NON-CLINICAL RESEARCH PROPOSAL GUIDELINES, JULY 2026, V5

Research Ethics Committee

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STANDARD OPERATING PROCEDURES AND GUIDELINES FOR NON-CLINICAL RESEARCH PROPOSALS

DEFINITIONS AND INTERPRETATIONS

In this document, unless the contents otherwise require:

1. **"Participant"** means the person participating in the study. The words **research participant or participant** may beused interchangeably, where applicable.
2. **"Patient"** is defined as a participant with a clinical condition.
3. **"Research"** means the creation, preservation, accumulation, and improvement of knowledge by means of scientific investigations and methods in the field of the medical and related sciences aswell as those sciences the application of which is important for the promotion of health or the combating of disease, and includes the acquisition, development and transfer of expertise and technology. The word **researcher** shall have a corresponding meaning and may be used interchangeably with the word **research**, when applicable.
4. **"Study Staff"** collectively refers to all researchers.
5. **"Study site"** is the location(s) where study-related activities are conducted.
6. **"Witness"** Is someone who witnesses the signing by the participant and not the consent procedure. However, when the participant is illiterate the meaning of *'witness'* changes and it means a person who witnesses the consent procedure.

1. INTRODUCING SAMAREC

LEGISLATIVE FRAMEWORK AND VALUE STRUCTURE

1.1 LEGISLATIVE FRAMEWORK

1.1.1 The South African Medical Association Research Ethics Committee (SAMAREC) was established by the South African Medical Association (SAMA) in 1992 to evaluate the ethics of research protocols developed for clinical trials to be conducted in the private healthcare sector. In terms of national and international regulatory requirements, all health research involving human participants must undergo an independent ethics review. The National Health Act (NHA), 61 of 2003, as amended, provides for the establishment of a National Health Research Ethics Council (NHREC) with which all research ethics committees are required to be registered. SAMAREC is thus registered on the National Department of Health (NDOH) National Research Ethics Council database.

1.1.2 The main responsibility of SAMAREC is to ensure the protection and respect of the rights, safety and well-being of participants involved in clinical trials and to provide assurance to the public of that protection, *inter alia,* by reviewing, approving, and providing comment on clinical trial protocols, the suitability of investigator(s), facilities, methods, and procedures used to obtain informed consent. The Bill of Rights which is entrenched in the Constitution of the Republic of South Africa,1996 provides that everyone has the right not to be subjected to medical or scientific experiments/research without their informed consent (See Section 12(2)(C).

1.1.3 In terms of the NHA "clinical trials" means a systematic study, involving human participants that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

1.1.4 In the execution of its responsibilities in evaluating the ethics of research protocols, SAMAREC is guided by the relevant South African law(s), research and ethics guidelines, professional standards, international standards and guidelines including codes of practice that might be relevant to the situation.

1.1.5 The NHA provides that health research ethics committees (HRECs) must be established by every institution, health agency and health establishment at which health research is conducted, alternatively must have access to a HREC, which is registered with the NHREC.

"The NHA further provides that a health research ethics committee must-

(a) review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability, or result in cures for communicable or non- communicable; and

(b) grant approval for research by the relevant institution, agency, or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee."

*The **NHREC**, established by the Minister of Health after consultation with the National Health Council. The Minister appoints as members of the NHREC not more than 15 persons nominated by interested parties at the invitation of the Minister by notice in the Government Gazette.*

1.1.6 In terms of the NHA the NHREC must: -

(a) determine guidelines for the functioning of health RECs.

(b) register and audit health RECs.

(c) set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials.

(d) adjudicate complaints about the functioning of health RECs and hear any complaint by a researcher who believes that he or she has been discriminated against by a health REC.

(e) refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a healthcare provider.

(f) institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conducting of research in terms of this Act.

(g) advise the national department and provincial departments on any ethical issues concerning

research."

1.1.7 According to the Guidelines for Ethics in Health Research, published by the National Department of Health, ethics review provides an objective appraisal of the research proposal as it affects the prospective participants and the general day to day functioning of the health system.

1.1.8 SAMAREC follows the standards adopted by:

a) the latest version of the American Food & Drug Administration (FDA) and
b) The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH): Guidelines for Good Clinical Practice;
c) World Medical Association, in particular, the latest version of the Declaration of Helsinki (2024),
d) the Belmont Report,
e) the NDOH,
f) the South African Health Products Regulatory Authority (SAHPRA), and
g) other relevant statutory bodies involved in the healthcare sector.

1.2 REGISTRATIONS OF SAMAREC

1.2.1 SAMAREC has been registered and audited in accordance with the NHA (61 of 2003). Registration number: 280808-016. Valid until 30 November 2027

1.2.2 In March 2002, SAMAREC became a registered REC at the Department of Health and Human Services (DHHS) of the USA (IRB: 0001 1624)

1.2.3 In May 2002, Federal Wide Assurance was also obtained from the Office of Human Research Protection (Office of Human Research Protection-Group) of the USA ***(FWA: 0002 7240).*** Valid until **06 July 2028**.

1.3 SAMAREC's Commitment to Ethical Principles

1.3.1 Foundational Ethical Principles in Research

SAMAREC is committed to upholding the highest ethical standards in all research activities involving human participants. These principles guide the conduct, review, and oversight of research and serve to protect the rights, dignity, and welfare of all involved, while promoting high-quality scientific inquiry.

