THE SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

STANDARD OPERATING PROCEDURES FOR RESEARCH ETHICS RISK ASSESSMENT AND RISK ASSESSMENT QUESTIONNAIRE

Standard operating procedure for research ethics risk assessment and risk assessment questionnaire

The purpose of the Standard Operating Procedure for research ethics risk assessment is to provide the Human Research Ethics Committee (HREC) and researchers 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.

1. SCOPE

This Standard Operating Procedure provides a framework for South African Medical research Council (SAMRC) researchers and/or research proposals and protocols submitted to the HREC to engage in a research ethics risk assessment and to provide the HREC with a risk mitigation tool to measure levels of risk prior to approval of the research proposal or protocol.

2. RESPONSIBILITIES

2.1 Researchers bear the primary responsibility to ensure that the research conducted in their respective disciplines will have a positive benefit-risk ratio, therefore maximising the potential benefits and minimising anticipated risks to research participants, institutions, communities, the environment, society and/or researcher(s) themselves.

2.2 The HREC is responsible for integrating the research ethics risk assessment in the research ethics review processes with a view to differentiate between negligible, low, medium, or high-risk research in adherence to international and national research ethics review guidelines. This will require that both the researcher and the HREC conduct an independent risk-benefit analysis.

3. TYPOLOGY OF RESEARCH ETHICS RISKS OF HARM

3.1 Types of risk cover a range of potential risks of harm that include physical risks, psychological or emotional, social, legal, and political risks and a possible combination of risks.

3.2 Physical risks are risks of harm through physical intervention or involvement of participants in experiments that may alter the physical condition or physical health of the participants. Such risks are seldom encountered in research conducted in the humanities, social sciences, and behavioural sciences. However, physical risk applies

in particular to interventions that require medical testing and/or interventions and research projects where participants may endure certain levels of irritation, stress or discomfort due to the experimental procedures applied.

3.3 Psychological or emotional risks are risks of harm related to the mental wellbeing of the participants or researchers, which may be caused through embarrassment, anxiety, or emotional distress. The risk of psychological harm must be evaluated on a scale of potential risks, ranging from mild discomfort to the possibility of severe trauma and triggered secondary trauma.

3.4 Social, legal, and political risks are risks of harm due to loss of status, privacy, social standing, or financial risk as a result of confidentiality breaches. Such risks may also appear when the participants belong to marginalised or minority groups with contentious social or political characteristics that may be liable to legal persecution or social exclusion, if research data is not treated confidentially.

3.5 Ethical research must consider the ability of the participants to act in their own interest and the protection of researchers against potential risk of harm related to the conduct of a specific research project.

3.6 Researchers should also consider the potential for reputational risk of harm of institutions involved in the research.

3.7 The potential risks of harm involved in research must be assessed against the degree of vulnerability of the human participants (children or young people under the age of 18, the elderly, physical or mentally ill, people with learning difficulties, prisoners, students or colleagues, over-researched participants, non-English speaking participants or those with a low functional literacy, participants engaged in illegal activities).

This ability may be impaired by the participants' lack of social and political autonomy in making independent decisions, or by a lack of mental or physical capability to understand the possible consequences of their involvement in the proposed research.

3.8 Any research that involves human participants must be based on the mutual understanding of all parties involved regarding the types of risk of harm that the research may entail. Any such project must also give the participants the opportunity to critically engage with the research and the researchers, ranging from the right to refuse to answer questions to the possibility of withdrawing altogether from the research without any negative consequences for the participants.

3.9 In addition, risk assessment must consider the following aspects:

3.9.1 *Nature of human participant involvement:* (no involvement, indirect or direct involvement);

3.9.2 *Perceived sensitivity of the research area:* (not sensitive at all, probability of being sensitive related to the context of the study and research that is usually categorised as sensitive in nature because it is controversial, contentious, embarrassing or upsetting in nature)

3.9.3 *The type of research, invasiveness of the recruitment and data collection procedures:* (deceptive, inducement practices, coercion or incentives to participate, approaching participants in a public space to an extend that it prejudices them)

3.9.4 *Confidentiality issues relevant to covert observation of participants*: recording or filming/photography, potential breaches and limitations of confidentiality, lack of anonymity and issues related to security and storage of data

3.9.5 *Participation is not voluntary, or there is undue coercion or bribery of participants*;

3.9.6 *Inappropriate financial interests of the researcher and/or the institution;*

3.9.7 *Health and safety issues including equipment hazards, chemical or biological hazards.*

4. PROCEDURE OF RESEARCH ETHICS RISK ASSESSMENT

4.1 Research applications for ethics approval provided to the HREC **should** include a risk assessment (identification, estimation and evaluation of potential benefits and risks), and this information **should** be contained and disclosed in the participant information sheet and/or Informed Consent Form.

