



NON CLINICAL RESEARCH PROPOSAL GUIDELINES, JUNE 2024, V3

Research Ethics
Committee



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

STANDARD OPERATING PROCEDURES AND GUIDELINES FOR NON CLINICAL RESEARCH PROPOSALS

DEFINITIONS AND INTERPRETATIONS

In this document, unless the contents otherwise require:

- **Study Staff** collectively refers to all researchers.
- **Study site** is the location(s) where study-related activities are conducted.
- **Participant** means the person participating in the study. The words **research participant** or **participant** may be used interchangeably, where applicable.
- **Patient** is defined as a participant with a clinical condition.
- **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 as well 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.
- **‘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

National Health Act

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 registered on the Department of Health (DOH) National Research Ethics Council database.



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

Research can be broadly classified as therapeutic and non-therapeutic. Therapeutic research is an investigation designed to determine the efficacy and safety of a therapeutic or diagnostic method. The interventions are not applied solely to enhance the well-being of the individual participant.

In contrast to therapeutic research, non-therapeutic research is an investigation that has no intent of producing a diagnostic, preventive, or therapeutic benefit to the research participant, who is usually healthy and is not seeking nor expecting a health benefit from the research.

Therapeutic research immediately also implies an intervention with the aim to heal. However, non-therapeutic research may or may not be interventional in nature i.e., where a device and or medicine is given to obtain a specific effect - meaning an intervention but not to heal e.g. phase one pharmacokinetic study; or where there is no intervention and the research is purely, for example, data collection from patients or healthy individuals to answer a clinical question.

In the execution of its responsibilities in evaluating the ethics of research protocols, SAMAREC is guided by the relevant South African law, research and ethics guidelines, professional standards, international standards and guidelines and codes of practice.

The NHA provides that health research ethics committees (RECs) must be established by every institution, health agency and health establishment at which health research is conducted, or they must have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

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

- i. review research proposals and protocols 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*
- ii. 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 National Health Research Ethics Council (NHREC) was established by the Minister of Health after consultation with the National Health Council. The Minister appoints as members of the NHREC not more than fifteen persons nominated by interested parties at the invitation of the Minister by notice in the Government Gazette.

In terms of the NHA the National Health Research Ethics Council must: -

- (a) determine guidelines for the functioning of health research ethics committees;*
- (b) register and audit health research ethics committees;*
- (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 research ethics committees and hear any complaint by a researcher who believes that he or she has been discriminated against by a health research ethics committee;*
- (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."*

According to the Guidelines for Ethics in Health Research, published by the 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.

SAMAREC has been registered and audited in accordance with the National Health Act (61 of 2003). Registration number: 280808-016. Valid until 30 November 2023.

In March 2002, SAMAREC became a registered Research Ethics Committee at the Department of Health and Human Services (DHHS) of the USA.

(IRB: 0001 1624)

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

American Food & Drug Administration (FDA) and International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Guidelines for Good Clinical Practice. SAMAREC follows the standards adopted by the latest version of the FDA and ICH Guidelines for Good Clinical Practice; and conforms to the guidelines laid down by the World Medical Association, in particular, the latest version of the Declaration of Helsinki, the Belmont Report, the National Department of Health, the South African Health Products Regulatory Authority (SAHPRA) and other relevant statutory bodies involved in the healthcare sector.

A REC should consider the following issues when reviewing a study:

- the scientific relevance of the study;
- the suitability of the researchers for the proposed study in terms of his/her availability, qualifications, experience, supporting staff, and available facilities;
- the relevance of the study rationale and the appropriateness of the inclusion / exclusion criteria to the South African context;
- the suitability of the study application in relation to the objectives of the study; i.e., the potential for reaching sound conclusions with the smallest possible exposure to risk of participants, and the justification of predictable risks and **inconveniences** weighed against the anticipated benefits for the participants and/or others;
- the suitability of the study population, whether they constitute a vulnerable group, if so whether justified and whether sufficient measures to protect their interest are in place;
- that the number of participants to be recruited is adequate to demonstrate the predicted effect;
- the risk-benefit analysis takes full cognisance of benefits and harms beyond the life of the study itself, particularly in relation to chronic life-threatening conditions;
- that by their participation in a study the participants are not denied timely access to medical personnel, investigations, equipment, or procedures;
- the means by which initial recruitment is to be conducted and by which full information is to be given and how informed consent is to be obtained;
- the adequacy and completeness of the written information to be given to the participants, their relatives, guardians and, if necessary, legal representatives. All written information for the participant and/or legal representative must be submitted in its final form;
- that the application allows the participants and/or their representatives adequate time to consider the



- participant information document before informed consent is sought;
- the content of any advertisements or public notices which will be used to recruit participants to a study;
 - the study protects participants' rights to privacy and confidentiality according to the provisions of the Protection of Personal Information (POPI) Act, Act 4 of 2013;
 - the provision of compensation/treatment in the case of injury or death of a participant if attributable to a study, and the insurance or indemnity to cover the liability of the researcher if necessary.
 - the extent to which participants and researchers are to be compensated for participation in the study;
 - and not unduly compromised;
 - the demographic information available to assess whether the population is adequate to support the study;
 - whether there is no cost to the participant, medical schemes, or insurance for specific procedures;
 - whether any restrictions will be placed on the publication of results by the researchers after completion of the study;
 - the adequacy of the statistical methods proposed to evaluate the data generated; and whether the study is advancing knowledge in the research field.