1.3.1.1 Ethical Principles for Research Involving Human Participants:

1.3.1.1.1 *Beneficence and Non-Maleficence*

SAMAREC recognises the ethical obligation to maximise potential benefits and minimise potential harms in all human research. Research must be scientifically valid, ethically designed, and conducted by competent professionals. No deliberate harm may be inflicted on participants, and risks must be reasonable in relation to anticipated benefits.

The guiding question remains: Does the research aim to enhance human understanding or well-being? If not, the study **may** not meet ethical standards. While curiosity-driven ("blue sky") research is supported, studies lacking

foreseeable value or purpose may not be ethically justifiable.

1.3.1.1.2 *Distributive Justice (Equity)*

Research must reflect fair distribution of risks and benefits among all involved – including individual participants, their communities, and broader South African society. No group should bear an undue burden or be unfairly excluded from research benefits. The source population should have a reasonable likelihood of benefiting from the research outcomes, either directly or in the future.

1.3.1.1.3 *Respect for Persons (Dignity and Autonomy)*

All individuals must be treated with dignity, respect, and fairness. Those capable of making informed decisions should be empowered to do so; individuals with diminished capacity must be protected from harm.

Respect for persons includes:

a) Autonomy and informed decision-making,
b) Protection of privacy, confidentiality, and wellbeing,
c) Recognition of cultural, societal, and contextual influences on consent.

These principles are rooted in the SAN Code of Research Ethics (2017) and are consistent with the African philosophy of *Ubuntu*, which emphasizes shared humanity, justice, and reciprocity. The interests of participants must generally outweigh those of science and society, except in exceptional contexts such as public health emergencies where societal interests may be prioritized.

1.3.2 Application of Ethical Principles

These ethical principles serve as the foundation for SAMAREC in reviewing protocols which include:

a) Safeguard participant welfare;
b) Promote integrity in research; and
c) Fostering the development of high-quality, socially beneficial knowledge.

All researchers conducting research are expected to adhere to these principles throughout the research lifecycle.

1.4 Core Norms for Ethical Human Research

SAMAREC applies the following operational norms in the review and approval of human research:

1.4.1 *Relevance and Value*

Research must respond to the needs of South Africa's people, contributing to knowledge that can inform meaningful interventions, policies, or practices that promote health and wellbeing.

1.4.2 *Scientific Integrity*

Protocols must reflect sound study design, methodology and analysis. Poorly designed studies that expose participants to risk without meaningful outcomes are ethically unacceptable and will be rejected.

1.4.3 *Stakeholder Engagement*

Researchers are expected to engage stakeholders early and continuously. This includes co-researchers, communities, and relevant institutions, to promote transparency, trust, and shared ownership of the research process.

1.4.4 *Favourable Risk-Benefit Ratio*

A robust risk-benefit analysis must demonstrate that potential benefits outweigh risks to participants or society. Studies with unjustified risks or those involving vulnerable populations require heightened justification and safeguards.

Social science research risks such as psychological, moral, or social harm must be considered and addressed with equal diligence.

1.4.5 *Fair Selection of Participants*

Recruitment must be based on scientific and ethical rationale, not discriminatory or exploitative criteria. Inclusion and exclusion must not be based on prohibited grounds as defined by the South African Constitution (see Section 9).

1.4.6 *Informed Consent*

Participation must be voluntary and informed. Researchers are responsible for ensuring a comprehensive consent process prior to and throughout the study. The necessary considerations much be given to vulnerable populations to protect their interests and wellbeing.

1.4.7 *Ongoing Respect for Participants*

Once enrolled, participants' rights, autonomy, and wellbeing must continue to be protected. Participants have the right to withdraw at any time and must be kept informed. Confidentiality must be rigorously maintained throughout the research process.

1.4.8 *Researcher Competence and Expertise*

All researchers must demonstrate appropriate qualifications, training, and experience. Principal Investigators (PIs) or research leaders are responsible for ensuring scientific integrity, ethical conduct, and participant safety. For international multi-site research, at least one (co-)PI must be

physically in South Africa.

Researchers must:

a) Hold relevant academic and ethical credentials;
b) Demonstrate recent ethics training (within 3 years);
c) Disseminate findings responsibly and inclusively, including to participant communities where appropriate.

2. COMPOSITION OF SAMAREC

2.1. General

2.1.1 Research Ethics Committees must consist of members who collectively have the necessary qualifications and experience to review and evaluate the science, health legal, and ethical aspects of proposed research. Committees must be independent, multi-disciplinary, multi-sectorial and pluralistic.

2.2 Appointment of Committee Members.

2.2.1 When a specific portfolio on the committee is required or becomes vacant (e.g., legal member), a new member will be recruited by means of advertisements in the applicable field. Prospective members are then requested to present their credentials and once the REC leadership (through consultation of the existing members) become satisfied of such a person meeting the necessary criteria, such a member will then attend a formal meeting (while signing a confidentiality agreement). Should the specific member have the required expertise and have a definite interest in the committee, they are requested to join the committee.

