Zoom, Teams, etc.) provided that the training is done properly; it is live, interactive; active engagement of participants is monitored; with a full- time facilitator (qualified to conduct training) available the entire duration for questions and answers. Both SAHPRA and NHREC support the virtual training for the purpose of increasing capacity building; accessibility; empowerment and inclusivity of the

researchers, healthcare personnel and Research Ethics Committees (RECs); and a reduction of travel and logistic costs for researchers and RECs. To ensure inclusivity and fairness, consideration should be given to the candidates who are unable to attend virtual training, especially those placed in remote areas where internet accessibility remains a challenge. A hybrid model could be considered in this case.

The duration of the training for basic GCP training should be in alignment with the prescribed outcomes or unit standards (approximately 2 days). The training content should be accredited by HPCSA.

5. Definitions and Abbreviations

FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practices
HPCSA	Health Professions Council of South Africa
ICH	International Council for Harmonisation
NHREC	National Health Research Ethics Council
SAHPRA	South African Health Products Regulatory Authority
WHC	Wits Health Consortium
WITS	University of the Witwatersrand

6. References

- South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition. (NDoH 2024).
- South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
- ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH – E6(R2) – Current Step 4 version dated 9 November 2016
- Declaration of Helsinki 2024
  - http://www.wma.net/en/30publications/10policies/b3/index.html
- FDA Guidelines – OHRP (Office of the Human Rights Protection, applicable FDA requirements for Institutional Review Boards
  - http://www.hhs.gov/ohrp/policy/
- 21 Code of Federal Regulations Part 56 – Institutional Review Boards
- 21 Code of Federal Regulations Part 50 – Protection of Human Participants