RISK LEVEL DESCRIPTORS FOR HUMAN PARTICIPANTS FOR USE AT THE NORTH-WEST UNIVERSITY

1. INTRODUCTION

The risk level descriptors (RLDs) have been adopted from those utilised by the Faculty of Health Sciences based on the DoH 2015 guidelines. This document is not only concerned with harm to the participants themselves, but also to the researchers, community or societal interests. This document provides guidelines that are applicable across disciplines. The RECs may add specific examples applicable to their respective contexts.

2. DEFINITION OF KEY TERMS

Below terms have been extracted from DoH 2015 guidelines[1]

2.1. *Risk* is the possibility that research may cause different types of harm to any participant. For the purpose of this document a *risk* is seen as the *potential of harm occurring to a participant as a result of participation in research*.

2.2. *Harm* could be anything that has a negative effect on participant's welfare. Any research with humans must be preceded by an assessment of potential harm or inconvenience and possible benefits of the potential participant. A basic prerequisite for conducting the risk-benefit ratio analysis is a critical reflection on and deliberation about the risks and the benefits by both the researcher and the ethics committee.

2.3. *Benefits* are *direct* if it positively affects the interest or welfare of the participant, e.g. learning a new skill or service received; or *indirect* if it is to the benefit of the researcher, scientific field of knowledge or the community, e.g. improvement in policy or community programme.

2.4. Vulnerability refers to 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; limited freedom to make choices; or relatively incapable of protecting own interest. Vulnerability is not an absolute condition but rather occurs on a sliding scale depending on personal or environmental circumstances

2.5. *Adverse event* refers to any undesirable or unintended response or occurrence in a research participant during research (related or not related to the research)

[1] (Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015).

2.6. Researchers with a conflict of interest (declared) increase the risk level of the research. Conflict of interest is where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research.

2.7. They have an obligation to ensure that the risks inherent in the proposed research have been reduced to the minimum necessary to achieve the research objective.

2.8. Clear measures and precautions should be in place to mitigate or avoid the potential identified risks.

3. RISK LEVELS for RESEARCH WITH ADULT PARTICIPANTS

Adjusted from: "Getting Ethics Approval for Your Research Project. Research Ethics Committee: Humanities. March 2015" University of Stellenbosch and guidance from the Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015.

Risk Category	**Definition**	**Explanation and/or examples**
No risk	No contact with human participants, animals or environment	• Systematic reviews • Literature Review • Document analysis (e.g. in public domain)
Minimal, low or negligible risk	The potential of harm or discomfort anticipated in the research are not greater in and of themselves, than those ordinarily encountered in daily life. Research in which the only foreseeable risk is one of minimal discomfort or inconvenience. The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information.	• There is a very small possibility of risk, if any • Market research surveys • Research on an uncontroversial topic • The study may be conducted through interviews, surveys and participant observation. • Research that focuses on opinions and/or perceptions. • Research not having any sensitive matters • This may involve interviews and surveys •
Medium risk (above minimal risk)	Research in which there is a potential risk of unexpected negative consequences, harm or discomfort, eg physical, psychological, social and environmental harm; but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial actions can be undertaken should harm occur. to	The risk of harm is considered reasonable relative to the envisaged benefit of the study, e.g. new knowledge • anticipated knowledge gained. - It involves personal sensitive information rather than opinions or attitudes or a combination of these. • The information needs to be collected with personal identifiers (name, student number, etc.).

		• It involves a vulnerable or marginalized group, e.g. people living with HIV, disabled individuals, etc. It uses patient records in existing health systems • It uses laboratory test results of patients in existing health systems
High Risk	Research in which there is a real and foreseeable risk of unexpected negative consequences, harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.	There is a higher possibility of various types of harm and adverse consequences. This may involve Pharmaceutical drug research. • Research involving highly sensitive topic • Research involving vulnerable and marginalized communities e.g. people with multiple vulnerabilities. • Research investigating illegal activities among participants • Research involving drawing of bloods, dry blood spots, etc. • Research with minors • Research with adults with mental incapacity • • Research that has impact on animal wellbeing • Research that has impact on the environment

ADDENDUM: RISK EVALUATION FORM FOR RESEARCH WITH HUMAN PARTICIPANTS

This form assists in identifying the nature of harm for low, minimum and high risk studies

Types of risks	Example	Potential (Mark with a √ if the probability exist)	Extent 1 – mild discomfort 5 – severe trauma	Justification	Precaution
Physical harm	Fatigue				
	Headaches				
	Physical discomfort				
	Muscle tension				
	Physical side-effects				
	Injury				
	Toxicity				
	Loss of physical capability				
	Loss of safety				
Psychological harm	Emotional discomfort				
	Emotional dependency				
	Loss of mental capability				
	Deception				
	Coercion				
	Emotional distress				
	Boredom				
	Inconvenience				
	Self-disclosure				
	Embarrassment				
	Anxiety				
	Fear				
	Anger				
	Sadness				
	Emotional trauma				
	Loss of privacy and confidentiality				
	Loss of autonomy				
	Loss of freedom of choice				
Social harm	Negative effects of interactions				
	Loss of status or social standing				
	Loss of reputation				
	Stigmatization				

	Discrimination				
Legal harm	Arrest				
	Conviction				
	Incarceration if researchers are bound to report certain actions				
Economic harm	Direct or indirect financial cost e.g. travelling or child care				
	Loss of income not being on the job				
	Time spent in the research				
Dignitary harm (harm to dignity)	Not treated as a person with own values				
	Preferences and commitments are mere a means to an end e.g. informed consent				
Community harm	General community knowledge becomes known				
	Abuse indigenous knowledge				

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