RISK ASSESSMENT 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. PURPOSE

The purpose of the Standard Operating Procedure for research ethics risk assessment is to provide office the SAMA Research Ethics Committee (SAMAREC) with a framework to identify, estimate and evaluate the potential risks of harm of research to human participants, researchers, the institution, community, environment and/or society in order to conduct a benefit-risk analysis.

2. SCOPE

As an institution committed to ethical research and the protection of human subjects, it is crucial to establish a robust scope for the analysis of research studies with varying risk levels. This SOP aims to guide the evaluation of studies falling into three distinct categories: Low Risk Studies, Medium Risk Studies, and High Risk Studies. The primary objective of this SOP is to ensure the safety, well-being, and rights of research participants while promoting the advancement of scientific knowledge.

3. DEFINING RISK

1 . Low Risk Studies:

Low Risk Studies are characterized by the presence of only foreseeable discomfort for participants. The analysis of such studies involves:

a. Risk Assessment: Evaluate the discomfort level to ascertain that it is minimal and within the acceptable bounds of ethical research.

b. Informed Consent: Ensure that participants are provided with clear, comprehensive, and easily understandable information about the discomfort they may experience. Verify that informed consent is obtained voluntarily.

c. Data Security: Verify that appropriate measures are in place to protect participants' data and maintain their confidentiality.

d. Participant Selection: Review the participant selection criteria to ensure they are not overly restrictive or discriminatory.

e. Benefit vs. Risk Analysis: Weigh the potential benefits of the research against the discomfort participants might experience.

2. Medium Risk Studies:

Medium Risk Studies involve risks no greater than those encountered in daily life or routine medical, dental, educational, or psychological tests. The analysis of these studies includes:

a. Risk Mitigation: Examine whether the research design incorporates measures to mitigate the risks, such as safety protocols and monitoring.

b. Ethical Review: Ensure that an independent ethics review board assesses and approves the study to determine if the benefits outweigh the risks.

c. Participant Vulnerability: Consider the potential vulnerability of participants and assess whether their rights and well-being are adequately protected.

d. Continual Monitoring: Assess whether the research team continually monitors and evaluates the risks during the study to adjust safety measures if necessary.

3. High Risk Studies:

High Risk Studies involve highly sensitive topics and/or the participation of vulnerable and marginalized individuals or groups. The analysis for such studies includes:

a. Comprehensive Risk Assessment: Conduct an in-depth evaluation of the potential risks, including psychological, social, and physical harm.

b. Ethical Oversight: Ensure that these studies undergo rigorous ethical review and are subject to additional scrutiny due to their high-risk nature.

c. Participant Safeguards: Examine the safeguards in place to protect the rights, autonomy, and well-being of vulnerable participants, including informed consent tailored to their specific needs.

d. Benefit Justification: Scrutinize the research's potential contribution to the welfare and understanding of the involved individuals or marginalized groups and assess whether the potential benefits genuinely outweigh the risks.

e. External Consultation: Consider involving external experts or stakeholders to provide additional perspectives on the ethical and risk-related aspects of the study.

Documenting assessments, justifications, and decisions meticulously. The goal is to ensure that the ethical principles of respect for persons, beneficence, and justice are upheld, and that research participants are protected while advancing scientific knowledge.

This SOP provides a structured framework for the analysis of research studies at varying risk levels, fostering ethical research conduct and promoting the highest standards of research integrity.

4. PROCEDURES

SAMAREC will consider the following issues when reviewing a proposal for a clinical study:

- the scientific relevance of the clinical study;
- the suitability of the investigator(s) 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;
- if placebos are to be used, whether their use can be justified;
- that by their participation in a clinical 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 patient 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 clinical study, and the insurance or indemnity to cover the liability of the investigator and sponsor;
- the extent to which investigator(s) and participants are to be compensated for participation in the study;
- making specific recommendations regarding the continuation of treatments beyond the duration of the study, or mechanisms to ensure that participants' access to treatment are fairly protected and not unduly compromised;
- the demographic information available to assess whether the patient population is adequate to support the study;
- whether there is no cost to the participant, medical schemes, or insurance for trial specific procedures.
- whether the product will be made available to participants after the trial ends, and if so whether there is any cost to the participant to continue treatment post-trial;
- whether any restrictions will be placed on the publication of results by the investigators after completion of the trial;
- 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 involving human participants, prior to initiation of such research and focuses on the ethical implications relating to the clinical 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 study doctors and applicants, when requested.

