UNIVERSITY OF LIMPOPO

TURFLOOP RESEARCH ETHICS COMMITTEE

Risk Classification and Reporting of Adverse Events

The purpose of the document is to guide researchers on the types of risks, their classification and guidelines on reporting unanticipated problems including adverse events occurring during the process of doing research.

SECTION A: TYPES OF RISKS

The different types of risk in research include among others, psychological, physical, emotional, social/economic, and legal and loss of confidentiality.

The risk types can be described as follows:

RISK TYPES	DESCRIPTION
Physical Risks	These risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. The risks are not commonly encountered in social and behavioural science research
Psychological Risks	Psychological risks may be experienced during participation in the research and/or afterwards as a result of participating in research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and/or altered behaviour.
Social/Economic Risk:	Economic risks include alterations in relationships with others that are to the disadvantage of the subject, and may involve embarrassment, loss of respect of others, labelling with negative consequences, or diminishing the subject's opportunities and status in relation to others. These risks include payment include payment by subjects for procedures, loss of wages or income,

	and/or damage to employability or insurability
Legal Risks	Legal risks include criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.
Loss of Confidentiality	Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks from breach of confidentiality include invasion of privacy, as well as the social, economic and legal risks outlined above. Loss of confidentiality is the common type of risk encountered in social and behavioural science research

SECTION B: CLASSIFICATION OF RISKS

Risk in research can be classified into Four (4) categories namely;

- Minimal risk
- Low risk
- Medium risk
- High risk

Different kinds of risk in research projects:

Minimal Risk

Research involving the analysis of information in public domain- for example in public libraries, public archives, on websites, newspapers, or newsletters, literature, secondary data (existing statistics). Any anticipated harm or discomfort to third parties related to this research is no greater than ordinarily encountered in daily life.

Low Risk

Low risk research is a research in which the investigation of largely uncontroversial topics is undertaken through interviews, survey and participant observation. The participants in such research are from ordinary citizens in terms of their social status, health status and or development. As such, there is the little potential for discomfort or inconvenience on the part of participants; where such potential does exist, the predicted discomfort or inconvenience would be minor.

Post-hoc analysis of large sample of existing documents not in the public domain like student assessment and patients' records where anonymity is assured; standard socio-economic survey and interviewing of employees on uncontroversial topics where standard protocols i.e informed consent, voluntary withdrawal and confidentiality are in place.

Medium Risk

Medium risk research is research in which there is an increased potential for emotional or psychological discomfort, due to either the topic investigated being controversial or connected to stigma or the participants themselves being vulnerable. For example, potentially sensitive topic such as HIV/AIDS, sexuality, rape, violence, but one cannot presume that sensitivity can be generated across all cultural/social context. Such research could be harmful to the participants if not managed properly by the researcher.

Participants will include the vulnerable groups e.g children, adolescents, pregnant women, foetuses, persons with incapacity to provide inform consent, persons in dependent relationships, persons highly dependent on medical care, persons with physical disability and prisoners.

High Risk

High risk research is research in which there is a foreseeable risk of physical and emotional or psychological discomfort or resulting in harm or discomfort if not managed in a responsible manner. Such involves intimate details of vulnerable participants, and highly sensitive topics.

High risk research involves for example, taking of tissue samples from the living or the dead, Invasive procedure that carry a risk of harm to the patient. Research that requires patients to be admitted to health facilities where they can contract facility acquired infections, criminal activities that are linked to names, or ones in which victims of sexual abuse are asked questions about their abuse in ways that provoke flashbacks.

A study involving vulnerable social categories where exploitation or severe personal loss is involved e.g. sexual abuse, abortion, crime, drugs, witchcraft accusations etc. the knowledge that is gained in this category of risk often involves intimate or secretive aspects. Information that is provided is often not meant to be published in detail.

Research on political and social sensitivity such as corruption, criminal activities, children's access to pornography, a study on bereavement, a study on political refugees; research on whistle-blowers etc.

SECTION C: REPORTING ON ADVERSE EVENTS

This section covers procedures and format on reporting of occurred adverse events to TREC by researchers

An **adverse event** is defined as any untoward or unfavourable medical or psychological occurrence in a participant, including any abnormal laboratory finding, symptom or disease. An adverse event does not necessarily have a causal relationship with the research or any risk associated with the research.

Unanticipated problems

An 'unanticipated' problem is any incident, experience or outcome that meets all the following criteria:

- **Any unforeseen occurrence** in terms of its nature, severity or frequency, or the research population being studied; or if anticipated it is not fully addressed or specified in information provided to the Turfloop Research Ethics Committee (TREC) or to participants and researchers.

- **Related or possibly related** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research). Suggests that the research places participants or others at a greater risk of physical, psychological, economic or social harm than was previously known or recognised.

Timelines for Reporting

The following procedure would be taken when reporting adverse events;

REPORTING REQUIREMENTS FOR ADVERSE EVENTS OCCURRING AT UL TREC APPROVED SITES:

- All deaths

- Serious, unexpected, adverse drug reactions which are fatal or life threatening

Researchers should report within 7 calendar days after first knowledge.

The initial notification should be followed by a complete report as soon as possible within an additional 8 calendar days

• Serious, unexpected, adverse drug reactions which are not fatal or life threatening

Researchers must report as soon as possible not later than 15 calendar days after first knowledge

• All Serious Adverse Events

• Non-serious unexpected adverse drug reactions

Researchers to report as part of the 6-monthly progress reports

OTHER REPORTING REQUIREMENTS:

- Serious, unexpected, adverse drug reactions occurring at other South African and Foreign sites
- New information which may affect the safety of participants or the conduct of a trial
- Change in the nature, severity or frequency of expected Adverse Drug Reactions