



DECISIONAL ANALYSIS SOP, OCTOBER 2023, V1

Research Ethics
Committee



| Final Version | Reason for Amendment | Effective Date |
|---------------|--|----------------|
| 1 | Developed and published for implementation | October 2023 |
| | Administrative changes | March 2024 |

1. DEFINITIONS

- I. **Doctor** refers to a medical practitioner (or dentist, when appropriate), as defined in terms of the Health Professions Act, no. 56 of 1974 (as amended),
- II. **Study doctor** refers to a doctor (or dentist, when appropriate), participating in the clinical trial / study. The words **study investigator, investigator, sub-investigator, co-investigator, trialist or researcher** may be used interchangeably, as long as the person is a clinician, where applicable. Whichever term is used, it must be used consistently throughout the documents.
- III. **Principal Investigator** is a person responsible for the conduct of the clinical trial at a trial site.
- IV. **Co-Principal Investigator** A qualified non-clinician scientist or equivalent qualified and experienced person who can provide trial oversight management, and who is jointly and severally liable for the clinical trial.
- V. **Associate Investigator** refers to a member of the health care team involved for specific investigations which are required for the conduct of the clinical trial / study. This will be in accordance with their relevant field(s) of expertise and training e.g., ophthalmologist or psychologist responsible for specific aspects but not taking clinical responsibility as sub investigators for trial participants.
- VI. **Sub-Investigator** – any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial- related decisions.
- VII. A **Clinical Trial** is a prospective biomedical or behavioural research study of human participants that is designed to answer specific questions about biomedical or behavioural interventions (vaccines, drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
- VIII. **Study Staff** collectively refers to the investigators, study coordinators, study nurses, pharmacists, raters, and any other people rendering support to the investigator.
- IX. **Study site** is the location(s) where trial-related activities are actually conducted.
- X. **Participant** means the person participating in the clinical trial / study and/or receiving treatment, including receiving blood or blood products, or using a health facility or establishment, as a result of participation in the clinical trial / study. The words **research participant or participant** may be used interchangeably, where applicable.
- XI. **Patient** is defined as a participant with a clinical condition.
- XII. **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 the term experiment or, clinical trial may be used interchangeably with the word **research**, when applicable.
- XIII. **Clinical Research** is usually conducted with patients in a medical setting (e.g., hospital, clinical or private consulting rooms) to obtain information on the natural history or pathogenesis of a condition that could assist with improving strategies for diagnosis, treatment, or prevention of disease.
 - Any reference to the singular includes the plural and vice versa;
 - Any reference to natural persons includes legal persons and vice versa;



- Any reference to a gender includes the other gender;
- The clause headings in the Standard Operating Procedures have been inserted for convenience only and shall not be taken into account in interpreting this SOP.

XIV. **'Physician'** means – a medical practitioner registered as a specialist in internal medicine, and this should not be used as an alternative term when referring to a family doctor/ general practitioner.

XV. **Amendments** – changes *in the PID to be forwarded to SAMAREC in the most recently approved PID of SAMAREC. All changes must be indicated with track changes.*

XVI. **'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.

2. PURPOSE

To provide comprehensive guidance to SAMAREC on the principles, processes, and considerations involved in decision analysis. Decision analysis is an essential aspect of our responsibilities, as it guides us in evaluating research proposals and making ethically sound decisions. This guidance is intended to serve as a reference and support in conducting duties effectively.

3. DECISIONAL ANALYSIS, PROTOCOL, AND INFORMED CONSENT REVIEW PROCESS

- A written response regarding decisions is usually forwarded to applicants within 10 working days after the meeting.
- 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 reasonably possible.
- SAMAREC Officer will prepare the meeting packs as per the submission dates and submit to the Committee at least 10 days prior to meeting dates.
- Final Decisions are discussed during the SAMAREC Meetings via voting, discussion and noted accordingly in the meeting minutes.
- SAMAREC will always ensure the privacy and confidentiality of patients and participants is the priority of the study.
- Decisions will be finalized by with the approval of the entire Committee and feedback will be provided to applicants within 10 working days of the SAMAREC Meeting.

4. FINAL DECISION CRITERIA

- I. **Ethical Foundations:**
Decision analysis within the context of clinical research ethics is rooted in ethical principles. These principles include respect for autonomy, beneficence, non-maleficence, justice, and respect for individuals. It is crucial that every decision made by the SAMAREC aligns with these ethical foundations.
- II. **Comprehensive Review:**
When assessing research proposals, the SAMAREC should engage in a comprehensive review process,



considering both the ethical and scientific aspects. The decision analysis should involve the following steps:

- a. Preliminary Review: Evaluate the proposal's initial feasibility, ethical considerations, and alignment with legal and regulatory requirements.
- b. In-Depth Review: Delve into the details of the proposal, focusing on the research design, data collection, potential risks, and the informed consent process. Assess whether the study upholds ethical standards and scientific rigor.

III. Risk-Benefit Assessment:

In decision analysis, the committee must carefully assess the risks and potential benefits associated with the research. Ensure that the risks to participants are minimized and that the potential benefits to individuals and society are maximized. Weigh these aspects to make an informed decision.

IV. Informed Consent:

The SAMAREC must pay special attention to the informed consent process. Evaluate whether the proposed methods for obtaining informed consent are clear, accessible, and respect participants' autonomy. Ensure that participants have all necessary information to make an informed decision about their involvement.

V. Vulnerable Populations:

Research involving vulnerable populations demands heightened scrutiny. Decision analysis should include a focus on protecting the rights and well-being of vulnerable individuals, including minors, the elderly, and those with cognitive impairments.

VI. Conflicts of Interest:

Evaluate and disclose any potential conflicts of interest among committee members or researchers. Transparency is vital to maintaining trust in the SAMAREC's decision-making process.

VII. Continuous Training:

To ensure that the SAMAREC remains informed about the evolving landscape of clinical research ethics, members should engage in ongoing training and education. This includes staying up to date with relevant laws, regulations, and emerging ethical issues.

VIII. Decision Documentation:

Every decision made by the SAMAREC should be well-documented, providing a clear rationale for approval or rejection. Transparent documentation ensures accountability and demonstrates that ethical principles have been followed.

IX. Consultation:

In complex cases, the SAMAREC should consider seeking external expert advice or consultation to ensure that the decision analysis is thorough and unbiased.

X. Continuous Improvement:

Finally, the SAMAREC should periodically review and reflect on its decision analysis processes. Continuous improvement ensures that the committee remains effective in its mission to safeguard ethical standards in clinical research.

Decision analysis is a pivotal function of the Research Ethics Committee, and it plays a critical role in ensuring the ethical conduct of research. By adhering to these guidelines and considering the principles outlined, SAMAREC can make well-informed, ethical decisions that protect the rights and well-being of research participants.



Approved by:

Prof J Snyman
SAMAREC Chairperson
Signed: 25 October 2023

Dr M Nodikida
SAMA CEO
Signed: dd mmmm yyyy