UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL)

STANDARD OPERATING PROCEDURE

STUDY REPORTS

SOP-HREC – 007*(VERSION 1)* **DATE: JANUARY 2025**

SUBJECT:	**Study Reports submitted to the University of the Witwatersrand, Human Research Ethics Committee (Medical), including Progress Reports, Final Progress Reports/End of Study Reports (EoS), Final Study Reports/Clinical Study Reports (CSR), Reports on final results/outcome and Early Study Termination Reports**
DIVISION / SCOPE:	**University of the Witwatersrand, Human Research Ethics Committee (Medical)**
AUTHOR: **REVISION:**	Ethics Secretariat
PURPOSE:	This procedure describes the requirements of the University of the Witwatersrand, Human Research Ethics Committee (Medical), for the review of: ♦ Progress Reports (6 monthly, 3 monthly, 1 monthly, 2 weekly) ♦ Final Progress Reports/End of Study Reports (EoS) ♦ Final Study Reports/Clinical Study Reports (CSR) ♦ Reports on final results/outcome ♦ Early Study Termination Reports The purpose is to ensure that all the relevant documents are sent to the Wits HREC (Medical) for review, as required by: ♦ South African Health Products Regulatory Authority ♦ South African Good Clinical Practice: Clinical Trial Guidelines. Third Edition (SA GCP 2020) ♦ South African Ethics in Health Research Guidelines: Principles, Processes and Structures, 2024, 3rd Edition (NDoH 2024)
PREVIOUS VERSIONS / ***(REASON FOR REVISION)***	First Version
CONTENTS:	1. Procedure For Handling Progress Reports, Final Progress Reports/End of Study Reports, Final Study Reports/Clinical Study Reports, Reports on final results/outcome and Early Study Termination Reports 2. Process followed by Ethics Secretariat 3. Attachments; examples of: ♦ Progress Reports ♦ Final Progress Report/End of Study Report (EoS) ♦ Final Study Report/Clinical Study Report (CSR) ♦ Final results/study outcome ♦ Early Study Termination Report 4. Definitions and Abbreviations
APPROVALS:	**Signature of Chair / Co-Chair of Wits HREC (Medical)** Paul Ruff **Date:** 2025/01/13

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STUDY REPORTS

SOP-HREC – 007*(VERSION 1)* **DATE: JANUARY 2025**

1. PROCEDURE FOR HANDLING PROGRESS REPORTS, FINAL PROGRESS REPORTS/END OF STUDY REPORTS (EOS), FINAL STUDY REPORTS/CLINICAL STUDY REPORTS (CSR), REPORTS ON FINAL RESULTS/OUTCOME AND EARLY STUDY TERMINATION REPORTS

The University of the Witwatersrand, Human Research Ethics Committee (Medical) requires that Sponsors / Applicants / Investigators submit progress reports, final progress reports/end of study reports, final study reports/clinical study reports, reports on final results/outcome and early study termination reports, for review by the Wits HREC (Medical).

1.1 Progress Reports

The Wits HREC (Medical) will decide on the required frequency of progress reports on a per-clinical investigation basis. This decision will be based on the degree of risk to human participants, however, the minimum requirement for these reports will be on a six (6) monthly basis, however higher risk studies will require more frequent monitoring.

Six (6) monthly progress must be submitted six-monthly from the date of approval of the clinical trial by the South African Health Products Regulatory Authority (SAHPRA) (if applicable), or; six-monthly from the date of approval of the study by the Wits HREC (Medical) where SAHPRA approval is not applicable.

SAHPRA's Six Monthly Progress Reporting Form may be submitted to the Wits HREC (Medical).

Three (3) monthly Progress Reports for Moderate to High-Risk Studies (especially clinical trials) and if there are any signals identified, more frequent reporting may be requested. A template has been developed.

Two (2) to Four (4) weekly Progress Reports for Very High-Risk Studies, including First In Human. Templates have been developed.

The Progress Reports will be reviewed by the Initial Reviewers.

1.2 Final Progress Report / End of Study Progress Report (EoS)

These progress reports should be submitted within 30 days after completion or termination of a study. (In exceptional cases justification should be provided in advance for submission more than 30 days and not exceed 60 days after Last Subject Last Visit).

Clinical trial closure occurs when no further data is being collected and not on termination of recruitment.

1.3 Final Study Report / Clinical Study Report (CSR)

These reports are due at 180 days of the completion or termination of the clinical trial.

1.4 A report of the final results/study outcome must also be submitted to the Wits HREC (Medical). This report may not have a timeline as the final results / study outcome may only be available after some years.

1.5 Early Study Termination Reports

Sponsors / Applicants / Investigator are required to immediately report if a project is terminated or suspended before the anticipated date of completion.

2. PROCESS FOLLOWED BY ETHICS SECRETARIAT

On receipt of the above-mentioned reports an *Acknowledgement of Receipt* (signed on behalf of the HREC by the Ethics Administrator) must be sent to the Sponsor / Applicant / Investigator (by email).

The reports will be sent to the Initial Reviewers. Any queries that may arise from the review of the reports will be sent to the Sponsor / Applicant / Investigator (by email).

A list of reports will be included in the Agenda of the monthly HREC meetings.

3. ATTACHMENTS

- Acknowledgement of Receipt of:
  - Progress Report
  - Final Progress Report / End of Study Progress Report (EoS)
  - Final Study Report / Clinical Study Report (CSR)
  - Final results/study outcome
  - Early Study Termination Reports

4. DEFINITIONS AND ABBREVIATIONS

CSR	Clinical Study Report
EOS	End of Study
GCP	Good Clinical Practices
HREC	Human Research Ethics Committee (Medical)
SAHPRA	South African Health Products Regulatory Authority
WHC	Wits Health Consortium
WITS	University of the Witwatersrand