HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

HREC PROCEDURE FOR APPROVALS OF RESEARCH STUDIES

SOP-HREC – 001*(VERSION 1)* **REVISED AND UPDATED: JANUARY 2025**

SUBJECT:	**Procedure for the approval 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 approval 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 ♦ National Health Research Ethics Council (2024) South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 3rd Edition (NDoH 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)
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	SOP-IEC-001v13 Revised and Updated
CONTENTS:	1. Scheduling Wits HREC (Medical) Meeting and Submission dates 2. Procedure for approval of research studies by Wits HREC (Medical) 3. Attachments: ♦ Submission Requirements ♦ In-house Pre-Screening Checklist ♦ PIL/ICON Screening Checklist ♦ Reviewer Template 4. Definitions and Abbreviations 5. References
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2025/01/13

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1. SCHEDULING WITS HREC (MEDICAL) MEETINGS AND SUBMISSION DATES

Responsible person		Action to be taken
Secretariat and Chair	1	At the Wits HREC (Medical) held in October, propose Meeting and Submission dates for the following year. If no objections from the committee are raised, Wits HREC (Medical) to agree upon and approve dates.
Secretariat	2	Once dates are approved by the Wits HREC (Medical), the Ethics Secretariat will update the website announcing the Wits HREC (Medical) Submission and Meeting dates for Sponsors / Applicants / Research Entities and Investigators.

2. PROCEDURE FOR OBTAINING WITS HREC (MEDICAL) APPROVAL OF RESEACH STUDIES CONDUCTED AT WITS AFFILIATED RESEARCH ENTITIES/DEPARTMENTS AND PRIVATE PRACTICE SITE/EXTERNAL SITES (WITHIN GAUTENG)

Responsible person		Action to be taken
Ethics Secretariat	1	The Ethics Secretariat will handle the administration of documents that are received for Wits HREC (Medical) approval, according to their internal procedures. The Secretariat will check that the following documents are accurate, complete and collate as per the submission requirements: ♦ 1 x HREC Application Form ♦ 1 x Protocol Review Application Form (if applicable) ♦ 1 x SANCTR Proof of capture Form (if applicable) ♦ 1 x Insurance Certificate (if applicable) ♦ 1 x Protocol / Amendment and Summary ♦ 1 x Investigator's Brochure and/or PI (Professional Information) (if applicable) ♦ 1 x Study Flow Charts including Visit and Payment Schedule ♦ 1 x Diary cards, and Advertisements (if applicable) ♦ 1 x Questionnaires, FGD and IDI guides (if applicable) ♦ 1 x Participant Information Leaflet and Informed Consent Form (PIL/ICON) (if applicable) ♦ 1 x Assent Forms (if applicable) 7-11 years and 12-17 years ♦ 1 x Separate PIL/ICON for **Genetic Testing / Transport and Storage of Samples for future research** ♦ 1 x Separate PIL/ICON for FGD and IDI (if applicable) ♦ 1x Regulatory Authority (SAHPRA) approval for study and Investigators involved in study (if already available, otherwise a statement stating that application has been made, and approval to be forwarded upon receipt) ♦ 1 x copy of Investigator Declarations (Principal and Sub-Investigators) ♦ 1 x copy of Investigator short/summarised Curriculum Vitaes (Principal and Sub-Investigators) ♦ SA GCP 2020 Training and Research Ethics Training Certificates ♦ **Essential Clinical Support Staff:** Include copies of CV's, Sub-

Investigator Declarations, statutory body registration and GCP Training Certificates for essential clinical support staff (Senior and Back-up Pharmacist(s); Only Study Nurses / Study Co-Ordinator's who have a direct clinical involvement with participants i.e., who are actively involved in the treatment of participants e.g., administering participants treatment with the investigational product, or independently taking Informed Consent or In-depth Interviews).

