RAPID/EXPEDITED PROTOCOL REVIEW GUIDELINES, OCTOBER 2023, V1

Research Ethics Committee

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

DEFINITIONS:

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

1. EXPEDITED REVIEW PROCESS

Expedited Review Process (Sub-committee review of minor ethical issues). SAMAREC has established procedures for expedited review of research when this is in the public interest. Expedited review will entail review, of the lower risk studies (minimal risk), by a Lay and a Medical Committee Member and the decisions will be included in the following meeting of the whole committee for oversight. In general, research with potential to cause physical or psychological harm would not be considered for expedited review. This includes to drug trials of new investigational products,

research involving non-interventional research procedures and research involving sensitive personal or cultural issues. Expedited review applications must be accompanied by a covering letter detailing the request for expedited review. Should the evaluators feel that the study poses more than minimal harm or risk to the patients, the study will be referred to the entire committee for a full review during a formal meeting. Turnaround time for an expedited review is 3 working days. Please ensure "Expedited Review Process" is requested in the covering letter.

2. RAPID REVIEW PROCESS

SAMAREC has established procedures for rapid review of research when this is in the public interest e.g., urgency of disease and value of research to society. Rapid review is done for research protocols where there is more than minimal risk to the subjects e.g., vaccine study of new investigational product. These more serious studies posing a higher risk must be reviewed by the whole Committee, but this can take place between meetings by way of "round robin" assessment and collation of inputs by the SAMAREC officer for final approval by ways of electronic approval. Rapid review and approval may be considered for research where participants have a disease that may be rapidly fatal. Rapid review applications must be accompanied by a covering letter detailing the request and motivation for rapid review clearly indicating the need for urgency. Should the evaluators feel that the study poses significant risk more than minimal harm or risk to the patients or participants, then the study will be referred to the entire committee as per usual process for a full review during a formal meeting. Turnaround time for rapid reviews is 10 working days. Please ensure "Rapid Review Process" is requested in the covering letter.

3. EVALUATION PROCESS

- Application received by Officer and sent through to Chairperson for approval of rapid review.
- Once approved the rapid review will be distributed to members for review within ten (10) working days.
- The application will be delegated to a subcommittee of three (3) main evaluators (rotational basis and within scope of qualifications) – all members will be copied in for general review purposes.
- The subcommittee should consist of one (1) medical professional, one (1) legal and one (1) layperson. (where possible)
- Feedback will be received, and final comments will be reviewed and approved by the Chairperson.
- Once final comments have been circulated to applicant, the information will be minuted at the following formal SAMAREC meeting.

Approved by:

Prof J Snyman

SAMAREC Chairperson

25 October 2023