4.2 The HREC should not rely exclusively on the view of the researcher when assessing the probability or the magnitude of harm. Independent expert opinion could be sought, whenever it is deemed necessary from the external experts.

4.3 The HREC and researchers have an obligation, to ensure that the risks inherent in the proposed research have been reduced to the minimum level necessary to achieve the research objective. This duty includes consideration of whether alternative methods of obtaining the research information are available and consideration of whether lower risks might prevail in a different group of participants.

4.4 The HREC may thus require that certain steps or measures should be taken by a researcher and/or institution to mitigate or avoid potential risks, in relation to a particular ethics review.

4.5 Negligible and low risk research applications can be processed by an expedited review procedure if motivated by the PI and agreed to by the HREC.

4.6 Medium and high-risk research must be approved through a full Research Ethics Committee review procedure and may not be expediated, except in case of emergencies such as the epidemic or pandemic.

4.7 The HREC should ensure that there is regular monitoring and evaluation of the ethical risks of approved studies, particularly in research that entails medium to high ethical risks.

4.8 High-risk research must reflect the HREC's role in ongoing monitoring of the high-risk research which may require regular feedback to the HREC.

RISKS CATEGORIES

RISK CATEGOTY	DEFINITION	EXPLANATION	MITIGATING RISK FACTORS
CATEGORY 1: Research involving negligible risk:	Research that does not involve human participants at all or involve human participants indirectly. The probability or magnitude of risk of harm or discomfort anticipated in the research is unlikely.	Research that involves non-invasive procedures with no apparent risk to participants (institutions and researchers) a research topic that is not sensitive and de-identified data collection procedures. This could typically include studies based on the analysis of existing statistics, documents, databases, and information in the public domain, for instance in public archives, on websites, newspapers, annual published reports of companies or newsletters. NB: Not all research involving material in the public domain is 'negligible risk' e.g. research involving data extraction from the social media may need a higher level of ethics scrutiny as may research involving secondary data in terms of the provisions of POPIA.	All exceptions should be motivated, and the proposal or protocol will need to be assessed by the full HREC Committee.
CATEGORY 2: Research involving low risk	Research involving human participants directly in which the probability or magnitude of risk of harm or discomfort anticipated in the research is not greater in itself than ordinarily experienced in daily life. .	• Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys, and observation. • The participants are adults and not considered a vulnerable research population. • The research will collect information that would generally be regarded as non-sensitive. • The information can generally be collected anonymously, or participants may not insist on keeping the collected information strictly confidential. • Use of questionnaires/surveys (that do not involve sensitive questions) sent to non-vulnerable adult participants and returned anonymously so that participants cannot be identified. • Recording information from groups of participants (rather than individual participants) in	The HREC must determine if the project may be considered low risk using risk assessment tool.

RISK CATEGOTY	DEFINITION	EXPLANATION	MITIGATING RISK FACTORS
		an educational setting where participants are not identified.	
CATEGORY 3: Research involving medium risk:	Research involving human participants directly in which there exists a potential risk of physical, emotional and/or psychological harm and/or social stigmatisation, prosecution, or persecution, but where appropriate steps can be taken to mitigate or reduce the overall risk. It is not expected that the research will cause severe risk or negative physical, emotional, social, cultural or political consequences.	• The research topic is 'sensitive'. • Information gathered is personal rather than opinion, attitudes, or a combination of both. • The information needs to be collected with personal identifiers. • The research participants may come from a vulnerable or marginalised group Research studies involving social media, could be medium risk, depending on the research question under investigation.	This research may require mitigation in the form of counselling, debriefing or other forms of support as well as consideration of Mandatory Reporting Requirement. The applicant needs to indicate how participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.
CATEGORY 4: Research involving high risk:	Research involving human participants **directly** in which there is a real and foreseeable risk of emotional or psychological harm and/or social stigmatisation or prosecution, which may lead to a serious adverse event, if not managed in a responsible manner. Research that may reveal information that requires action on the part of the researcher that could place the participant or others at risk.	• Research involving highly sensitive topics • Research involving vulnerable and marginalised individuals or communities • Research involving deception of research participants • Any research that may place the researcher, participant, animals, at real risk of harm Any plant, biological or molecular related research that may result in contamination, injury to the researcher or destruction of the environment in any form • Information revealed during the course of the research that may place the researcher at risk of breaking the law	The applicant needs to indicate how participants will benefit from the research and describe the steps that will be undertaken to mitigate the risk.

