Faculty of Health Sciences **Research Ethics Committee**

Standard Operating Procedure: Risk and Vulnerability Assessments

1. Purpose

The purpose of the SOP is to describe the parameters by which vulnerability of a study population and risks to various stakeholders in research related to human health should be assessed.

This SOP was approved by resolution of the Faculty of Health Sciences Research Ethics Committee on 27 September 2023 and replaces all previous SOPs in this regard. It should be reviewed within 3 years after this date of approval.

_____ Date: 27 September 2023

Signed by the Chairperson

2. Scope

The SOP is intended to inform and guide the REC, its members , and researchers. This SOP should also be interpreted with reference to the Terms of Reference (TOR) of the REC and other SOPs that may be relevant.

3. Definitions and criteria

3.1 *Risk of harm* (as per DoH 2015 Guidelines): The probability and the magnitude of harm to anyone or any institution and include physical, psychological, social, economic, legal or political harms.

3.2 *Vulnerability* (as per DoH 2015 Guidelines): The diminished ability to fully safeguard one's own interests in the context of a specific research project. This may be caused by limited capacity or limited access to social goods like rights, opportunities and power. A person's individual vulnerability depends on context as well as group characteristics, and can vary according to circumstances.

3.3 *Privacy risk* (as per DoH2015 Guidelines) in research. Potential harm to participants from collection, use and disclosure of personal information for research purposes.

4. Responsibilities regarding assessment of risk of harm and vulnerability

4.1 Risk of harm

The REC should routinely for each study assess the risk of harm to relevant stakeholders, especially but not exclusively, research participants. This assessment should draw on the following definitions of the levels of risks as obtained from the DoH Guidelines (2015):

4.1.1. Risk of harm to research participants

Minimal – Risks of participation are no greater than those posed by daily life in a stable society or routine medical, dental, educational or psychological tests or examinations.

Example are:

- research of largely uncontroversial topics undertaken through interviews, surveys, and participant observation;
- information will be collected that would generally not be regarded as sensitive, such as opinions rather than personal information;
- the foreseeable risk is no more than an inconvenience to participants, e.g., filling in a form or participating in a de-identified survey.

Medium – The potential risk is above the everyday norm, but steps can be taken to minimise the likelihood of harm occurring. (Also known as minor increase over minimal risk)

Example are:

- the foreseeable risk is one of discomfort, e.g., measuring blood pressure and limited anxiety induced by an interview on a sensitive topic. The research topic is considered 'sensitive';
- information gathered is personal, rather than opinion or attitudes, or is a combination of these;
- the information needs to be collected with personal identifiers (name, student number, etc).

High – A real and foreseeable risk of harm that may lead to serious adverse consequences if not managed in a responsible manner. (Also known as major increase over minimal risk)

Examples are:

• Research involving highly sensitive topics, such as sexual behaviour and orientation; sexually transmitted infections such as HIV.
• Research on interventions for which the consequences are known to carry significant risks of harm, or where only little is known about the risks of harm.
• Phase I to III clinical trials are usually considered to be of a high risk.
• Research involving that participants are kept in the dark about crucial information.
• Research investigating illegal activities e.g., involving participants who are illegal immigrants or engaged in illgal activities (drug use, sex work, poaching or illicit wildlife trade).
• The research may reveal information that requires action on the part of the researcher that could place the participant or others at risk, e.g., research involving child victims of physical or sexual abuse, victims of domestic violence, etc.

4.1.2. Risk of harm to researchers

Minimal risk
• Researchers will not be placed at any additional risk **than those posed by daily life in a stable society** while conducting the research.

Medium risk
• Researchers may be placed at some physical risk while conducting the research due to recruiting or conducting the study in an area that is not considered safe such as taxi ranks.
• Researchers may be placed at some physical risk while working with a population that could be aggressive.
• Researchers may be placed at some emotional risk e.g. vicarious trauma upon exposure to traumatic events or memories.

High risk
• The researcher may be placed at risk of breaking the law by carrying out certain activities e.g., research investigating gang activities and possession of illegal firearms, wildlife trafficking and/or poaching.
• Researchers place themselves at definite risk by conducting risky activities in unsafe environments.

4.1.3 Risk of harm to communities

Minimal risk
• No specifically identifiable community is involved in the research or no specific community will be identified when the study is reported.

