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

1. **HEALTH AND HEALTH-RELATED RESEARCH**
2. **RESEARCH WITH CHILDREN**
3. **ADULTS INCAPABLE OF GIVNG ADEQUATE INFORMED CONSENT**
4. **RESEARCH IN HUMANITIES, SOCIAL SCIENCES AND RELATED FIELDS**

INTRODUCTION

- There is the possibility that research may cause varying degrees of harm to any participant. For the purpose of this document a *risk* is seen as the "*probability of harm occurring to a participant as a result of participation in research"* (Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015).
- *Harm* could be anything that has a negative effect on participant's welfare (Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015).
- A risk-benefit ratio analysis should precede any research with humans to evaluate whether there is an ethically justifiable balance between the anticipated research results and any harm or inconvenience that may be caused to any participant.
- The potential risk of harm should be outweighed by the likelihood of benefit – it should be a *favourable ratio.*
- *Probability*, *magnitude* and *seriousness* of harm should be assessed.
- If any harm (physical, psychological, social, legal, economic, dignitary or community) is possible, it should be justified. (See the attached addendum for types of risks).
- *Benefits* are *direct* if it positively affects the interest or welfare of the participant or *indirect* if it is to the benefit of the researcher, scientific field of knowledge or the community.
- *Vulnerability* refers to the diminished ability to fully safeguard one's own interests in the context of a specific research project; may be caused by limited capacity or limited access to social goods like rights, opportunities and power (Department of Health. Second edition. Ethics in Health Research. Principles, Processes and Structures, 2015).
- *Adverse event* refers to any undesirable or unintended response or occurrence in a research participant during research (related or not related to the research)
- This document is not only concerned with harm to the participants themselves, but also to the researchers, community or societal interests.
- 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.

- 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.
- In the case of minimal risks the evaluation can be done by a non-registered research ethics committee. Medium and high risk evaluations should be done by a registered research ethics committee. The review of the independent REC is the ultimate decision. 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.
- Clear measures and precautions should be in place to mitigate or avoid the potential identified risks.

1. RISK LEVELS FOR HEALTH AND HEALTH-RELATED RESEARCH

- 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	• Certain systematic reviews • Review of literature available in the public domain.
Minimal, low or negligible risk	The probability, magnitude or seriousness of harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of **minimal discomfort or inconvenience**.	• Market research surveys • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. • The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information. • Document analysis. • Bio-physical research involving previously collected or collection of human blood through finger prick, sputum or urine. • Commercially available cell line research where cells are not infected or undergo genetic

		modification. • The participants are adults and not considered to be a vulnerable research population (Children are generally considered to be a vulnerable research population. See section 2). • Use of anonymized data from medical schemes database
Medium risk (above minimal risk)	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Remedial interventions can be undertaken should harm occur.	One or more of the following apply: • The risk of harm is reasonable in relation to the anticipated benefit. • The risk of harm is reasonable in relation to the importance of the anticipated knowledge gained. • The risk of harm includes several identified risks. • The research topic is considered "sensitive". • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • Involves face-to-face contact with participants through: - interviews dealing with personal sensitive information or within a power differential - focus groups with the potential of loss of anonymity and sensitive topics. • Psycho-social intervention studies • The intervention can cause physical, psychological or social harm. • Research involving collection of more than

		human blood (through needle prick), sputum or urine samples e.g. venepuncture. • Commercially available cell line research where cells are infected or undergo genetic modification. • The information needs to be collected with personal identifiers (name, student number, etc.). • The research participants may come from a vulnerable or marginalized group, such as those involved in dependent relationships, with disabilities, people living with HIV or other chronic disease, the economically disadvantaged, etc. • Use of patient information in existing health systems • Use of laboratory test of patients in existing health systems
High Risk	Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.	One or more of the following apply: • The intervention can cause serious physical or psychological adverse consequences. • Pharmaceutical drug research. • Research involving highly sensitive topics and/or very vulnerable and marginalized communities e.g. people with multiple vulnerabilities. • Research involving the deception of the participants. • Research investigating illegal activities: e.g. involving participants

		who are illegal immigrants or engaged in illegal activities. • Collection of biological samples through invasive techniques e.g. surgery. • By agreeing to participate in the research participants will be placed at a real risk of harm. • The researcher (or research team) will be placed at a real risk of harm. • 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. • The research may reveal information that requires action on the part of the researcher or an institution (private or public) 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.

2. RISK LEVELS FOR RESEARCH WITH CHILDREN

- Minors are all persons under 18 years of age.
- The research is not contrary to the **best interest** of the minor.
- **Greater than minimal risk** of harm should represent no more than a **minor increase** over minimal risk.
- **Absolute restrictions**:
    - No biological materials that are not naturally replaceable may be taken from a minor without ministerial permission.
    - This is also true for gametes from a minor or foetal biological material without ministerial permission except for umbilical cord progenitor cells.