5. RISK ASSESSMENT TOOL

In order to assess the ethical risk of a proposed research project, the researcher engages in a systematic and comprehensive assessment of the project.

For the researcher and the HREC, it provides a means to examine whether potential risks that will be presented to participants (and other entities) are justified.

For prospective participants, the assessment will guide their decision whether to participate or not to participate, after reading the Informed Consent documentation and/or the Participant Information Sheet.

The checklists below have been designed to guide researchers to assess the potential risk of the proposed research.

If the researcher answers **YES** to any of the questions below, the research may be intending to use more invasive research methodology or represent more complex ethical or privacy issues, in which case the researcher needs to explain the ethical implications and procedures to minimise harm to the participants (animals, institutions, communities and/or society).

RISK ASSESSMENT QUESTIONNAIRES

Complete the Research Ethics Risk Assessment by answering each question below. If you answer **"YES"** to any of the items, the outcome of the risk assessment is considered to vary from a low to high risk level.

1. DOES YOUR RESEARCH CONTRIBUTE TO KNOWLEDGE OF?

Statement	**YES**	**NO**	**If YES to any option, please describe it in detail**
a) The biological, clinical, psychological, or social processes in human beings' social processes refer to those activities, actions, and operations that involve the interaction between people			
b) Improved methods for the provision of health services			
c) Human pathology			
d) Causes of disease			
e) Effects of the environment on the human body			
f) Development or new application of pharmaceuticals, medicines, and related substances			
g) Development of new applications of health technology referring to machinery or equipment that is used in the provision of health with the exception of medicine			

2. DOES YOUR RESEARCH INCLUDE THE DIRECT INVOLVEMENT OF ANY OF THE FOLLOWING GROUPS OF PARTICIPANTS?

Statement	**YES**	**NO**	**If YES to any option, please describe it in detail**
a) Children or young people under the age of 18: Include the parental consent letter and explain how assent will be obtained in the application form			
b) Persons living with disabilities *(physical, mental and/or sensory) that could potentially* increase risk of harm when participating in this research			
c) Persons that might be considered vulnerable, thus finding it difficult to make independent and/or informed decisions for socio, economic, cultural, political and/or medical reasons (such as the elderly, the dying, unconscious patients, prisoners, those in dependent relationships, women considered to be vulnerable due to pregnancy, victimisation, etc.)			
d) Communities that might be considered vulnerable, thus finding it difficult to make			

Statement	YES	NO	If YES to any option, please describe it in detail
independent and informed decisions for socio, economic, cultural, political and/or medical reasons			
e) SAMRC staff			
f) Persons who cannot read, speak or understand the language used for the research, i.e. English: Attach the translated data collection instrument(s), interview guide(s), participant information sheet and consent form in the participants' first language, as well as a letter from the language practitioner certifying the credibility of the translated material in the application form. The services of an interpreter may need to be secured for fieldwork activities.			
g) There is a likelihood that a person or definable group will be identified during the research process, and it is likely to be of concern			
h) Other: Please describe			

3. DOES YOUR RESEARCH INVOLVE ANY OF THE FOLLOWING TYPES OF ACTIVITY THAT COULD POTENTIALLY PLACE THE PARTICIPANTS AT RISK OF HARM?

Statement	YES	NO	If YES to any option, please describe it in detail
a) Collection, use or disclosure of personal, identifiable information without the consent of the individual or institution that is in possession of the required information (with the exception of aggregated data or data from official databases in the public domain)			
b) Collection, use or disclosure of personal, identifiable information directly from participants with consent (consult the summary of the POPIA on this link)			
c) Personal, identifiable information to be collected about individuals from available records (e.g. employee records, student records, medical records, etc.) and/or archives			
d) Personal, identifiable information to be collected outside or transferred outside of South Africa			

