
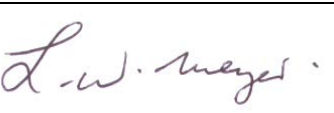
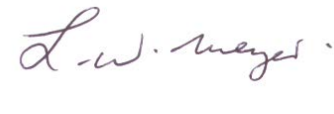





NWU-EMELTEN-REC

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

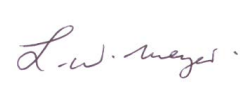

North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Office (NWU-EMELTEN-REO)			Terms of Reference
Title	Terms of reference for the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC)		
ToR No	ToR_EMELTEN_Ethics_1.1	Version no	4
Date of approval	22 September 2017	Revision date	22 September 2021
Email address	Ethics-EMELTEN@nwu.ac.za	Page no	Page 1 to 19

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by: Prof Minrie Greeff and amended by Prof Lukas Meyer	Prof Lukas Meyer		6 December 2016
Revised and Checked by:	NWU-EMELTEN Research Ethics Office: Prof Lukas Meyer		1 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		9 March 2020
	Faculty Board: Faculty of Education Chair: Prof Lloyd Conley		15 April 2020
	SCRE Chair:		27 August 2020

Authorised by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		28 August 2020
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2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		28 August 2020
Deputy Dean: Research and Innovation			
NWU-EMELTEN-REC Administrator	Mrs Villera le Roux		31 August 2020

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
9 Nov 2016	1	Formulated the SOP
7 Mei 2018	2	Changing old NWU Logo to new NWU Logo
1 December 2018	3	Changing committee's name EMHS-REC to NWU-EMELTEN-REC
4 September 2019	4	Revision of ToR

4 PURPOSE OF THE ToR

These terms of reference provide guidelines and a minimum standard for the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee's (NWU-EMELTEN-REC) operational management of research ethics processes. It ensures the essential purpose of the NWU-EMELTEN-REC to protect the dignity, rights, safety, and wellbeing of all human participants. This is done through *independent, prospective* and *on-going* ethics review of all research studies undertaken by *staff, registered students* and *affiliates* of the University.

Note: The terms of reference should be read in conjunction with all the other SOPs of the NWU-EMELTEN-REC as well as national and international documentation (see section 9).

5 SCOPE

Ethics approval must be obtained for all research proposals before a research study commences.

Note: The NWU-EMELTEN-REC will not consider research studies for approval if it is apparent that the research has already been conducted (retrospective).

The NWU-EMELTEN-REC functions according to the requirements as stipulated by the National Health Act No 61 of 2003, the concomitant regulation (Regulations Relating to Research with Human

Participants, 19 September 2014) and the guidelines of the Department of Health (Ethics in Health Research: Principles, Processes and Structures, 2015), national and international research ethics guidelines (see section 9), as well as the terms of reference provided by the ToR for the management of research ethics at the North-West University, 2018.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Research Ethics Office
REC	Research Ethics Committee
NWU	North-West University
SCRE	Senate Committee for Research Ethics
NHREC	National Health Research Ethics Council
SOP	Standard Operating Procedure/s

7 RESPONSIBILITIES

The NHREC stipulates the responsibilities of RECs as follows:

- The main responsibility of a REC is to conduct rigorous ethics review of all research proposals to ensure that the welfare and other interests of participants, researchers used in research, are properly protected and that the research will be conducted in accordance with the required ethical norms and standards.
- RECs must ensure that research proposals stand up to scientific and ethical scrutiny as is appropriate to the discipline concerned.
- The review must ensure the maintenance of ethical and scientific standards to:
 - Protect participants from harm by weighing the risk of harm against the likelihood of benefit;
 - Hold researchers accountable for their research activities;
 - Promote the highest scientific standards and best available techniques or approaches for optimal use of participating humans;
 - Promote important social and ethical values.
- RECs must review research proposals prospectively (not retrospectively) to ensure that they meet the accepted ethical norms and standards before research commences, using the guidelines indicated in the “Ethics in Health Research: Principles, Processes and Structures” (2015) document as a minimum benchmark.
 - The primary responsibility of each REC member is to decide independently whether the proposed research study protects the interest of participants adequately and keeps to exemplary standards.