Risk Category	Definition	Explanation and/or Examples

No more than minimal risk of harm (negligible risk) (NWU Category 1)	The probability or magnitude of harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.	• Children are generally considered to be a vulnerable research population. • Selected projects with children can be evaluated as "low risk" e.g. non-sensitive topics. • The research will collect information that would generally not be regarded as sensitive. • The research is age appropriate.
Greater than minimal risk but provides the prospect of direct benefit to the child (NWU Category 2)	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner. There is a **direct benefit** to the child.	• Research with children to obtain information from them but which leads to their own **benefit.** One or more of the following apply: • The research topic is considered "sensitive". • Information gathered is on opinions or attitudes and is personal in nature or is a combination of these aspects. • The information needs to be collected with personal identifiers (name, student number, etc.). • The child may also come from a vulnerable or marginalized group, such as those with disabilities, people living with HIV or other chronic diseases, the economically disadvantaged, etc. • The research may reveal information that requires action on the part of the researcher that could place the child or others at risk, e.g. research involving child victims of physical or sexual abuse, victims

		of domestic violence, etc. • Involves face-to-face contact with participants e.g. interviews and focus groups about sensitive topics.
Greater than minimal risk with no prospect of direct benefit to the child but has a high probability of providing significant generalizable knowledge (NWU Category 3)	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner. There is **no benefit** to the child.	• Research to obtain information from children but of **no benefit** to the child. One or more of the following apply: • The research topic is considered "sensitive". • Information gathered is on opinion or attitude and personal in nature or is a combination of these. • The information needs to be collected with personal identifiers (name, student number, etc.). • The child may further come from a vulnerable or marginalized group, such as those with disabilities, people living with HIV or other chronic disease, the economically disadvantaged, etc. • 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. • Involves face-to-face contact with participants e.g. interviews and focus groups about sensitive topics.

3. RISK LEVELS FOR ADULTS INCAPABLE OF GIVING ADEQUATE INFORMED CONSENT

- The research to be undertaken, including observational research, is not contrary to the best interest of the individual.
- The research, including observational research, places the incapacitated adult at no more than minimal risk.
- The greater than minimal risk must represent no more than a minor increase over minimal risk.
- No biological materials may be taken from mentally ill persons without ministerial permission.

Risk Category	Definition	Explanation and/or Examples
No more than minimal risk of harm (negligible risk)	The probability or magnitude of harm or discomfort anticipated in the research is **negligible** and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.	• Research in which the investigation of largely uncontroversial topics is undertaken through interviews and participant observation. • The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information. • Use of anonymized data from medical records
Greater than minimal risk but provides the prospect of direct benefit for the incapacitated adult	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner. There is a **direct benefit** to the incapacitated adult.	One or more of the following apply: • The risk of harm is reasonable in relation to the anticipated benefit to the participant. • The risk of harm includes several identified risks. • The research topic is considered "sensitive". • Review of privileged documentation e.g. privileged records of a health institution. • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • Involves face-to-face contact with participants through:

		- interviews dealing with personal sensitive information or within a power differential - focus groups with the potential of loss of anonymity and sensitive topics. • Psycho-social intervention studies • The intervention can cause physical or psychological harm. • The information needs to be collected with personal identifiers (name, student number, etc.). • Use of patient information in existing health systems. • Use of laboratory tests of patients in existing health systems.
Greater than minimal risk with no prospect of direct benefit to the incapacitated adult, but a high probability of providing generalizable knowledge	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner. There is **no benefit** to the incapacitated adult.	One or more of the following apply: • The risk of harm is reasonable in relation to the importance of the anticipated knowledge gained. • The risk of harm includes several identified risks. • The research topic is considered "sensitive". • Review of privileged documentation e.g. privileged records of a health institution. • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • Involves face-to-face contact with participants through: - interviews dealing with personal sensitive information or within a power

		differential - focus groups with the potential of loss of anonymity and sensitive topics. • The information needs to be collected with personal identifiers (name, student number, etc.). • The intervention can cause physical or psychological harm. • Use of patient information in existing health systems • Use of laboratory tests of patients in existing health systems.

4. RISK LEVELS FOR HUMANITIES AND RELATED FIELDS

Adjusted from: "Getting Ethics Approval for Your Research Project. Research Ethics Committee: Humanities. March 2015" University of Stellenbosch.

Risk Category	Definition	Explanation and/or Examples
No risk	No contact with human participants	• Certain systematic reviews • Review of literature available in the public domain. • Studies based on theory analysis and theory development
Minimal and/or low risk	The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country). Research in which the only foreseeable risk is one of minimal discomfort or	• Market research surveys • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. • The participants are adults and not considered to be a vulnerable research population (as discussed above). • The research will collect information that would

	inconvenience.	generally not be regarded as sensitive, such as opinions/perceptions rather than personal information. • Interviews with officials and practitioners in their official capacity e.g. consultation with a practicing attorney who specializes in mineral law to understand how applications for mining rights are done or with educational translators. • Focus groups with the potential loss of anonymity but not a sensitive subject. • Review of privileged literature/documentation e.g. privileged records of a company's annual meetings with a low level of sensitivity
Medium risk	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk.	One or more of the following apply: • The research topic is considered "sensitive". • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • The information needs to be collected with personal identifiers (name, student number, etc.). • Review of privileged literature/documentation e.g. privileged records of a company's annual meetings with a low level of sensitivity. • The research participants may come from a vulnerable or marginalized group, such as those involved in dependent relationships, with

		disabilities, people living with HIV or other chronic disease, the economically disadvantaged, etc. • Involves face-to-face contact with participants through: - interviews dealing with personal sensitive information or within a power differential - focus groups with the potential loss of anonymity about a sensitive subject.
High Risk	Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.	One or more of the following apply: • The intervention can cause serious psychological or social harm. • Research involving highly sensitive topics and/or very vulnerable and marginalized communities e.g. people with multiple vulnerabilities. • Research involving the deception of the participants. • Research investigating illegal activities: e.g. involving participants who are illegal immigrants or engaged in illegal activities. • By agreeing to participate in the research participants will be placed at a real risk of harm. • The researcher (or research team) will be placed at a real risk of harm • 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. • The research may reveal information that requires action on the part of the researcher or institutions (private and public sector) 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.

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23 February 2016

ADDENDUM: RISK EVALUATION FORM FOR RESEARCH WITH HUMAN PARTICIPANTS

Types of risks	Example	Probability (Mark with a √ if the probability exist)	Magnitude 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				