



GENERAL AUDITING GUIDELINES, OCTOBER 2023, V2

Research Ethics
Committee



Final Version	Reason for Amendment	Effective Date
2	Updated and published for implementation	October 2023
	Administrative changes	March 2024

1. DEFINITIONS

- 1.1. **Doctor** refers to a medical practitioner (or dentist, when appropriate), as defined in terms of the Health Professions Act, no. 56 of 1974 (as amended),
- 1.2. **Study doctor** refers to a doctor (or dentist, when appropriate), participating in the clinical trial / study. The words study investigator, investigator, sub-investigator, co-investigator, trialist or researcher may be used interchangeably, as long as the person is a clinician, where applicable. Whichever term is used, it must be used consistently throughout the documents.
- 1.3. **Principal Investigator** is a person responsible for the conduct of the clinical trial at a trial site.
- 1.4. **Co-Principal Investigator** A qualified non-clinician scientist or equivalent qualified and experienced person who can provide trial oversight management, and who is jointly and severally liable for the clinical trial.
- 1.5. **Associate Investigator** refers to a member of the health care team involved for specific investigations which are required for the conduct of the clinical trial / study. This will be in accordance with their relevant field(s) of expertise and training e.g., ophthalmologist or psychologist responsible for specific aspects but not taking clinical responsibility as sub investigators for trial participants.
- 1.6. **Sub-Investigator** – any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions.
- 1.7. A **Clinical Trial** is a prospective biomedical or behavioral research study of human participants that is designed to answer specific questions about biomedical or behavioural interventions (vaccines, drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
- 1.8. **Study Staff** collectively refers to the investigators, study coordinators, study nurses, pharmacists, raters, and any other people rendering support to the investigator.
- 1.9. Study site is the location(s) where trial-related activities are actually conducted.
- 1.10. **Participant** means the person participating in the clinical trial / study and/or receiving treatment, including receiving blood or blood products, or using a health facility or establishment, as a result of participation in the clinical trial / study. The words **research participant or participant** may be used interchangeably, where applicable.
- 1.11. **Patient** is defined as a participant with a clinical condition.

2. PURPOSE

SAMAREC is registered with the National Health Research Ethics Council (NHREC). It will be regularly audited by the NHREC and has required that Active Auditing of Sites be conducted.

- 2.1. SAMAREC may be entitled to conduct audits, without prior notification to the principal investigators (Declaration of Helsinki 2024 par 23).
- 2.2. SAMAREC may recommend and adopt any appropriate mechanisms for monitoring, including random inspection of research sites, welfare monitoring sheets, data and signed consent forms, and records of interviews.

3. SCOPE

- 3.1. SAMAREC may request regular reports from principal investigators pertaining to progress to date, or outcome in the case of completed research, and/or current enrolment status.
- 3.2. SAMAREC is entitled to request the following information: whether participant follow-up is still active or completed; information concerning maintenance and security of records; evidence of compliance with the approved protocol; evidence of compliance with any conditions of approval; negative reports from monitors or GCP inspectors; list all adverse events in the past twelve (12) months; list all amendments made in the past twelve (12) months. SAMAREC should inform principal investigators in writing of concerns arising from such monitoring activities.
- 3.3. The audits must be conducted in accordance with the applicable laws, regulations, and ethical guidelines.
- 3.4. The audit must be conducted by independent auditors – SAMAREC members - who are free from any conflicts of interest. The auditors will maintain objectivity and impartiality throughout the auditing process.
- 3.5. A comprehensive audit plan that outlines the audit objectives, procedures, and timelines must be made available, which should specify key areas of focus, such as ethical review processes, decision-making, and adherence to regulatory requirements.

4. PROCESS

- 4.1. SAMAREC must conduct frequent reviews of its documentation practices and record-keeping systems to ensure accurate and complete documentation. SAMAREC must assess the adequacy of records in terms of ethical reviews, decisions, and communications.
- 4.2. SAMAREC must conduct a compliance assessment, which requires evaluating the committee's compliance with relevant laws, regulations, and ethical guidelines governing research activities. In addition, a review the SAMAREC's adherence to its own policies, procedures, and a Code of Conduct must be undertaken.
- 4.3. SAMAREC must assess the effectiveness of its ethical review processes, including the evaluation of research proposals, protocols, and amendments. This includes, but is not limited to, evaluating the consistency and transparency of decision-making in granting approvals, providing feedback, and ensuring participant protection.
- 4.4. A review the SAMAREC's procedures for identifying, assessing, and managing conflicts of interest among members must be conducted. This serves to evaluate the effectiveness of conflict-of-interest disclosure processes and SAMAREC's actions in mitigating conflicts.
- 4.5. An assessment of SAMAREC's efforts in providing training and educational resources to members regarding research ethics, regulations, and emerging ethical issues. Must be undertaken. Reviewing the member's ongoing professional development initiatives to enhance members' knowledge and expertise is vital.
- 4.6. A review of the SAMAREC's mechanisms for monitoring approved research projects must be done to ensure ongoing compliance and research participant welfare. This includes assessing the adequacy and effectiveness of SAMAREC's reporting mechanisms, including reporting to regulatory bodies (NHREC) and relevant stakeholders.
- 4.7. SAMAREC must identify any areas of non-compliance or deficiencies in the protocol and provide recommendations for improvement. It must monitor the implementation of corrective actions and follow-up on the progress made in addressing identified issues.
- 4.8. SAMAREC must maintain proper documentation of audit activities, findings, and conclusions, and collect sufficient and appropriate audit evidence to support conclusions.
- 4.9. SAMAREC must prepare clear, accurate, and concise audit reports that highlight findings, recommendations, and action plans, as well as communicate audit results to relevant stakeholders in a timely manner.
- 4.10. SAMAREC must strive for continuous improvement within the auditing function. This requires regular reviews and enhancement of audit methodologies and processes to align with best practices.
- 4.11. Passive Monitoring & Auditing: Following approval of a protocol, six-monthly reports on the trial must be



submitted to SAMAREC. Failure to forward these reports will result in suspension of approval for the protocol, without any prior notification by SAMAREC. Any decisions taken by SAMAREC after the review of the Progress Reports will be conveyed to the investigator or sponsor. Once the study has been completed, the final study report must be submitted. Copies of the SAHPRA reports will suffice. SAMAREC would also appreciate copies of relevant publications arising from reviewed work. All information will be placed on record and kept confidential at the offices of the SA Medical Association for at least three years after the completion of a trial. All passive reports will be reviewed by the

- 4.12. Chairperson and the Main Evaluators of the study, final comments and summarized report will reflect in the SAMAREC Minutes Supplement Report for the review of entire SAMAREC Committee.
- 4.13. Active Monitoring & Auditing. SAMAREC will randomly select sites for auditing, or when there are ethical concerns. The SAMAREC Officer will notify the Sites or Sponsors of the audit. The Audit will be conducted by at least two members of the SAMAREC Committee and the SAMAREC Officer. The findings and feedback will be deliberated with the SAMAREC Chairperson. Feedback will be provided to the Site or Sponsor within 10 days of the physical audit.

Please see detailed SAMAREC SOP on Active and Passive Monitoring

5. REFERENCES

[National Health Research Ethics Council \(2024\) *South African Ethics in Health Research Guidelines: Principles, Processes and Structures*, 3rd ed. National Department of Health of the Republic of South Africa. Pretoria: NDoH. 137p. ISBN 978-0-621-52027-9.](#)

Approved by:

Prof J Snyman
SAMAREC Chairperson
Signed: 25 October 2023

Dr M Nodikida
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Signed: 10 October 2024