HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

RECERTIFICATION OF RESEARCH STUDIES

SOP-HREC – 002*(VERSION 1)* **REVISED AND UPDATED: JANUARY 2025**

SUBJECT:	**Procedure for the Recertification of 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 review and recertification of 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 Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) – Current Step 4 version dated 9 November 2016 ♦ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024) ♦ 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-IEC-002v13 - Previous SOP split into separate SOPs
CONTENTS:	1. Procedure for Recertification of research studies by Wits HREC (Medical) 2. Attachments: • Recertification Application Form 3. Definitions and Abbreviations 4. References
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2025/01/13

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

The University of the Witwatersrand, Human Research Ethics Committee (Medical) requests that Applicants / Investigators submit a Recertification Application after the initial ethics approval (which is valid for FIVE (5) years), has expired.

Re-certification Applications require review and approval 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. Recertification Applications will be due once the initial ethics approval has expired (unless more frequent recertification is required by the Sponsor).
- **The Re-certification approval issued by the Wits HREC (Medical) will be valid for an additional FIVE (5) years** (unless more frequent recertification is required by the Sponsor).
- Where more frequent recertification is required by the Sponsor, it remains the responsibility of the Applicant/Sponsor and Investigator/Research Entity/Dept, to track due dates and apply for recertification.

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

2. ATTACHMENT

- 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)
WHC	Wits Health Consortium
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 Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH – E6(R2) – Current Step 4 version dated 9 November 2016
- South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024)
- 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)