SAMAREC reviews health research, prior to initiation of such research and focuses on the ethical implications relating to the research. Ensuring protection of the rights and welfare of the participants is the Committee's primary concern. Based on the above-mentioned standards and guidelines, SAMAREC will advise and make suggestions to the study and applicants, when requested.

2. COMPOSITION OF SAMAREC

Research ethics committees must consist of members who collectively have the qualifications and experience to review and evaluate the science, health, legal aspects, and ethics of proposed research. Committees must be independent, multi-disciplinary, multi-sectorial and pluralistic. When a specific portfolio on the committee is required (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 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. 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 General Manager 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 function as Chairperson as necessary and also assist the Chairperson with responsibilities as required.

The current composition of SAMAREC is as per Annexure 5

- 3.1 The SAMAREC Composition will be updated as and when changes occur.
- 3.2 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.
- 3.3 *Curricula vitae* of the Committee members and external experts (if applicable) are available on request. These are kept by the Officer.

a. CONTACT DETAILS

The SAMAREC Officer may be contacted at:

Telephone: (012) 481 2082



Postal Address: P O Box 74789
Lynwood 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 = R4 729 ex vat

Annual Renewal = R2 364 ex vat

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.

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

3. PROCEDURES AND ADMINISTRATIVE GUIDELINES

MEETINGS

- SAMAREC meets on the second Wednesday of each month unless circumstances require otherwise.
- Applications for consideration must be submitted via e-mail to the SAMAREC Officer at the offices of the South African Medical Association 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.
- A written response regarding decisions is usually forwarded to applicants within ten working days after the meeting.
- Sixty percent (60%) of the Committee constitutes a quorum.
- Confidentiality of the content of applications, the protocols, and the procedures of SAMAREC, is maintained as far as is possible.

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

4. SUBMISSION OF RESEARCH PROTOCOL REVIEWS

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

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

- SAMAREC Application Form (Refer to Annexure 2)
- Covering letter
- Research Summary
- Protocol
- Participant Information and Informed Consent Document (PID) (*pro forma* attached as Annexure 4). This document must be submitted in MS Word format.



- Data collection tools (e.g., Questionnaires (if any) or Interview Guides (if any))
- Details and breakdown of financial arrangements with researchers, if any
- Information pertaining to recruitment e.g., advertisements, bulletins and information placed on the Internet (Guidelines attached as Annexure 7).
- *Curricula Vitae* of all study personnel (CV format attached as Annexure 3)
- Declarations by Researchers (Please refer to Annexures 8 for the declaration template)
- If applicable, GCP certificates (SAMAREC recommends that site staff be trained in latest version of both ICH GCP and SA GCP).

Please ensure that submitted documentation includes the following information in footers “Protocol number/ Participant Information and Informed Consent Document, SAMAREC Version XX dated XXX.” Furthermore, no product logos should be displayed on any documentation.

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.

Submitting of additional research staff staff once approval obtained:

- Covering letter listing study staff must be presented with an indication of their submitted documents (example attached as Annexure 9)
- Relevant documentation as mentioned above.

5. COVERING LETTER

The Covering Letter must contain the following details:

- A summary of the protocol
- Study staff must be listed with an indication of their submitted documents.

6. DECLARATIONS

Declarations by all study staff, must reflect the protocol number and title, as well as the study staff’s name and designation (Declarations must be properly completed and signed).

7. CURRICULUM VITAE

The approval criteria for Researchers:

- must be a suitably qualified researcher suitable to the study.

8. ABBREVIATIONS

Abbreviations may not be used without initially writing the words out in full with the appropriate abbreviation 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 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' 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 present during the consent process, the information provided to the participant should clearly stipulate that the privacy of the consent will be compromised to that extent (DOH 2024).

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

10. AMENDMENTS

Amendments are to be submitted to the Chairperson. These submissions will also be ratified by the full Committee at the subsequent meeting. Ensure that the submission includes the SAMAREC Application Form.

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.

All amendments must be submitted electronically.

Administrative amendments: will be processed by the Officer.

Major Amendments: a full review by committee. (Protocol and PID's – Ethical Changes)

Minor amendments: will be reviewed by and reported to full committee in-between formal meetings.

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 meeting agenda for final approval.

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

Furthermore, no product logos should be displayed on any documentation.

11. REPORTS AND MONITORING

Following approval of a protocol or research, six-monthly 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.

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



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 years after the completion of a study.

12. ANNUAL RENEWAL

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.

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.