2.2.2 The composition of SAMAREC complies with the prescriptions of the Department of Health Guidelines for Ethics in Health Research and consists of members as approved by the SAMA Board of Directors. Once elected, members will receive formal appointment letters signed by the current Chief Executive Officer of SAMA (on behalf of the Board of Directors of SAMA). The Chairperson and Vice (Deputy)-Chairperson are elected by the current committee members based on their expertise and experience levels. The Vice (Deputy) Chairperson will assist the Chairperson and will act as Chairperson when necessary and will also assist the Chairperson with responsibilities as required.

2.2.3 The SAMAREC Composition will be updated as and when changes occur. The Committee may request other individuals to assist in the review of complex issues outside the expertise of the members, but such individuals may not vote on matters requiring a decision to be taken. These individuals will also only be approached should they not have a conflict of interest in the study in question and will also be required to sign a confidentiality agreement. These individuals will be approached based on a referral basis and shall be provided to the necessary appointment letter from SAMA which confirms their scope of function. Curricula vitae of the Committee members and external experts (if applicable) are available on request as these are kept by the SAMAREC Officer.

The current composition of SAMAREC is as per Annexure 5

2.3 Training Requirements for SAMAREC Members:

2.3.1 All SAMAREC Committee members and Administrators/Officers will receive internal training which includes a Mentorship 'Program', as well as external training involving Research Ethics and Good Clinical Practice training, funded by SAMA in order to remain compliant with the NHREC's training requirements. SAMAREC maintains record of training activities for all Committee members in a training log which is reviewed annually by SAMAREC and NHREC.

a. CONTACT DETAILS

The SAMAREC Officer or Assistant may be contacted at:

Telephone:	(012) 481 2082
Postal Address:	P O Box 74789 Lynnwood Ridge 0040
Physical Address:	Castle Walk Office Park, Block F, Nossob Street Erasmuskloof Ext.3 Pretoria 0183
E-mail:	samarec@samedical.org

b. REVIEW FEES

SAMAREC Submission Fee for New Research Proposal = R6 271 ex vat
Annual Renewal = R3 860 ex vat

Other relevant Fees for evaluation of protocols appears in Annexure 6 (hereto attached)

No refunds will be given should the protocol, once evaluated, not be approved. Administrative changes, report-back and adverse event reports will not be charged for.

NB: SAMA reserves the right to retain approval letters until payment is received in full.

If a protocol submitted for review is of a unique, complex, or highly specialised nature that requires consultation with external subject-matter experts or specialist reviewers, additional costs may be incurred beyond the standard protocol review fee. In such instances, the Ethics Committee reserves the right to obtain appropriate expert input to ensure a thorough and competent scientific and ethical review of the study. Any such additional costs will be reasonable and directly related to the specialist consultation required, and the applicant will be informed in advance where applicable.

3. PROCEDURES AND ADMINISTRATIVE GUIDELINES MEETINGS

a) SAMAREC meets on the second Wednesday of each month unless circumstances require otherwise.
b) Applications for consideration must be submitted via e-mail to the SAMAREC Officer or Assistant at least one month before the next scheduled meeting. Kindly contact the Officer if you are unable to meet a submission deadline for alternative arrangements.
c) A written response regarding decisions is usually forwarded to applicants within ten working days after the meeting.
d) Confidentiality of the content of applications, the protocols, and the procedures of SAMAREC is maintained, unless a subject matter expert is co-opted or disclosure is required by the NHREC .

(A list of the scheduled meetings for the current year is annexed as Annexure 1)

4. SUBMISSION OF RESEARCH PROTOCOL REVIEWS

4.1. All submissions to SAMAREC should be done electronically (via e-mail) to samarec@samedical.org

4.2. For new applications, the following documents relevant to the proposed study need to be submitted: -

a) SAMAREC Non Clinical Research Application Form
b) Covering letter
c) Research Summary
d) Protocol
e) Proof of scientific review
f) Supervisor Approval Letter (please justify if not available)
g) Site Permission Letter (if applicable)
h) Participant Information and Informed Consent Document (PID) (*pro forma* attached as Annexure 13). This document must be submitted in MS Word format.
i) Data collection tools (e.g., Questionnaires (if any) or Interview Guides (if any)
j) Data Management Plan
k) Details and breakdown of financial arrangements with researchers, if any
l) Information pertaining to recruitment e.g., advertisements, bulletins and information placed on the Internet (Guidelines attached as Annexure 7).
m) *Curricula Vitae* of all study personnel (CV format attached as Annexure 14).
n) Declarations by Researchers (Please refer to Annexures 15 for the declaration template)
o) Evidence of Research Ethics Training during the last three years
p) If applicable, GCP certificates (SAMAREC recommends that site staff be trained in latest version of both ICH GCP and SA GCP).

4.3. Submitted documentation required to include the following information in footers "Document Name (i.e., Protocol number/ Participant Information and Informed Consent Document), SAMAREC Version XX dated XXX." Furthermore, no product logos should be displayed on any documentation.

4.4. All documentation should be properly indexed, with the protocol number clearly visible on all the sections of each document. All relevant attachments about the study staff **should be put together per person**, i.e., CV, Declaration, evidence of research ethics training .