Such responsibility regarding participant interest shall always take precedence over the interest of the scientific project.

The SCRE in its governance role, further stipulates that the NWU-EMELTEN-REC will:

- Function according to a strict code of conduct as appropriate for the NWU-EMELTEN-REC and approved by the SCRE (see 8.2 in this document).
- Formulate and seek approval from the SCRE for a set of operational rules for ethics applications by the NWU-EMELTEN-REC (SOP_Ethics_EMELTEN_1.4).
- Formulate and seek approval for a set of research discipline-specific examples of Risk Level Descriptors, in line with the SCRE guidelines, to make a suitable classification of the risk levels of research studies (see Risk level descriptor for research with human participants).
- Provide feedback on specific matters as requested by the SCRE.
- Ensure confidentiality of all information revealed to it.
- Ensure that all researchers of the NWU, sign the NWU research ethics code of conduct.

- Ensure that researchers have a proper understanding of research ethics, as applicable to the specific research conducted, by providing proof of research ethics training.
- Receive applications for research ethics approval from researchers via the provided research management system.
- Consider these applications at its regular meetings, as well as minute discussions and decisions and communicating the NWU-EMELTEN-REC's decisions, regarding applications, to applicants.
- Approve the issuing of research ethics certificates (valid for a year) for approved projects.
- Consider and approve any amendments to the original approved research proposal.
- Manage a monitoring system for approved projects that includes an annual reminder system, the evaluation of the submitted reports, as well as providing written approval for continuation of the study.
- Consider and act appropriately in cases of ethical misconduct by researchers.
- Report all ethical matters to the Dean of the Faculty of Education via the NWU-EMELTEN-REC.
- Report to the SCRE on an annual basis, using the NHREC template.

8 PROCEDURE/S

8.1 Formal character of the NWU-EMELTEN-REC

The NWU-EMELTEN-REC must be a NHREC registered committee, as well as approved by the SCRE of the NWU. See detail for NWU-EMELTEN-REC member selection, appointment and functioning (SOP_Ethics_EMELTEN_1.2).

8.2 Code of conduct for NWU-EMELTEN-REC members

All NWU-EMELTEN-REC members will be expected to sign the NWU code of conduct for researchers.

Over and above this code of conduct it will be expected of NWU-EMELTEN-REC members to:

- Agree to a term of office of five years;
- Familiarise themselves with the institutional documentation as well as national and international research ethics guidelines;
- Attend research ethics training sessions to keep abreast with the latest changes in this field (proof of evidence at least once every three years);
- Always act with integrity;
- Regularly attend NWU-EMELTEN-REC meetings;
- Be punctual in the attendance of these meetings;
- Diligently perform all responsibilities delegated to them;
- Maintain all of these responsibilities in compliance with national and international ethical and regulatory requirements;
- Consider and declare any prior interest and/or involvement in any matter being discussed at a NWU-EMELTEN-REC meeting to avoid potential conflict of interest (personal or financial);
- Keep all matters coming to their attention during NWU-EMELTEN-REC meetings confidential?

8.3 Relationship to non-affiliated researchers

Researchers with no affiliation to the North-West University can approach the NWU-EMELTEN-REC to review and approve their research proposals, where the NWU-EMELTEN-REC may on case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the NWU-EMELTEN-REC is willing, has proper expertise and capacity to evaluate the application. A fee will be levied for such a service.

8.4 Accountability responsibilities of NWU-EMELTEN-REC

The NWU-EMELTEN-REC functions within the legislative framework of Section 73 of the National Health Act No 61 of 2003, which requires a University, at which health and health-related research is being conducted, to have a NHREC registered REC. The REC is the single body vested with the explicit authority and legal accountability for the final determination regarding the ethical acceptability of the proposal.

