THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL HUMAN RESEARCH ETHICS COMMITTEE (HREC) TERMS OF REFERENCE FOR ACTIVE MONITORING OF APPROVED PROTOCOLS/STUDIES

Preamble

The South African Medical Research Council–Human Research Ethics Committee (SAMRC-HREC) is established under the mandate of the National Health Research Ethics Council, in accordance with Section 73(1) of the National Health Act (2003). This Act requires that all organisations, institutions, health agencies, and health establishments conducting health or health-related research involving human participants must establish or have access to a registered Human Research Ethics Committee (HREC). The SAMRC-HREC is responsible for protecting the rights and welfare of research participants and for promoting ethical standards and research integrity within the SAMRC.

1. Purpose

1.1 The purpose of this document is to outline the process of active monitoring, as mandated by the National Department of Health,(NDoH) Health Research Ethics Guidelines 2024, to ensure the ongoing ethical conduct of human research. Active monitoring goes beyond routine site visits; it serves as a comprehensive oversight mechanism to verify that research is being conducted in accordance with the approved protocol, applicable ethical guidelines, and regulatory requirements.

2. Specifically, active monitoring aims to:

2.1 Protect Participants: Ensure that participants continue to be treated ethically and that any risks to their well-being are identified and managed promptly.

2.2 Ensure Compliance: Confirm that researchers adhere to the approved study protocol and any conditions set by the HREC, including ethical and legal standards.

2.3 Identify Issues Early: Detect any deviations, adverse events, or unanticipated problems that may arise during the study, allowing for timely corrective actions.

2.4 Promote Transparency and Accountability: Encourage responsible conduct of research and maintain public trust in the research process and the institutions involved.

2.5 Support Researchers: Provide guidance and oversight to researchers in maintaining ethical standards and managing emerging ethical concerns during the study.

3. Composition of the active monitoring team

3.1 The active monitoring team is designated and approved by the Human Research Ethics Committee (HREC).

3.2 For clinical studies, it is recommended that a qualified clinician be included as part of the team to provide subject-matter expertise. The composition of the team may be adapted as necessary to include additional expertise relevant to the specific nature and requirements of the study being monitored.

4. Scope of Work

4.1 Active monitoring activity plans are executed as stated in paragraph 5.5.1.12, NDoH guidelines, 2024.

5. Roles and Responsibilities of monitoring team:

5.1 Ensure that all monitoring activities are conducted in alignment with the mandate of the SAMRC Human Research Ethics Committee (HREC), as outlined in the National Department of Health,(NDoH) Guidelines (2024). Any deviations from approved protocols or ethical standards must be promptly reported to the Chairperson of the HREC.

5.2 Develop and implement monitoring strategies that promote and ensure compliance with the NDoH Guidelines (2024), with specific focus on safeguarding participant rights, maintaining data privacy and confidentiality, and upholding ethical standards in all aspects of research conduct.

6. Reporting and Follow-Up

6.1 Monitoring findings will be documented and reported to the HREC.

6.2 Non-compliance may lead to recommendations for corrective actions, suspension, or withdrawal of approval.

6.3 Researchers will be given an opportunity to respond to findings and implement corrective actions.

7. Confidentiality and Integrity

7.1 All monitoring activities will be conducted with respect for participant confidentiality and researcher integrity. Information obtained through monitoring will be handled in accordance with institutional and legal privacy obligations.

References

- SA-GCP guidelines, https://www.sahpra.org.za/document/sa-gcp-guidelines/
- SAHPRA Clinical Trials regulations, https://www.sahpra.org.za/clinical-trials-guidelines/
- NHREC guidelines, https://www.health.gov.za/nhrec-guidelines/

Level	3
Risk:	Strategic
Effective Date:	1 October 2025
Review Date:	September 2028
Policy Owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
Board Approval:	

Confirmation of Approval

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Date