Statement	YES	NO	If YES to any option, please describe it in detail
e) Personal, identifiable information to be shared with third parties for research purposes			
f) Participants being exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have unpleasant or harmful side effects			
g) Participants being required to commit an act which might diminish self-respect or cause them to experience shame, embarrassment, or regret			
h) Any form of deception of participants, concealment or covert observation			
i) Examining potentially sensitive or contentious issues that could cause harm to the participants			
j) Research which may be prejudicial to participants			
k) Research which may intrude on the rights of third parties or people not directly involved			
l) Audio-visual recordings of participants which may be of a sensitive or compromising nature (with or without consent)			
m) Disclosure of the findings of the research could place participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships			
n) Any form of physically invasive diagnostic, therapeutic or medical procedure such as blood collection, an exercise regime, body measurements or physical examination			
o) Psychological inventories / scales / tests			
p) Research involving any sensory analysis through the ingestion, smell, taste or feel of food or food related products of any kind			
q) Other. Please describe			

4. DOES YOUR RESEARCH INVOLVE ANY ACTIVITY THAT COULD POTENTIALLY PLACE THE RESEARCHER(S) AND/OR FIELD WORKERS AT RISK OF HARM?

Statement	YES	NO	If YES to any option, please describe it in detail
a) There is a possible risk of physical threat, abuse or psychological trauma as a result of actual or threatened violence or the nature of what is disclosed during the interaction			

Statement	YES	NO	If YES to any option, please describe it in detail
b) There is a possible risk of being in a compromising situation, in which there might be accusations of improper behaviour			
There is an increased exposure to risks in everyday life and social interactions, such as working with hazardous materials or sensitive information			

5. DOES ANY OF THE FOLLOWING APPLY TO YOUR RESEARCH PROJECT?

Statement	YES	NO	If YES to any option, please describe it in detail
a) Participants will be offered inducements or incentives to encourage their involvement in the research			
b) Participants will incur financial obligations as a result of their participation in the research			
c) The researcher(s) can anticipate financial gains from involvement in the research (i.e. contract research)			
d) Any other potential conflict of interests, real or perceived, that could be seen as compromising the researcher(s) professional judgement in carrying out or reporting on the research			
e) Research will make use of SAMRC laboratories			
f) Research will be funded by SAMRC or by an external funding body that could compromise the integrity of the research project			

6. GUIDED BY THE INFORMATION ABOVE, CLASSIFY YOUR RESEARCH PROJECT BASED ON THE ANTICIPATED DEGREE OF RISK

[The researcher completes this section. The HREC critically evaluates this benefit-risk analysis to protect participants' rights]

CATEGORY 1

Negligible YES___ NO___

No to indirect human participant involvement.

CATEGORY 2

Low risk YES___ NO___

Direct human participant involvement. The only foreseeable risk of harm is the potential for minor discomfort or inconvenience, thus research that would not pose a risk above the everyday norm.

CATEGORY 3

Medium risk YES___ NO___

Direct human participant involvement. Research that poses a risk above the everyday norm, including physical, psychological and social risks. Steps can be taken to minimise the likelihood of the event occurring.

CATEGORY 4

High risk YES___ NO___

Direct human participant involvement.
A real or foreseeable risk of harm including physical, psychological and social risk which may lead to a serious adverse event if not managed responsibly.

Statement	**Response**
a) Briefly justify your choice/classification	
b) Indicate the potential benefits of the study for the research participants and/or communities or other entities	
c) Describe the risks relating to the research procedures, which participants, communities or third parties may or will suffer. This refers to, but is not limited to any discomfort, pain/physical or psychological problems/side-effects; persecution, stigmatisation or negative labelling that could arise during the course or as an outcome of the research undertaken and may include Mandatory Reporting requirements	
d) Indicate how the potential risks of harm will be mitigated by explaining the steps that will be taken to minimise the likelihood of the event occurring (e.g. referral for counselling, debriefing, etc.)	
e) Describe the steps to be taken in the case of adverse events or if injury or harm attributable to participation in the study is experienced by the participants, communities or third parties	
f) Describe your arrangements regarding indemnity/compensation for research-related adverse events (if applicable)	
g) Describe any other factors or considerations the HREC should take into consideration	

Level:	3
Risk:	Strategic
Effective Date:	14 February 2024
Review Date:	January 2027
Standard Operating Procedures Owner:	Chief Research Operations Officer
Policy Manager / Cognisant Person:	Research Integrity Officer
EMC Approval:	25 January 2024

Confirmation of Approval

16 February 2024

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Prof Glenda Gray **Date**