8.5 Mechanisms for reporting by NWU-EMELTEN-REC

The NWU-EMELTEN-REC is managed and supported by the NWU-EMELTEN-REO, functions directly under the Dean of the Faculty of Education for all administrative purposes. The NWU-EMELTEN-REO consists of one support staff member. The NWU-EMELTEN-REC works in close collaboration with the Research Committees of the six other faculties, as well as with other Faculties' structures involved in research. All decisions will go through Faculty Board of Education for approval and will be distributed by the six faculties' Deputy Deans of Research and Innovation for further distribution. The Faculty Board of Education and SCRE also serve to internally audit the NWU-EMELTEN-REC in terms of its operational mandate and standards, and where applicable, to ratify the NWU-EMELTEN-REC's decisions. NWU-EMELTEN-REC must report annually on their activities to the NHREC and the SCRE.

8.6 Mechanisms for remuneration of NWU-EMELTEN-REC members

NWU-EMELTEN-REC members who are on the payroll of the North-West University are not remunerated for their services as REC members, in order to reduce conflict of interest and increase independence. Should the services of a member not on the payroll of the University be required e.g. layperson, attorney, etc. their services should be viewed as part of service delivery to their community.

However, they may be remunerated according to an honorarium negotiated before the appointment, where they are compensated for time, inconvenience and expenses (TIE principle) provided they are:

- 1) Not employed and might lose the opportunity to earn income for the day by attending to certain NWU-EMELTEN-REC duties;
- 2) Employed but have to add hours to their workday to serve on the NWU-EMELTEN-REC and do its work; or
- 3) In a private practice and their involvement as a member of the NWU-EMELTEN-REC will lead to a loss, as they are not able to earn an income during the NWU-EMELTEN-REC meeting.

8.7 Authority of the NWU-EMELTEN-REC

The National Health Act No 61 of 2003 provides statutory authority for the governance of "health research" through the registered RECs, as well as the necessary ethics regulatory infrastructure through the NHREC.

The RECs further derive their authority from the minimum standards and guidelines for research ethics of the NHREC, as well as the governance rules formulated by the SCRE:

- The National Health Act No 61 of 2003, section 73, which requires the University to establish RECs which are registered with the NHREC.
- The Department of Health's minimum national benchmark of norms and standards for conducting responsible and ethical research *Ethics in Health Research: Principles, Processes and Structures*, 2015 (chapter three and four).
- The ToR for the Management of Research Ethics at the North-West University, 2018 (SCRE).

In all instances the latest versions or amendments of the Act, regulations or standards will take immediate effect as they are published or promulgated, where this ToR will then be amended as soon as possible to reflect the latest changes.

The SCRE approved NWU-EMELTEN-REC is managed by the NWU-EMELTEN-REO and functions as a sub-committee of the Faculty Boards of the Faculty of Education and other faculties. If the NWU-EMELTEN-REC is dissolved by the Faculty of Education, it must be reported to the NHREC and SCRE.

9 REFERENCE DOCUMENTS

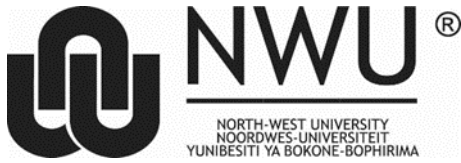
- The National Health Act, No 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- The Declaration of Helsinki, 2013.
- The Belmont Report, 1979.
- The Singapore Statement on Research Integrity, 2010.

- The Code of Federal Regulations of the USA (Title 45 Part 46).
- The ToR for the Management of Research Ethics at the North-West University, 2018.

10 ADDENDA

No	Document name
1	NWU Code of conduct for NWU-EMELTEN-REC Members
2	Risk level descriptors for human participants

ADDENDUM 1



NWU-EMELTEN-REC

Code of conduct for members of the NWU-EMELTEN-REC

As a member of the research ethics committee, I

- Agree to a term of office of five years;
- Agree to familiarise myself with the institutional documentation as well as the national and international research ethics guidelines;
- Agree to attend research ethics training sessions to keep abreast of the latest changes in this field (provide proof of evidence at least once every three years);
- Will always act with integrity;
- Will regularly attend REC meetings;
- Will be punctual in the attendance of these meetings;
- Will diligently perform all responsibilities delegated to me;
- Will maintain all of my responsibilities in compliance with the national and international ethical and regulatory requirements;
- Will consider and declare any potential conflict of interest and/or involvement in any matter being discussed at a REC meeting to avoid potential conflict of interest (personal and financial);
- Will keep all matters coming to my attention during REC meetings confidential.