5. COVERING LETTER

5.1. The Covering Letter must contain the following details:

a) A summary of the protocol or submission, and

Names, version numbers and dates of documents submitted must be listed. For Study Staff submissions, the covering letter must list the additional Study Staff and indicate the submitted documents (example attached as Annexure 10),

6. DECLARATIONS

Declarations by all study staff, must reflect

a) the protocol number and title, as well as

b) the study staff's name and designation on the study

q) Please note, declarations must be properly completed and signed (Please refer to Annexures 15 for the declaration template)

7. CURRICULUM VITAE

The approval criteria for Researchers and study staff:

a) All researchers and study staff must demonstrate appropriate qualifications, training, and experience for their role on the study.

8. ABBREVIATIONS

Abbreviations may not be used without initially writing the words out in full with the appropriateabbreviation in brackets. Words need to be written out in full in the PID, in the first instance, even if abbreviated elsewhere in other documents included in the application for approval. Only South African English abbreviations for Standard International (SI) units must be used (e.g., ml not mL).

9. LANGUAGE

The Committee will only consider and approve English documentation. South African English spelling should be used in all documents, including the Participant Information and Informed Consent Documents. Should translations be required, the researcher must obtain the services of a professional translator and keep a record of their certification as to the accuracy of the translation. Where research involves the participation of persons unfamiliar with the language in which the research is to be conducted the PID and related documentation must be translated into the participants' preferred language.

When utilising the services of an interpreter, the researcher must ensure that the participant's informed consent is obtained and that an interpreter is present during discussions with the participants about the research study. As a rule, the interpreter should be an independent person and the participant should consent to the presence of the interpreter. Should a translator be presentduring the consent process, the information provided to the participant should clearly stipulate that the privacy of the consent will be compromised to that extent (NDOH 2024).

SAMAREC-approved documents translated into other languages must be sent to SAMAREC along with the translation certificates for record purposes.

10. SUBMISSION OF REGISTRIES AND SECONDARY DATA ANALYSIS

10.1. Research Registries

a) A research registry is a structured system that collects, stores, and maintains data on individuals—usually patients—with the goal of conducting future research.

b) Participants are enrolled (with informed consent, unless waived), and their data is entered into the registry.

c) Registries can be prospective (data is collected over time) or retrospective (existing data is compiled).

d) Examples: Cancer registries, disease-specific patient databases.

e) **Ethical Consideration:** Must comply with ethical guidelines, especially regarding informed consent, data privacy, and data sharing.

10.2. Secondary Data Analysis

a) Involves the use of existing data (from registries, medical records, surveys, databases, etc.) for a new research question.

b) The researcher does not collect new data but re-analyses data already gathered- often for a different purpose than the original study.

c) **Ethical Consideration:** Requires approval from a research ethics committee (REC), especially if data is identifiable. Consent may be waived if the data is anonymised and the research poses minimal risk.

10.3. Submission Documentation:

a) **Covering Letter**
   - Brief summary of the research, including objectives, methods, and ethical considerations.

b) **Completed SAMAREC Application Form**

c) **Full Research Protocol**
   - Objectives, background, methodology, analysis plan, risk-benefit assessment etc.

d) **Data Management Plan (DMP)**
   - As required by the 2024 NDOH guidelines: includes storage, security, access control, anonymisation, retention, sharing, de-identification plan etc.

e) **Participant Information and Informed Consent Materials**
   - If consent is required, Informed Consent Documentation
   - If consent is not being obtained, submit a request for waiver of informed consent, with justification (e.g., anonymised data, minimal risk, retrospective review).

f) **Data Collection Tools**
   - Questionnaires, case report forms, registry templates, etc.

g) **CVs of Principal Investigator and Key Study Staff**

h) **Proof of Research Ethics Training**
   - Certificates of completion, or proof of registration

i) **Institutional Approvals or Letters of Support**
   - From data custodians, registries, hospitals, or collaborating institutions.
   - As per the NDOH 2024 guidelines, Final Approval may not be granted until Institutional Approval is obtained

j) **Risk Assessment Statement**
   - Especially for secondary use of sensitive data.

10.4. Additional Documents (by Study Type)

10.4.1. For Research Registries:

- Registry Protocol detailing:
  - Data to be collected
  - Purpose of the registry
  - Duration of data storage
  - Data sharing and access policies
- Ongoing Consent Strategy (if longitudinal)
- Plans for Future Use of the registry data

10.4.2. For Secondary Data Analysis:

a) Source of the Data: description of where the data comes from (e.g., dataset, registry, records)
b) Data Access Agreement or Permission Letter from data custodian

11. AMENDMENTS

11.1 These submissions will also be ratified by the full Committee at the subsequent meeting. The Amendment's will also be allocated to the original main evaluators of the first submission of protocol as main evaluators wherein additional evaluators may be appointed by the Committee as deemed necessary. Please ensure that the submission includes the SAMAREC Application Form.

11.2. Covering letters accompanying amended PIDs must state the date of their original approval. A brief paragraph or summary in the covering letter outlining the amendments must be provided. Amendments must be shown on the latest SAMAREC approved documents containing the changes recommended by SAMAREC, and the changes should be highlighted to facilitate review.

11.3. All amendments must be submitted electronically.
a) ***Administrative amendments:*** will be processed by the Officer.
b) ***Major Amendments***: a full review by Committee. (Protocol and PID's – Ethical Changes)
c) ***Minor amendments:*** will be reviewed by the main evaluators and reported to full committee in-between formal meetings.

11.4. Should the reviewer feel that the minor amendment needs formal Committee input, the amendment will be distributed to the entire Committee and added to the next scheduled meetingagenda for final approval.