Medium risk
• The research participants may come from an identifiable community which could potentially be at risk of stigmatisation, or which reputation may be at risk.

High risk
• Communities may well be stigmatised by the outcomes of the research, e.g., research reporting on incidence of HIV or gender-based violence in multiple relatively small identified neighbourhoods; reporting of various illegal activities, etc
• Communities may be subject to unwanted attention, e.g., from the police because the research has drawn attention to activities (e.g. drug trafficking)

• The 'community' that is the subject of the research may be one that is historical or viewed negatively and hence negative outcomes are viewed as justifiable.

4.1.4 Risk of harm to institutions

Institutions include universities, hospitals, clinics, etc.

Minimal risk
• No additional risk than what would be encountered in the daily activities of the institution.

Medium risk
• Institution might be placed at reputational risk by unfavourable findings.

High risk
• Institution is placed at risk by having particular research projects and activities, such as controversial or covert/undercover research, associated with it.
• Funding of research by 'dubious' sources.
• Potential for legal action against the institution by aggrieved parties.

4.1.5 Risk mitigation strategies

The following strategies may mitigate the risks:
Medium risk:
• Support/counselling services must be provided for participants, when appropriate.

High risk:
• Remedial interventions by external professionals should be taken should harm occur.
• External support/counselling services must be provided for participants and/or for the researcher.
• A debriefing strategy should be given, if appropriate.
• Legal guidance should be obtained, if appropriate.

4.2 Vulnerability of the study population

The REC should routinely for each study assess the vulnerability of the study population using the descriptions below, but cognisant that a person's individual vulnerability depends on context as well as group characteristics, and can vary according to circumstances.

Vulnerability levels:
Minimal – Ability to protect own interest similar to general population.
An example is where Participants are able to provide voluntary individual informed consent.

Medium – Individual or situational circumstances that might impair participants' ability to protect their own interests.
Examples are when:
• Participants who require assistance to provide voluntary informed consent arising from limitations in decision-making capacity or situational circumstances.
• Lack of alternative means of obtaining medical care.
• Unequal power relationships that might increase the participant's risk of exploitation, such as those found between patients and doctors; students and teachers; children or prisoners and custodians; refugees and government employees; members of the military and their

superiors; committed mental health patients and health professionals; employees and employers; LGBTQI people, disabled people and people who are low-income and service providers.

High – Individual or situational circumstances that will impair participants' ability to protect their own interests, leaving them open to exploitation if protections are not put in place.

Examples are:

- Participants who are unable to provide voluntary individual informed consent.
- Participants who are especially at risk for exploitation, coercion[1] and undue influence.
- Participants belonging to a known vulnerable group as defined by 2016 DoH *Guidelines for Good Clinical Practice* including
    - children and adolescents;
    - pregnant and breastfeeding women;
    - persons with intellectual or mental impairment;
    - people with mental illness or handicaps;
    - disabled persons;
    - persons in a dependent relationships;
    - members of communities unfamiliar with medical concepts;
    - people for whom English is not a first language,
    - persons participating in research as groups (referred to as collectivities);
    - persons with restricted freedom such as prisoners;
    - people with substance abuse disorders;
    - members of hierarchical structures where individual agency is severely limited (e.g. members of the armed forces; persons kept in detention);
    - persons in dependent relationships or comparable situations where individual agency is severely limited (e.g. older persons and their caregivers; persons with chronic conditions or disabilities and their caregivers; wards of State and their guardians; prisoners and prison authorities);
    - persons with life-threatening illnesses, persons in nursing homes;
    - patients with incurable diseases and those highly dependent on medical care;
    - patients in emergency situations, traumatised patients and comatose patients;
    - unemployed or impoverished persons, homeless persons;
    - ethnic minority groups;
    - nomads and refugees.

4 Procedures

1) Members of the REC should routinely assess the risk to the various stakeholders and the vulnerability of the study population for each study they review according to the descriptions above.
2) Members of the REC should routinely report on their assessments of the risk and the vulnerability on the prescribed evaluation form in reviewing the study.
3) The REC should classify the outcomes of the risk and the vulnerability assessments according to the levels described above. Unless the REC makes a different study-specific decision, the default

[1] Coercion is an extreme form of undue influence, involving a threat of harm or punishment for failure to participate in research (DoH 2015 definition).

outcome will be that of the majority of reviewers of that study or the higher level in case an equal number of reviewers indicated two levels for a particular study.