



# **CONTINUING/ ANNUAL RENEWAL & RECERTIFICATION SOP OCT 2023, V1**

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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 behavioral research study of human participants that is designed to answer specific questions about biomedical or behavioural interventions (vaccines, drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).
- 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

This Standard Operating Procedure (SOP) outlines the process for conducting continuing reviews in clinical research to ensure that research activities remain in compliance with ethical and regulatory standards. This SOP aims to provide guidance on the ongoing monitoring and oversight of research studies after initial approval.

## 3. SCOPE

This SOP applies to all clinical research studies conducted within SAMAREC that require periodic continuing review, in accordance with relevant laws, regulations, and institutional policies.

## 4. PROCESS

Protocols are approved for a maximum period of one year only. For projects, which continue beyond one year, it is the responsibility of the Principal Investigator or Applicant to submit to SAMAREC an Application for Annual Renewal supported by the latest 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 for 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).

## 5. RESPONSIBILITIES

- a. **Principal Investigator (PI):** The PI is responsible for ensuring that the research study complies with the approved protocol and conducting the continuing review process in a timely manner.
- b. **Clinical Research Coordinator (CRC):** The CRC assists the PI in the review process and ensures that all required documentation is prepared and submitted.
- c. **Research Ethics Committee (REC):** The REC is responsible for reviewing and approving or disapproving the continuation of the research study, considering ethical, scientific, and regulatory factors.

## 6. PERIOD OF ANNUAL RENEWAL

Continuing reviews will be conducted at intervals specified by SAMAREC and set out in the SAMAREC SOP. These intervals will be documented in the research protocol and indicated on the initial approval documentation.

## 7. DOCUMENTATION REQUIRED

- a. The PI or Applicant must prepare a submission package for continuing review, including the following documents:
- b. Progress report on the status of the study, including recruitment, adverse events, and protocol deviations.
- c. Updated Investigators Brochure

## 8. REVIEW PROCESS

SAMAREC will conduct a thorough review of the continuing review submission. This review will focus on the following aspects:

- a. The safety and welfare of research participants.
- b. Adherence to the approved protocol.
- c. Any ethical concerns or challenges that may have arisen during the course of the study.
- d. Compliance with applicable regulations and institutional policies.
- e. The scientific validity and quality of the study.

## 9. SAMAREC DECISIONS

After reviewing the submission package and conducting discussions, SAMAREC will make one of the following decisions regarding the continuation of the research study:

- a. Approval of the study to continue without modification.
- b. Approval of the study with specific modifications or conditions.
- c. Disapproval of the study's continuation.



## 10. COMMUNICATION

SAMAREC will communicate its decision to the PI or Applicant in a timely manner. If modifications or conditions are required, SAMAREC will outline the specific requirements.

## 11. RECORD KEEPING

All documentation related to the continuing review process, including SAMAREC decision, will be maintained in a secure and accessible location for audit and inspection purposes.

## 12. PERIODIC REPORTING

The PI or Applicant will provide periodic updates to SAMAREC as required by institutional policy and regulations, to ensure ongoing oversight and compliance.

## 13. TRAINING AND EDUCATION

All members of SAMAREC involved in the continuing review process will receive appropriate training and education to ensure they are knowledgeable about their responsibilities and the regulatory requirements for conducting continuing reviews.

## 14. REVISIONS OF SOP

This SOP will be reviewed periodically and updated as necessary to reflect changes in regulations, institutional policies, or best practices in the field of clinical research.

This SOP serves as a reference for conducting continuing reviews for approved protocols. Adherence to this procedure is crucial to maintaining the highest ethical and regulatory standards in our research activities.

**Approved by:**

A handwritten signature in black ink, appearing to read "J Snyman", is written over a horizontal line.

**Prof J Snyman**

**SAMAREC Chairperson**

**25 October 2023**