11.5. Please ensure that submitted documentation includes the following information in footers "Document Name (i.e., Protocol number/ Participant Information and Informed Consent Document) , SAMAREC Version XX dated XXX."

11.6. NB: No product logos should be displayed on any documentation.

12. REPORTS AND MONITORING

12.1. Following approval of a protocol or research, six-monthly (bi-annual) reports on the study 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. For report templates refer to *SAMAREC Passive Audit Report.* Any decisions taken by SAMAREC after the review of the Progress Reports, will be conveyed to the applicant.

12.2. Once the study has been completed, the final study report must be submitted in due course.

12.3. SAMAREC would also benefit from obtaining 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 (3) years after the completion of a study.

13. ANNUAL RENEWAL

13.1. Protocols are approved for a maximum period of one year only. For projects, which continue beyond one year, it is the responsibility of the Researcher to submit to SAMAREC an Application for Continuing Review supported by the study progress report. The SAMAREC Application for Annual Renewal must be submitted in time to allow for review and approval no later than 12 months from the initial review date. Upon receipt of the application, SAMAREC will review and approve, if appropriate, continuation of the project for the subsequent approval period.

13.2. Continuation of projects beyond five years requires submission of a revised, updated SAMAREC application, protocol, and consent/assent document. The Application for Annual Renewal must also be submitted to SAMAREC for approval via the SAMAREC Application form.

13.3. Annual Renewal applications must be accompanied by progress reports / reference to already submitted progress reports (within the last 6 months).

13.4. For more information on the requirements and review process, refer to the *SAMAREC Continuing Review Annual Renewal Recertification.*

14. REPORTING PROPOSED CHANGES IN A RESEARCH PROTOCOL.

14.1. Any proposed change in a protocol which affects participants must be reviewed and approved by SAMAREC prior to implementation except where an immediate change is necessary to eliminate a hazard to the participants. Researchers should submit a document by way of an expedited review procedure.

14.2. If a change in protocol is minor e.g., changes in statistical analysis, it is not necessary to have a revised PID or an addendum to the PID. If, however, the change is major and significantly changes the content of the originally

signed PID, (e.g., addition of an intervention not addressed in the original PID or disclosure of a previously unidentified risk) the study researcher should have all new participants sign a revised PID. All currently enrolled participants should sign the revised PID or an addendum to the originally signed PID.

15. STUDY CLOSURE PROCESS

15.1. When a study is closed, cancelled for any reason, or is prematurely completed, a Closure Report must be completed. The closure form is intended to accompany the final summary of study results and should be submitted once the study has been completed and final results are available for reporting to SAMAREC. This serves as notification to SAMAREC that continuing review of the study is no longer required.

15.2 Where a site close-out visit (COV) has been conducted but final study results are not yet available, you should proceed with submitting the COV notification to SAMAREC at this stage. The Study Closure Form should then be submitted separately once the study has been formally completed and the final results are available.

15.3 A Notification Letter and a detailed Closure Report must be submitted.

16 COMPLAINTS PROCESS

16.1. Complaints may be lodged by researchers, or any other persons involved in the research being conducted. Complaints should be directed to the Committee first. Should the matter not be resolved, the complaint may be escalated to the NHREC.

16.2. Complaints may be lodged, in writing, with the SAMAREC Officer who will submit such complaints to the Chairperson as soon as possible for investigation.

16.3. Formal written feedback will be provided to the complainant once received from the Chairperson.

17 APPEALS AGAINST DECISIONS

Refer to Appeal SOP

18 EDUCATION

18.1. Research Ethics Committees must ensure that their members receive initial and continued education in research ethics and GCP training as well as to ensure they are kept aware of current issues and developments in the broad area of research ethics and science.

18.2. The current members of SAMAREC are qualified and experienced in these aspects and are afforded the opportunity of attending ethics and research ethics related courses, workshops and conferences as indicated.

19. RECRUITMENT

Additional members and new members to the Committee will be recruited regularly, to comply with the N*DOH*

Ethics in Health Research Principles, Processes and Structures (2024) REC Membership list.

20. LABORATORY VALIDATIONS AND VERIFICATIONS

When establishing a laboratory, assay validations and verifications are required. In the case where participants would not be identified in any validation and verification results, there is no ethical approval required.

21. BIOLOGICAL MATERIAL

21.1. Informed consent to use biological materials in research must be obtained from the tissue donor. Human biological materials and their products may not be used for commercial purposes without the consent of the tissue donor. All information on biological material to be used must be submitted the applications and submissions.

21.2. For further considerations on using biological materials in research - refer to the *SAMAREC Biological Materials, Databases, Registries and Repositories SOP.*

22. DATA, REGISTRIES AND REPOSITORIES

22.1. The Informed Consent Documents should clearly explain the purposes and nature of Databases, Registries and Repositories.

22.2. Include the purpose, nature and specifics for which consent is being sought, and how and what types of research it supports.

22.3. Further considerations on using databases, registries and repositories in research reference to the *SAMAREC Biological Materials, Databases, Registries and Repositories SOP* is recommended.

22.4. **Data Handling**: In ensuring data security of all study related documentation, inclusion to fit for purpose data tools and validity must be considered. Source records are needed to allow the applicable evaluation of the study's conduct.