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

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

13. REPORTING PROPOSED CHANGES IN A RESEARCH PROTOCOL.

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.

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.

14. STUDY CLOSURE PROCESS

When a study is closed, cancelled for any reason, or is prematurely completed a Closure Report must be completed. This serves as notification to SAMAREC that continuing review of the study is no longer needed. A Notification Letter and a detailed Closure Report must be submitted.

15. COMPLAINTS PROCESS

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.



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

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

16. APPEALS AGAINST DECISIONS

Appeals against decisions should be lodged, in writing, to the full Committee, who will then investigate the complaint and endeavour to deal with it to the satisfaction of the complainant.

17. EDUCATION

Research ethics committees must ensure that their members receive initial and continued education in research ethics and GCP training and are kept aware of current issues and developments in the broad area of research ethics and science.

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.

18. RECRUITMENT

Additional members and new members to the Committee will be recruited regularly, to comply with the *DOH Ethics in Health Research Principles, Processes and Structures (2024)* REC Membership list.

19. BIOLOGICAL MATERIAL

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.

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

20. DATA BASES, REGISTRIES AND REPOSITORIES

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

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

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



21. SUSPENDED OR TERMINATED PROJECTS

The REC 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.

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

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

22. USE OF ARTIFICIAL INTELLIGENCE (AI) IN RESEARCH

Artificial intelligence tools (i.e., ChatGPT) 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.

23. THE SAMAREC REVIEW PROCESS

23.1 INTRODUCTION

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

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:

Study Design

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

Volunteer Participation

- The recruitment of participants is free of coercion;
- The method used to obtain informed consent is ethically and legally acceptable;
- The degree to which confidentiality is maintained is acceptable;
- Injury compensation is provided in accordance with the Association of British Pharmaceutical Industry (ABPI) Guidelines (where applicable);
- Any other factors deemed appropriate.



23.2 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.

23.3 REVIEW OF METHOD(S) OF PARTICIPANT RECRUITMENT

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.

23.4 REVIEW OF EXPERIMENTAL DESIGN

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

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

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.

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.

23.5 REVIEW OF THE POTENTIAL RISKS

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 concept of 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.

The five major types of risk are: -

- **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);
- **Psychological risk** (e.g., depression and confusion because of administration of drugs, feelings of guilt precipitated by a sensitive survey);
- **Social risk** (e.g., invasion of privacy, loss of community standing);
- **Legal risk** (e.g., compromising medical scheme benefits); and
- **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.

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



Assessment SOP.

23.6 REVIEW OF POTENTIAL BENEFITS

A benefit is a valued or desired outcome. 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.

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 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.

23.7 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*.

23.8 REVIEW OF PARTICIPANT COMPENSATION AND ASSESSMENT OF FINANCIAL ARRANGEMENTS

SAMAREC will review the amount of compensation (monetary as well as other forms) paid to the participants 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.

23.9 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.



23.10 REVIEW OF THE PARTICIPANT 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 of the person’s legally authorised representative prior to the person’s participation in the experiment. The principal reason for informing participants about the experiment is that they have a right to know what would be done to them and what risk this entails, before they grant consent. 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. The researcher has no right to conduct health research without informed consent.

Patient information and informed consent documents (PID) should align with SAMAREC’s *pro forma* (See Annexure 4). 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 4 for ethics approval and contact detail standard wording)

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

23.11 E-CONSENT

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.”*

23.12 CONFLICT OF INTEREST

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 should declare before each meeting any real or potential conflicts of interest with any of 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. (DOH 2024 Guidelines).



23.13 ACCESS TO AND PROTECTION OF INFORMATION

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 Department of Health, all records and documentation relating to the functioning of SAMAREC are open to the National Health Research Ethics Council. All other requests for access must be done in terms of the Promotion of Access to Information Act. All personal information is treated as confidential and shall be processed in accordance with the Protection of Personal Information (POPI) Act, 2013.

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:

- Main protocol and all supporting documents.
- Date of provisional approval and/or final approval
- If applicable – special conditions of approval
- Administrative, Minor and Major Amendments
- General Notifications
- Translation with translation certificates
- Annual renewal
- Protocol Deviations

23.14 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:

1. Study question to be researched must be clear.
2. Hypothesis statement and alternative to be included where appropriate.
3. Methodology and data collection must be well described and be fitting to answer research question.
4. Statistical methodology must be sound.
5. Research subject/participant/ institution must be clearly defined and motivated.
6. All protocols must be signed off by study leader as adhering to these principles.

23.15 SAMAREC Resolution

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

Approved: The Committee accepts the concept of the Study and has granted ethics approval. No further changes are required, and the Study may commence.

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.

Not Approved: The Committee does not accept the concept of the Study. There are major scientific or ethical concerns. The Protocol should be revised. The Study may not commence.



Approved by:

Dr N Naidoo
SAMAREC Chairperson

Date Signed: 23 Aug 2024

Dr T Nodikia
SAMAREC CEO

Date Signed: 10 October 2024