UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

RENEWAL / RECERTIFICATION OF RESEARCH STUDIES

SOP-HREC – 002*(VERSION 2)* **REVISED AND UPDATED: JULY 2026**

SUBJECT:	**Procedure for the Renewal / Recertification of ongoing research studies on human participants by the University of the Witwatersrand, Human Research Ethics Committee: (Medial)**
DIVISION / SCOPE:	**University of the Witwatersrand, Human Research Ethics Committee (Medical)**
AUTHOR: **REVISION:**	Ethics Secretariat
PURPOSE:	This procedure describes the process to be followed by the Wits HREC (Medical) for the renewal / recertification of ongoing research studies on human participants at Wits Affiliated Research Entities/Departments, and Private Practice/External Sites (within Gauteng) to ensure that the approvals granted by the Wits HREC (Medical) are in compliance with the following requirements: ♦ South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) ♦ ICH GCP E6(R3) Guidelines dated 06 January 2025 ♦ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2 (NDoH 2024, 3rd ed. (v3.2)) ♦ Code of Federal Regulations: (21 Part 50) Protection of Human Subjects, (21 CFR Part 56) Institutional Review Boards, (45 CFR Part 46) Protection of Human Subjects ♦ International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016. ♦ Association of British Pharmaceutical Industries (ABPI 2014)
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	SOP-HREC-002.v1 Updated ICH GCP, NDoH guideline version, Grace for lapse period increased from 3 to 6 months, added MoA details for private sites, clarified renewal (five yearly approval) vs recertification (annual approval)
CONTENTS:	1. Procedure for Renewal / Recertification of research studies by Wits HREC (Medical) 2. Duration of Approval 3. Attachments: • Renewal / Recertification Application Form 4. Definitions and Abbreviations 4. References
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** **Date:** Paul Ruff 2026/07/23

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1. PROCEDURE FOR RENEWAL / RECERTIFICATION OF RESEACH STUDIES BY WITS HREC (MEDICAL)

The University of the Witwatersrand, Human Research Ethics Committee (Medical) requests that Investigators and Sponsors / Applicants submit a Renewal Application where the initial 5-year approval is set to expire.

- Renewal / Re-certification Applications require formal review by the full Wits HREC (Medical) at the monthly HREC meetings.
- The initial ethics approval granted for a study is valid for five (5) years. Where the 5-year approval is set to expire, a **Renewal Application** should be submitted before the expiry date. A maximum of six (6) months grace period will be allowed once the approval has expired. The **Renewal Approval** issued by the Wits HREC (Medical) will be valid for an **additional FIVE (5) years.**
- Where more frequent recertification (i.e. annual) is required by the Sponsor/Funder, it remains the responsibility of the Investigator / Applicant / Sponsor to keep track of due dates and apply for annual recertification.

2. DURATION OF APPROVAL

2.1 Expiry Dates of Initial Ethics Approval Letters And Recertification Approvals

HREC (Medical) hereby requests that Investigators and Sponsors/Applicants regularly review their initial ethics approval letters to determine the expiry date of the ethics approval.
As per the initial ethics approval letters provided by the HREC, approval is valid for 5 years. Where the 5-year approval is set to expire, a renewal application should be submitted before the expiry date. A maximum of six (6) months grace period will be allowed once the approval has expired. The committee reminds Investigators and Sponsors/Applicants of the potential implications resulting from a lapse in ethics approvals, such as discarding of data collected during the lapse period.

2.2 Renewal / Recertifications and Memorandum of Agreement (MoA) for External/Private (non-Wits) Research Sites inside of the Gauteng Province

The National Ethics Committee regulations require direct legal supervision of the research sites by the HREC (Medical) including monitoring visits to the site and the authority to intervene should there be an identified risk of ethical misconduct. The HREC (Medical) developed a Memorandum of Agreement (MoA) for External/Private Research Sites/Principal Investigators based inside of Gauteng.

Applications for these sites may be submitted to the HREC (Medical) for review and approval, however 1) there must be at least one Wits affiliated Site/Investigator involved in the study, and 2) the MoA for the external/private sites must be completed and submitted with applications.

The MoA is an agreement between the University of the Witwatersrand, the Sponsor/Applicant and the External Site/Principal Investigator and will give the HREC (Medical) proper jurisdiction to oversee these external/private sites. This MoA is required for all external/private site applications (i.e., new applications and additional sites added to ongoing studies).
External/private sites based inside of the Gauteng Province that have previously been approved by the HREC (Medical) will be supported until the initial 5 year ethics approval expires, after which they may be renewed for an additional five years, but on condition that they complete MoAs.