22.5. An SOP should be available for the maintenance of equipment in order to maintain the integrity of the data. Computer systems must be fir for purpose and electronic records securely maintained.

22.6. Essential Records: Documents, data and meta data should be able to determine the reliability of study results produced. Site File should be controlled by the Principal Investigator. Some records may be retained by the Sponsor or Investigator as per the essential list record documents.

22.7. A Data Management Plan should be included with all new study submissions (*refer to the SAMAREC SOP Annexures*).

23. SUSPENDED OR TERMINATED PROJECTS

23.1. The SAMAREC may withdraw approval of a study, should the study be non-compliant with the approved protocol. A due process must be followed for withdrawal of approval.

23.2. Once the SAMAREC becomes aware of an indication that warrants non-compliance with the approved protocol, the situation will be investigated, and all parties involved will be expected to be transparent regarding their practices.

23.3. Findings during the investigation may warrant the study be suspended or discontinued.

23.4. The Researcher will be requested to comply with certain recommendations and provide evidence that same have been implemented before the study will be reviewed and approved to resume.

24. USE OF ARTIFICIAL INTELLIGENCE (AI) IN RESEARCH

Artificial intelligence tools (i.e., ChatGPT, Machine Learning etc) may be used in research however, the researcher must clearly state where and to what extent it was used. The researcher will be held accountable for any AI input, thus human oversight over AI tools is required. Furthermore, AI tools may not be referenced as an author as it does not meet the authorship requirements. For additional considerations refer to the COPE position statement on Authorship and AI tools.

25. THE SAMAREC REVIEW PROCESS

25.1.1. INTRODUCTION

a) The principles, processes, and considerations of the review process are detailed in the *SAMAREC Decisional Analysis Guidelines.*

b) The following description of the SAMAREC review process reflects the various ethical principles and regulatory requirements that a study should consider during the design phase of their project. To approve a research project involving participants, SAMAREC must assure itself of the following:

25.1.2. Study Design

a) The experimental design of the study is sound;
b) Consideration that any risks associated with the research project are minimised to the greatest extent possible;
c) Consideration that the potential benefits are maximised to the greatest extent possible;
d) The risks to the participant are outweighed or balanced by the potential benefits;
e) The prospective participant population is appropriate in terms of characteristics and number;
f) The researchers have the appropriate qualifications, experience, and facilities to conduct the research;
g) Monitoring requirements are reviewed and adequate;
h) Any other factors deemed appropriate.

25.1.3. Volunteer Participation

a) The recruitment of participants is free of coercion;
b) The method used to obtain informed consent is ethically and legally acceptable;
c) The necessary consideration has been given to protect vulnerable populations/groups;
d) The degree to which confidentiality is maintained is acceptable;
e) Injury compensation is provided in accordance with no fault compensation principles
f) Any other factors deemed appropriate.

25.1.4. REVIEW OF THE PROSPECTIVE PARTICIPANT POPULATION

The prospective participant population must be appropriate with respect to the nature and goals of the research. In addition, the study researcher should be guided by the principles that lead to an equitable selection of participants about the potential risks and benefits of the research. Therefore, SAMAREC will carefully examine the characteristics of the participant population. Factors such as the required number of participants, age range, sex, ethnic background, and health status will be considered. The utilisation of any vulnerable classes of participants such as foetuses, prisoners, children, mentally incompetent persons, *non compos mentis* persons, persons living with HIV / AIDS, frail and terminally ill persons, and persons of low socio- economic status must be clearly justified.

25.1.5. REVIEW OF METHOD(S) OF PARTICIPANT RECRUITMENT

25.3.1. SAMAREC will review the method of prospective participant identification and recruitment to be assured it is ethically and legally acceptable. Advertisements used to recruit participants are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by SAMAREC.

25.1. REVIEW OF EXPERIMENTAL DESIGN

25.4.1. SAMAREC will review the experimental design to be assured that it is scientifically and socially soundand that the potential risks to the participants are minimised and the potential benefits maximised by using procedures consistent with acceptable research design.

25.4.2. The research design should be described in a clear and detailed protocol.

25.4.3. The use of socially constructed categories (race, gender, religion etc.) in the research need to be justified, with the onus lying on the researcher to explicitly clarify the role of these categories in the research and risks and benefits associated with their description.

25.4.4. If the research study is part of obtaining a higher qualification, the approval from the scientific or research committee of the training institution must be attached as part of the supporting documents.

25.2. REVIEW OF THE POTENTIAL RISKS

25.5.1. A risk is a potential harm (injury) associated with the research that a reasonable person would likely consider significant in deciding whether to participate in the research or not. The conceptof risk includes discomfort, burden, or inconvenience that a participant may experience because of the research procedures. Underlying

the consideration of risk is the implicit moral guideline that all researchers have a duty not to harm their participants and must minimise potential risk to the greatest extent possible.

25.5.2. The five major types of risk are: -

a) **Physical risk** (e.g., pain, bruising and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain because of exercise testing, heart attack induced by maximum exercise testing);
b) **Psychological risk** (e.g., depression and confusion because of administration of drugs,feelings of guilt precipitated by a sensitive survey);
c) **Social risk** (e.g., invasion of privacy, loss of community standing);
d) **Legal risk** (e.g., compromising medical scheme benefits); and
e) **Economic risk** (e.g., loss of employment, loss of potential monetary gain, cost to state or participant or medical scheme). Financial reimbursement of the research site or study researcher must not be excessive to result in a conflict of interest.

