UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

PROCEDURE FOR CONDUCTING RAPID REVIEW DURING PUBLIC HEALTH EMERGENCIES

SOP-HREC – 009*(VERSION 1)* **DATE: JULY 2026**

SUBJECT:	**Procedure for the review and approval of rapid reviews of research studies during public health emergencies, 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 rapid review and approval of research studies on human participants during public health emergencies, to ensure that the approvals granted by the Wits HREC (Medical) are in compliance with the following requirements: ♦ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, Third Edition, Version 3.2 (NDoH 2024, 3rd ed. (v3.2)) ♦ South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) ♦ ICH GCP E6(R3) Guidelines dated 06 January 2025 ♦ The applicable FDA requirements for Institutional Review Boards (21 CFR Part 56) ♦ SAHPRA (SAHPGL-CEM-CT-12) Pre-clinical testing guidelines and clinical requirements for phase 1/FIH studies (30 March 2026) ♦ SAHPRA (SAHPGL-CEM-CT-09) Guideline for Clinical Trial Investigators (24 October 2022) ♦ SAHPRA (SAHPGL-CEM-CT-10) Safety Reporting During Clinical Trials (06 October 2022)
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	First Version
CONTENTS:	1. Rapid Review during public health emergencies 2. Procedure for rapid review of research studies during public health emergencies 3. Definitions and Abbreviations 4. References
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2026/07/23

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1. RAPID REVIEW DURING PUBLIC HEALTH EMERGENCIES

Although, in a public health emergency, preparations for research should occur rapidly, a thorough processing of ethics review applications remains essential. The HREC should carefully assess the nature of the research to determine the appropriate expedited (for minimal risk research only) or full HREC (for more than minimal risk or clinical trial studies) review process. Careful ethical consideration is essential, notwithstanding any perceived urgency and external pressures including those of a political nature. A rapid full HREC review process by a sub-committee, between scheduled HREC meetings, is feasible for processing of urgent ethics review applications, provided the usual quorum requirements are satisfied.

Rapid review

- Rapid review process permits rapid but thorough processing of ethics review applications in circumstances that require accelerated preparation for a research study or project. The usual example of such circumstances is a major incident. However, accelerated preparation for research could be justifiable in a localised emergency context too, e.g., an outbreak of cholera in one geographical area.
- Rapidity of review processes refers to the speed at which administrative processes are carried out, rather than implying the review process becomes cursory and lacking in thoroughness.
- The HREC must carefully assess the nature of the research to determine the appropriate review process, bearing in mind that not all research during a major incident is necessarily urgent.
- When appropriate during a public health emergency, an HREC sub-committee will meet to discuss rapid reviews of research applications.
- Careful ethical consideration is essential, notwithstanding any perceived urgency. All the usual ethical norms and standards must be followed.
- The deliberations and outcome of the HREC sub-committee meeting must be minuted and reported to the full HREC at its next meeting.

2. PROCEDURE FOR OBTAINING RAPID HREC (MEDICAL) APPROVAL OF RESEACH STUDIES CONDUCTED AT WITS AFFILIATED RESEARCH ENTITIES/DEPARTMENTS AND PRIVATE PRACTICE SITE/EXTERNAL SITES DURING A PUBLIC HEALTH EMERGENCY

		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: **Initial Submission Documents:** ♦ 1 x HREC Application Form ♦ 1 x Protocol Review Application Form (if applicable) ♦ 1 x Current Study Insurance Certificate ♦ 1 x Current Indemnity Certificate (if applicable ♦ 1 x Protocol / Amendment (a summary may be appropriate)

- 1 x Questionnaires, FGD and IDI guides (if applicable)
- 1 x Participant Information Leaflet and Informed Consent Form (PIL/ICON)
- 1 x Assent Forms (if applicable) 7-11 years and 12-17 years
- 1 x Separate PIL/ICON for FGD and IDI (if applicable)
- 1 x 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 short/summarised Curriculum Vitae (Principal/Co-Principal and Sub/Co-Investigator)
- 1 x copy of Investigator Declarations (Principal/Co-Principal and Sub/Co-Investigator)
- 1 x copy of Investigator Curriculum Vitae (Principal/Co-Principal and Sub/Co-Investigator)
- Current locally based GCP Training and Research Ethics Training Certificates. **Note**: The ethics component of GCP training is not sufficient as Ethics Training, with formal Ethics Training being required in addition to GCP training.

Follow up Submission Documents

- 1 x SANCTR Proof of capture Form (if applicable)
- 1 x Investigator's Brochure and/or PI (Professional Information) (if applicable)
- 1 x Study Flow Charts including Visit and Payment Schedule
- **Essential Clinical Support Staff:** Include copies of the Sub-Investigator Declaration, Statutory Body Registration, GCP Training Certificates, Ethics 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). CVs are not required.
- 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.
Ethics Secretariat	4	Prepare and email Reviewer Form and study documents to the nominated

		Reviewers. Reviewers have 7 days to review the protocols before the HREC sub-committee meeting, set up to deal with public health emergencies.
Reviewers	5	Review the study documents received from the Secretariat and forward Reviewer's Form and queries to the Secretariat. The Reviewer to select a recommendations category: 1A. Approved unconditionally 1B. Approved pending Hospital/Facility/District approval only 2. Approved subject to minor administrative revisions delegated to the secretariat to complete. 3. Pending Approval subject to response to comments provided by the HREC (Medical), to be resolved by the original Reviewer(s). (Will not require review at the next HREC meeting) 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 due to significant deficiencies. 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), are screened for compliance with NdoH 2024, SA GCP 2020, ICH GCP and 21 CFR Part 50.25 in accordance with the latest version of the Secretariat Checklist
Chair / Co-Chair	7	The Chair will chair the HREC sub-committee meeting. A Co-Chair will chair if the Chair is unavailable.
Ethics Secretariat	8	Representatives from the Ethics Secretariat will be responsible for arranging the HREC sub-committee meeting and recording the minutes of the meeting.
Ethics Secretariat	9	Prepare draft minutes of the HREC sub-committee meeting according to the Ethics Secretariat procedures. The minutes of the HREC sub-committee meeting should contain the following information: • Attendance at meeting • Conflicts of interest • Categories assigned to each new application/protocol. • Summary of discussion of controversial issues

Chair / Co-Chair	10	Review draft minutes and make corrections as necessary then forward to Ethics Secretariat for finalisation.
		Email Approval Letters or Queries raised by the HREC sub-committee to Applicants / Investigators within 7 days.
Ethics Secretariat	11	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).

3. 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
PIL/ICON	Participant Information Leaflet and Informed Consent Form
SAGCP	South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020)
SAHPRA	South African Health Products Regulatory Authority
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))
- 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)
- Various SAHPRA Guidelines – www.sahpra.org.za