5. PROTOCOL APPLICATIONS AND AMENDMENTS

Any proposed change in a protocol or new submissions which affects participants or patients must be reviewed and approved by SAMAREC prior to implementation except where an immediate change is necessary to eliminate a hazard to the participants. Study doctors/Sponsors should submit a document byway of an expedited review procedure.

If a change in protocol is relatively minor e.g., changes in statistical analysis, it is not necessary to have a revised Patient Information Document (PID) or an addendum to the PID. If, however, the change is not minor and therefore changes the content of the originally signed PID, (e.g., addition of an intervention not addressed in the original PID, disclosure of a previously unidentified risk) the study doctor 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. See Major and Minor Amendment Process.

6. RISK ASSESSMENT TOOL

Protocol Number:	
Protocol Title:	
Main Evaluator:	

I. General Information:

1. **Research Objectives and Purpose:**
    - Briefly describe the research goals and purpose.
2. **Study Population:**
    - Describe the characteristics of the study participants.
3. **Data Collection Methods:**
    - Summarize the methods and instruments used for data collection.
4. **Ethical Review Board:**
    - Identify the institution or body responsible for ethical review and approval.

II. Risk Assessment:

For each potential risk, assess the probability and severity:

A. Physical Risks:

1. **Injury or harm to participants:**
    - Probability: Low / Moderate / High
    - Severity: Low / Moderate / High

B. Psychological Risks:

2. **Emotional distress or psychological harm:**

- Probability: Low / Moderate / High
- Severity: Low / Moderate / High

C. Social Risks:

3. **Stigmatization or harm to participants' reputation:**
    - Probability: Low / Moderate / High
    - Severity: Low / Moderate / High

D. Privacy Risks:

4. **Data breaches or loss of confidentiality:**
    - Probability: Low / Moderate / High
    - Severity: Low / Moderate / High

E. Other Risks:

5. **Any other risks relevant to the study:**
    - Probability: Low / Moderate / High
    - Severity: Low / Moderate / High

III. Risk Mitigation:

For each identified risk, describe the measures in place to mitigate or manage them:

1. **Measures to minimize physical risks:**
2. **Measures to minimize psychological risks:**
3. **Measures to minimize social risks:**
4. **Measures to protect participant privacy:**
5. **Other risk mitigation measures:**

IV. Ethical Considerations:

1. **Informed Consent:**
    - Describe the informed consent process and the information provided to participants.
2. **Benefit vs. Risk Analysis:**
    - Explain how the potential benefits of the research outweigh the identified risks.
3. **Participant Vulnerability:**
    - Assess the vulnerability of study participants and describe special protections in place.

V. Monitoring and Oversight:

1. **Data Safety Monitoring Board (DSMB):**
    - If applicable, describe the DSMB and its role in monitoring risks.

2. **Continual Risk Assessment:**
    - Explain how risks will be monitored throughout the study and what actions will be taken if risks change.

VI. Reporting and Documentation:

1. **Incident Reporting:**
    - Outline procedures for reporting and addressing adverse events.
2. **Documentation:**
    - Describe how risk assessments and mitigations will be documented for future reference and auditing.

VII. External Consultation:

1. **Engagement with external experts or stakeholders:**
    - Explain any consultations with external parties regarding risk assessment.

VIII. Approval and Review:

1. **Ethical Review Approval:**
    - Note the status and date of ethical review board approval.
2. **Review and Approval of Risk Assessment:**
    - Indicate if and when the risk assessment was reviewed and approved.

7. CONCLUSION:

Summarize the overall risk assessment and the ethical considerations for the research study.

This Research Risk Assessment Tool should be adapted to the specific requirements and risks associated with the protocol reviewed.

Approved by:

Prof J Snyman

SAMAREC Chairperson

25 October 2023