25.5.3. For further considerations on SAMARECs review of risks and a risk assessment tool, refer to the *SAMAREC Risk Assessment* SOP.

25.3. REVIEW OF POTENTIAL BENEFITS

A benefit in research ethics, refers to the positive outcomes or advantages that may arise from a research study, both for participants and for society as a whole. It encompasses the potential for improved health, well-being, or knowledge generation. A key aspect of research ethics is ensuring that the potential benefits of a study outweigh any associated risks to participants. Benefits associated with participation in research can be classified as those that accrue to the participant directly (e.g., improvement of the participant's health status; acquisition of knowledge considered of value by the participant) and those that accrue to society (e.g., additions to the knowledge base). SAMAREC will review the anticipated benefits to both the participants and to others. In addition, SAMAREC will consider whether the benefits are maximised to the greatest extent possible through proper protocol design. Therefore, an underlying moral notion of "beneficence" should guide the researcher as an underlying value construct.

Financial and other forms of compensation are not considered a benefit to be derived from research participation. Although the participant may consider financial compensation a desirable outcome, this fact will not be used in the risk-benefit analysis and should not be mentioned in the PID. For example, the fact that participants may receive a certain sum of money per visit to defray travel expenses, cannot be reflected as a benefit. Please note that it may be stated in the protocol document that the participant would receive an exact amount for travel and / or other associated costs. However, the exact amount of money must not appear in the Participant Information and Informed Consent Document (PID) as this could be seen as coercive.

25.4. RISK-BENEFIT ANALYSIS

Once the potential risks and benefits are identified, an ethics review of research requires an examination of the relationship of the risks to the benefits. Risks and benefits cannot be considered parallel constructs and, therefore, no formula is applicable. The various ethical codes and regulations, however, require a favourable balance between harm and benefit. To assist the researcher and SAMAREC in assessing the risk-benefit relationship refer to *SAMA SOP REC v10.*

25.5. REVIEW OF PARTICIPANT COMPENSATION AND ASSESSMENT OF FINANCIAL ARRANGMENTS

SAMAREC will review the amount of compensation (monetary as well as other forms) paid to theparticipants to ensure that the payment is not coercive (or deemed to be an enticement)and only covers reasonable actual expenses, e.g., relating to travel.

Financial arrangements involving participants and researchers form part of the assessment by the Committee.

25.6. REVIEW OF MEASURES TO PROTECT PERSONAL INFORMATION

SAMAREC will review the methods to be used to preserve confidentiality. If research data and participant identifiers will be made available to persons other than the listed researchers, SAMAREC will review the justification for sharing this data and determine acceptability.

SAMAREC will also consider whether the appropriate consent has been sought for the retention and use of confidential personal information in line with the requirements of the POPI Act, 2013 as well as other laws applicable for the protection of such confidential information.

25.7. REVIEW OF THE PARTICPANT INFORMATION AND INFORMED CONSENT DOCUMENT PROCESS

The Bill of Rights states that –
"Everyone has the right to bodily and psychological integrity, which includes their right - (c) not to be subjected to medical or scientific experiments without their informed consent."

Therefore, no research may be conducted on a person without his/her consent or the consent ofthe person ('s) legally authorised representative prior to the person's participation in the research study. The principal reason for informing participants about the research study is founded by their right to know what would be done to them and what risk such participation entails before they grant consent thereto. Persons are regarded as autonomous, and the requirement of informed consent is designed to uphold the ethical principle of "respect for persons". The use of humans as research participants is a privilege and a favour granted to the researcher and such should privilege should be protected and respected at all times. The researcher has no right to conduct health research without informed consent.

25.10.1. Patient information and informed consent documents (PID) should align with SAMAREC's *pro forma* (See Annexure 13). SAMAREC requires that all PIDs include a paragraph informing the patient that the study received ethics approval. Furthermore, all PIDs include SAMAREC's contact details (refer to Annexure 13 for ethics approval and contact detail standard wording)

Informed consent must be obtained for all studies that involve access to patient records, including case series study

designs. In circumstances where data are aggregated and fully anonymised, the requirement for informed consent may be waived. However, any waiver of consent must be formally requested by the researcher and is subject to review and approval by the REC.

25.10.2. For further considerations and SAMAREC guidelines, refer to *SAMAREC Informed Consent* SOP.

25.8. E-CONSENT

25.11.1. SAMAREC accepts Advanced Electronic Signatures (AES), in the place of wet signatures. Section 1 of the *Electronic Communications and Transactions* Act No. 25 of 2002 defines AESs as "*an electronic signature which results from a process which has been accredited by the Authority as provided for in section 37*". This form of E-Consent is also permitted through clause 10.9 of the South African Good Clinical Practice: Clinical Trial Guidelines (2020), which states that "*An electronic signature is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. In general, a signature may not be denied legal effect or validity solely because it is in electronic format, and a contract or other record relating to a transaction may not be denied legal effect, validity, or enforceability solely because an electronic signature or electronic record was used in its formation. To be considered equivalent to full handwritten signatures, electronic signatures must comply with all applicable requirements under 21 CFR part 117. Electronic records that are electronically signed must contain information associated with the signing that clearly indicates the printed name of the signer, the date and time when the signature was executed, and the meaning associated with the signature. In addition, electronic signatures and handwritten signatures executed to electronic records must be linked to the respective electronic records to ensure that the signatures cannot be excised, copied or otherwise transferred to falsify an electronic record by ordinary means.*"

25.12. TELEPHONIC CONSENT

25.12.1. From a South African National Department of Health (NDOH) ethics perspective, particularly aligned with the 2024 NDOH Ethics in Health Research Guidelines, telephonic consent is permissible under certain conditions, especially in low-risk research or in circumstances where in-person contact is impractical or may pose a risk (e.g., during public health emergencies or in geographically remote areas).