- 1 x Financial Contract (Draft)
- 1 x Budget and Payment Schedule
- 1 x Submission Fee and Proof of Payment

Responsible person		Action to be taken
Ethics Secretariat	2	The Ethics Secretariat will enter and process the data regarding the applications into the current database and will email an In-house Pre-Screening checklist to the Applicant / Investigator to clarify any missing or unclear information.
Chair or Co-Chair	3	The Chair or Co-Chair will assign two Reviewers for each new protocol application based on their fields of experience and expertise.
Ethics Secretariat	4	Prepare and email Reviewer Form and study documents to the nominated Reviewers. Reviewers have 14 days to review the protocols.
Reviewers	5	Reviewers to review the study documents received from the Secretariat and forward completed Reviewer's Form and queries to the Secretariat, 7 days before the meeting takes place. The Reviewer to select a recommendations category: 1. Approved unconditionally. 2. Approved subject to minor revisions delegated to the secretariat and/or chair to complete. 3. Pending Approval subject to response to comments provided by the reviewers, to be resolved by the original reviewers. 4. Not Approved as requires major revision and/or reviewer comments to be resolved. Will require review at the next HREC meeting. 5. Rejected in the current form. Must be resubmitted and will receive a new application number and review timeline. 6. Rejected due to substantive ethical concerns, will not be reviewed again.
Ethics Secretariat	6	The Participant Information Leaflet and Informed Consent Form (PIL/ICON), Assent Forms (7-11 and 12-17 years of age), is screened for compliance with SA GCP, ICH GCP and 21 CFR Part 50.25 in accordance with the latest version of the Secretariat Checklist
Chair / Co-Chair	7	The Wits HREC (Medical) Chair to chair the meetings. A Co-Chair will chair if

		the Chair is unavailable for any reason including recusal due to conflict of interest. The meeting is split over two days being the last two Fridays of the month (WHC Section for Grant/Commercial funded studies, and the WRO Section for university research for degree or non-degree purposes). The meeting usually commences at 12:00 but may be brought forward to 11:00 if necessary.
Ethics Secretariat	8	Representatives from the Ethics Secretariat will be responsible for arranging the meeting and recording the minutes of the meeting.
Chair / Co-Chair	9	Minutes of the last meeting are to be confirmed / approved.
Reviewers	10	Present Reviewer's Report on the protocol reviewed from an ethical and scientific perspective.
All members present at Meeting	11	The committee to discuss concerns, recommendations and queries relating to the presented applications/protocols. Scores the application/protocol according to the following Categories: 1. Approved unconditionally. 2. Approved subject to minor revisions delegated to the secretariat and/or chair to complete. 3. Pending Approval subject to response to comments provided by the reviewers, to be resolved by the original reviewers. 4. Not Approved as requires major revision and/or reviewer comments to be resolved. Will require review at the next HREC meeting. 5. Rejected in the current form. Must be resubmitted and will receive a new application number and review timeline. 6. Rejected due to substantive ethical concerns, will not be reviewed again.
Chair / Co-Chair	12	Call for vote on which category to assign to a application/protocol, if consensus is not reached during the meeting.
Ethics Secretariat	13	Prepare draft minutes of meeting according to the Ethics Secretariat procedures. The minutes should contain the following information: • Actual attendance at meeting (both face-to-face and virtual) • Conflicts of interest • Quorum • Items to be noted and/or discussed • Recertifications • Applications/protocol carried over from the previous meeting • Categories assigned to each new application/protocol. • Summary of discussion of controversial issues

Chair / Co-Chair	14	Review draft minutes and make corrections as necessary then forward to Ethics Secretariat for finalisation.
Ethics Secretariat	15	Email Approval Letters or Queries raised by the Wits HREC (Medical) to Applicants / Investigators as required within 7-14 days after the meeting.
Ethics Secretariat	16	Retain all relevant records, (e.g., written procedures, membership and reviewer lists, list of qualifications/expertise/affiliations of members, submitted documents, minutes of meetings, and correspondence) for a period of at least fifteen (15) years and make them available on request to the regulatory authority/(ies). Records will be archived according to the relevant WHC procedures for archiving by the Ethics Secretariat, WHC.

3. ATTACHMENTS

- Submission Requirements
- In-house Pre-Screening Checklist
- PIL/ICON Screening Checklist
- Reviewer Template

4. DEFINITIONS AND ABBREVIATIONS

ABPI	Association of British Pharmaceutical Industries (ABPI 2014)
CIOMS	Council for International Organisations for Medical Sciences
CFR	Code of Federal Regulations (USA)
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
NHREC	National Health Research Ethics Council
SAGCP	South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
SAHPRA	South African Health Products Regulatory Authority
WHC	Wits Health Consortium
WITS	University of the Witwatersrand
HREC	Human Research Ethics Committee

5. 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)
- International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva. Council for International Organizations of Medical Sciences (CIOMS); 2016.
- WMA, Declaration of Helsinki 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
- Association of British Pharmaceutical Industries (ABPI 2014)