2.3 Studies previously approved by the HREC (Medical) for sites outside of the Gauteng Province, that require annual recertification

These will be reviewed under the following categories:

2.3.1 An ongoing study where participant enrollment and follow-up is ongoing will be considered for a single recertification to provide the investigators with an opportunity to approach a local or private ethics committee for further approval. This recertification will require the institution, site and principal investigator to sign the MoA referenced above. Category 2.3.1 is subject to application by the principal investigator and should be accompanied by a cover letter motivating the required period of recertification while awaiting review from the local institutional or private ethics committee.

2.3.2 An ongoing study where the participant enrollment and follow-up has been completed but the study remains open under the Wits HREC (Medical) for the completion of the data, secondary analysis, laboratory investigations or sample storage may be recertified by the Wits HREC (Medical) as required.

2.3.3 A study that is closed to participant follow-up and where the primary database has been closed, but the study remains registered with the HREC (Medical) for the maintenance of laboratory samples stored in a biorepository may be recertified by the HREC (Medical).

2.3.4 Studies conducted at sites under the supervision of a Principal Investigator that are affiliated by an appointment to the University of the Witwatersrand may continue to under the recertification of the HREC (Medical). Should this affiliation cease, the Wits HREC will no longer be able to provide ethics cover for the applicable site/PI.

2.4 External/Private (non-Wits) Research Sites outside of Gauteng

The HREC (Medical) no longer approves external/private research sites outside of the Gauteng province. This decision is due to monitoring pressures and difficulties in oversight.

As per South African Ethics in Health Research Guidelines: Principles, Processes and Structures 2024, Third Edition, Chapter 5, Section 5.5.1.4 a):
“The South African ethico-legal framework requires that PIs or research leaders must obtain approval from their institutional REC. In principle, this means that RECs have authority to review and approve research protocols only for research sites or geographic areas within their own South African jurisdiction. Thus, when a protocol proposes a research study or project that is to collect data from multiple sites or geographic areas within South Africa, more than one REC may be involved in the review and approval processes.”

Therefore external/private research sites outside of Gauteng should be submitted to HRECs with jurisdiction in their own geographical area.
The HREC (Medical) will however continue to provide ethics support for previously approved external/private research sites outside of Gauteng, until the expiry of the initial 5 year approval, after which they will be provided with HREC approval for a maximum of one year only, until either the study closes, or to provide support until an alternative ethics approval can be obtained elsewhere, should the study continue for a number of additional years. These sites must complete MoAs for the additional year, but may not be granted a five year renewal.

Note: WITS affiliated sites and Investigators outside of Gauteng will be accepted for HREC review and approval as they fall under the jurisdiction of the University of the Witwatersrand

Responsible person	Action to be taken
Ethics Secretariat	Process the Renewal / Recertification Applications for studies that are due to expire (either initial five year approval or annual approval)
	Check that the documents listed on the 'Summary of documents currently in use' have been previously approved by the Wits HREC (Medical).
	Prepare Renewal / Recertification Approval letter on the database, to be signed by the Chair.
	Enter expiry date – Renewal Approval will be valid for a further five (5) years) unless more frequent approval is required.
	Enter the Renewal / Recertification Applications received for a meeting, onto the Agenda. Copies of the Renewal / Recertification Application Forms are available for review at the monthly meetings
	After the HREC meeting, email the Renewal / Recertification Approval letters to the Applicants / Investigators.
	Attach the HREC Attendance Register.

2. ATTACHMENT

- Renewal / Recertification Application Form

3. DEFINITIONS AND ABBREVIATIONS

CFR	Code of Federal Regulations (USA)
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
SAGCP	South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
WITS	University of the Witwatersrand
HREC	Human Research Ethics Committee

4. REFERENCES

- South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
- ICH GCP E6(R3) Guidelines dated 06 January 2025
- South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2 (NDoH 2024, 3rd ed. (v3.2))
- WMA, Declaration of Helsinki 2024
- International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.
- Code of Federal Regulations: (21 Part 50) Protection of Human Subjects, (21 CFR Part 56) Institutional Review Boards, (45 CFR Part 46) Protection of Human Subjects
  Association of British Pharmaceutical Industries (ABPI 2014)