25.12.2. Key Considerations for Telephonic Consent:

25.12.2.1. Justification Must Be Clearly Provided

You must justify:

a) Why telephonic consent is necessary (e.g., geographical limitations, time sensitivity, safety considerations).

b) Why written consent is not feasible, and how the telephonic process will maintain ethical and legal standards.

25.12.2.2. Participant Information and Understanding

Even though consent is not written:

a) A Participant Information and Informed Consent Document should still be developed.

b) The contents must be read out or explained in full to the participant in a language they understand.

c) Allow the participant time to ask questions and ensure their comprehension.

25.12.2.3. Voluntariness and Documentation

Participation must be voluntary, and this must be clearly affirmed by the participant. It is required that the researcher must document the consent process, including:

a) Time and date of the call
b) Name of the participant
c) Name of the staff member obtaining consent
d) Confirmation that the participant understood and agreed;
e) Confirmation that the participant has been informed that they may withdraw their consent at any time.
f) Confirmation that the research study has been explained including associated risks and benefits; and
g) Confirmation of the original method used (audio recording or written field notes) to obtain consent.

If the interview is being audio recorded, it is required that the participants consent to the recording before the recording begins.

25.12.2.4. Your protocol must include:

a) A full script of the telephonic consent process (i.e., what will be said to participants).
b) Explanation of how confidentiality and data protection will be maintained during and after the call.
c) Steps for documenting and storing consent.
d) If participants are vulnerable persons, additional ethical safeguards may be required.
e) If research involves any health intervention or collection of sensitive data, further justification for not using written consent may be required.

25.13. CONFLICT OF INTEREST

25.13.1. SAMAREC ensures that no member of the Committee adjudicates on research in which that member has any conflict of interest in relation to the research project under consideration. Members are required to declare before each Committee meeting of any real or potential conflicts of interest with anyof the studies to be evaluated and offer to recuse themselves from the evaluation of the study concerned. The member in question may remain in the meeting for the discussion of the protocol (should the Chairperson feel that this is appropriate), however, the member may not be allowed to participate in the final decision-making of the specific protocol (NDOH 2024 Guidelines).

25.14. ACCESS TO AND PROTECTION OF INFORMATION

25.14.1. Protocol information and documentation are regarded as confidential and are treated as such by SAMAREC and SAMA. In terms of the Guidelines for Ethics in Health Research, published by the NDoH, all records and documentation relating to the functioningof SAMAREC are open to the National Health Research Ethics Council. All other requests for accessmust be done in terms of the Promotion of Access to Information Act

2 of 2000. All personal information is treated as confidential and shall be processed in accordance with the Protection of Personal Information (POPI) Act, 2013.

25.14.2. All documents are stored electronically for record keeping and are accessible only to current SAMAREC members. These records are available for audit, conflict, and query purposes.Records will be kept of the following:

a) Main protocol and all supporting documents.
b) Date of provisional approval and/or final approval
c) If applicable – special conditions of approval
d) Administrative, Minor and Major Amendments
e) General Notifications
f) Translation with translation certificates
g) Annual renewal
h) Protocol Deviations

26. GENERAL

SAMA will express on the ethical conduct of the study as well as the scientific suitability of the study as these are interlinked, i.e., a study cannot be ethical if it is not scientifically sound:

a) Study question to be researched must be clear.
b) Hypothesis statement and alternative to be included where appropriate.
c) Methodology and data collection must be well described and be fitting to answer research question.
d) Statistical methodology must be sound.
e) Research subject/participant/ institution must be clearly defined and motivated.
f) All protocols must be signed off by study leader as adhering to these principles.

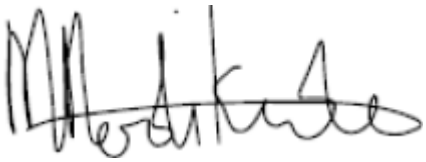
27. SAMAREC RESOLUTION (OUTCOMES)

After noting and considering the submission, the Committee will resolve as follows:

a) **Approved:** The Committee accepts the concept of the Study and has granted ethics approval. No further changes are required, and the Study may commence until approval status is obtained.
b) **Provisionally Approved:** The Committee accepts the concept of the Study; however, corrections must be made before final approval will be granted. The Study may not commence.
c) **Not Approved:** The Committee does not accept the concept of the Study. There are major scientific or ethical concerns. The Protocol should subsequently be revised whereby. The Study may not commence. Should feedback from SAMAREC be considered and amendments attended to, a new submission is to be presented as this will not be recognised as an amendment.

Name Of SAMAREC Chairperson:

Date Signed:29/06/2026



Name of SAMA CEO: **Dr Mzulungile Nodikida**

Date Signed: 26 June 2026