Signature of the member

Name in print

Date

Signature of the Chairperson

Name in print

Date

ADDENDUM 2

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

RISK LEVEL DESCRIPTORS FOR THE PURPOSE OF NWU-EMELTEN-REC:

- 1. RESEARCH WITH CHILDREN**
- 2. ADULTS INCAPABLE OF GIVING ADEQUATE INFORMED CONSENT**
- 3. 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 risk, 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 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.

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.	Children are generally considered to be a vulnerable research population. <ul style="list-style-type: none"> • 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	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.	<ul style="list-style-type: none"> • Research with children to obtain information from them but which leads to their own benefit. <p>One or more of the following apply:</p> <ul style="list-style-type: none"> • 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, 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

		<p>child victims of domestic violence, etc.</p> <ul style="list-style-type: none"> • Involves face-to-face contact with participants e.g. interviews and focus groups about sensitive topics.
<p>Greater than minimal risk with no prospect of direct benefit to the child but has a high probability of providing significant generalizable knowledge</p>	<p>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.</p>	<ul style="list-style-type: none"> • Research to obtain information from children but of no benefit to the child. <p>One or more of the following apply:</p> <ul style="list-style-type: none"> • 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, 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 domestic violence, etc. • Involves face-to-face contact with participants e.g. interviews and focus groups about sensitive topics.

2. 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.

Risk Category	Definition	Explanation and/or Examples
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<p>No more than minimal risk of harm (negligible risk)</p>	<p>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 and stable society).</p> <p>Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.</p>	<ul style="list-style-type: none"> • 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
<p>Greater than minimal risk but provides the prospect of direct benefit for the incapacitated adult</p>	<p>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.</p> <p>There is a direct benefit to the incapacitated adult.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • 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 an institution. • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • Involves face-to-face contact with participants through: <ul style="list-style-type: none"> - 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 human information in existing health systems.
<p>Greater than minimal risk with no prospect of direct benefit to the incapacitated</p>	<p>Research in which there is a potential risk of harm or discomfort, but where</p>	<p>One or more of the following apply:</p>

<p>adult, but a high probability of providing generalizable knowledge</p>	<p>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.</p> <p>There is no benefit to the incapacitated adult.</p>	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> – 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 human information in existing health systems
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3. RISK LEVELS OF NWU-EMELTEN-REC

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
<p>No risk</p>	<p>No contact with human participants</p>	<ul style="list-style-type: none"> • Certain systematic reviews • Review of literature available in the public domain. • Studies based on theory analysis and theory development
<p>Minimal and/or low risk</p>	<p>The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily</p>	<ul style="list-style-type: none"> • Market research surveys • Research in which the investigation of largely uncontroversial topics is undertaken through

	<p>life (“Daily life” as a benchmark should be that of daily life experienced by the average person living in a safe stable society. Research in which the only foreseeable risk is one of minimal discomfort.</p>	<p>interviews, surveys and participant observation.</p> <ul style="list-style-type: none"> • The participants are adults and not considered to be a vulnerable research population (as discussed above). • The research will collect information that would 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
<p>Medium risk</p>	<p>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.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • 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, the economically disadvantaged, etc.

		<ul style="list-style-type: none"> • Involves face-to-face contact with participants through: <ul style="list-style-type: none"> - interviews dealing with personal sensitive information or within a power differential - focus groups with the potential loss of anonymity about
<p>High Risk</p>	<p>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.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • 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 domestic violence, etc.

ADDENDUM: RISK EVALUATION FORM FOR RESEARCH WITH HUMAN PARTICIPANTS

Types of risks	Example	Probability (Mark with a \checkmark 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				
	General community knowledge becomes known				
	Abuse indigenous knowledge				