SOP 17: Risk Assessment

The South African College of Applied Psychology Research Ethics Committee	
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1. COMPILATION AND AUTHORISATION

Action	Designated person	Date	Signature
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Amended for SACAP by	REC Office	26 October 2021	K. J. Young
Checked by	Academic Manager	11 November 2021	C. E. Ford
Authorised by	Academic Dean	18 January 2022	J.O. Lotter
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2. DOCUMENT HISTORY

Date	Version no	Reason for revision
July 2021	1	Development of the document
March 2022	2	Amendment to the risk assessment tool and distress protocol by REC office

3. ABBREVIATIONS AND DEFINITION

Abbreviation	Definition
SACAP REC	The South African College of Applied Psychology Research Ethics Committee
SOP	Standard Operating Procedure/s

4. PURPOSE OF THE SOP

The purpose of this SOP is to assist researchers and SACAP REC members to identify, estimating, and evaluating the potential risk of research to human/animal participants, the researcher or a research team, the academic department, institution, community, or society.

5. SCOPE

5.1. This SOP provides a framework for SACAP researchers (staff, academic associates, fellows, and students), non-SACAP researchers (visiting researchers and students), and the SACAP REC to engage in research ethics risk assessment.

5.2. The concept of 'risk' denotes the possibility that research may cause varying degrees of harm to human and animal participants in different contexts, the respective research institution(s), communities, the environment, and society. Any such risks must be considered before the commencement of research.

5.3. The assessment of any proposed research must evaluate whether there is an ethically justifiable balance between the anticipated research results and any harm or inconvenience that may be caused to any of the participants, research institution(s), communities, and society. This process is referred to as risk/benefit analysis.

5.4. Researchers have the primary responsibility to ensure that the research conducted in the discipline will have a positive risk/benefit ratio, therefore maximising the potential benefits to human participants, institutions, communities, society, and/or the environment and minimising anticipated risks to research participants, institutions, communities, the environment, society and/or researcher(s).

5.5. Research that is conducted by researchers that are connected to SACAP (SACAP researchers and non-SACAP researcher(s) must be assessed by the SACAP REC to identify, estimate, and evaluate the potential risks to human participants, institutions, communities, society, or the researchers.

5.6. A basic prerequisite for conducting the risk assessment is a critical reflection on and deliberation about the potential ethical risk(s) of the research and not on the completion of the risk assessment as a mere administrative requirement.

6. PROCESS OF RISK ASSESSMENT

6.1. The SACAP REC is responsible for integrating the ethics risk assessment in their research ethics review process to differentiate between negligible, low, medium, or high-risk research in adherence to national and international research ethics review guidelines.

6.2. This SOP provides the members of the SACAP REC with standardised documentation and information on risk assessment in research, and where appropriate, training will be offered to the committee members to ensure uniformly high standards in the execution of this task.

6.3. The SACAP REC must ensure that researchers and supervisors are informed of the risk assessment process and that, where necessary, training and guidance is offered to SACAP researchers.

6.4. Research applications for ethical clearance submitted to SACAP REC must include a risk assessment (identification, estimation, and evaluation of potential risks) (*Annexure A of SOP 17: Risk Assessment*), and this information should be contained in the participant information sheet. The SACAP REC should not rely exclusively on the view of the researcher when assessing the probability or the magnitude of harm (physical and/or emotional). Independent expert opinion should be obtained whenever deemed necessary.

6.5. The SACAP REC and researchers must ensure that the risks inherent in the proposed research have been reduced to a minimum necessary to achieve the research objective. This duty includes consideration of whether alternative methods of obtaining the research information are available and consideration of whether lower risks might prevail in a different group of participants.

6.6. The SACAP REC may thus require that certain steps or measures be taken by a researcher to mitigate or avoid potential ethical risks about a particular ethics review:

6.6.1. **Negligible and low-risk research**: applications can be processed by an expedited review procedure (*refer to Annexure B for an outline of the procedure*).

6.6.2. **Medium and high-risk research:** is approved through a comprehensive Research Ethics Review procedure (*refer to Annexure B for an outline of the procedure*).

6.6.3. **High-risk research**: must be reported in writing to the Academic Dean. The report must reflect the SACAP REC's role in the ongoing monitoring of high-risk research.

6.7. The SACAP REC will ensure that there is regular monitoring and evaluation of the ethical risks of approved studies, particularly in research that entails medium-to-high ethical risks (*See SOP 4: Proposal Applications and Decisions, Appeals, and Monitoring, and SOP 8: Annual Progress and Monitoring Reports*).

6.8. This SOP should be read in conjunction with *SOP 18 - Distress Protocols for Research on Sensitive Topics.*

7. TYPOLOGY OF RESEARCH RISKS

7.1. Types of risk cover a range of potential risks that include physical risks, psychological or emotional, social, legal, and political risks.

7.2. Physical risks are risks of harm through physical intervention or involvement of participants in experiments that may alter the physical condition or physical health of the participants. Such risks are seldom encountered in research conducted in the humanities, social sciences, and behavioural sciences.

7.3. Psychological or emotional risks are risks related to the mental well-being of the participants or researchers which may be caused by embarrassment, anxiety, or emotional distress. The risk of psychological harm must be evaluated according to the risk categories (*See Annexure B*) and risk assessment tools (*see table under Section 8*).

7.4. Social, legal, and political risks are risks of harm due to loss of status, privacy, social standing, or financial risk as a result of confidentiality breaches. Such risks may also appear when the participants belong to marginalized or minority groups with contentious social or political characteristics that may be liable to legal persecution or social ostracism if research data are not treated confidentially.

7.5. Ethical research must consider the ability of the participants to act in their own interest, and the protection of researchers against potential risks related to the research project.

7.6. Researchers should also consider the potential for reputational risk of institutions involved in the research.

7.7. The potential risks involved in research must be assessed against the degree of vulnerability of the human participants (children or young people under 18 years, women, older persons, LGBTI persons, physical or mentally ill, people with learning difficulties, offenders, students or colleagues, over-researched participants, non-English-speaking participants or those with low functional literacy, or participants engaged in illegal activities). This ability may be impaired by the participants' lack of social and political autonomy in making independent decisions, or by a lack of mental or physical capability to understand the possible consequences of their involvement in the proposed research.

7.8. Any research that involves human participants must be based on the mutual understanding of all parties involved regarding the kinds of risks that the research may entail. Any such project must also allow the participants to engage critically with the research and the researchers, ranging from the right to refuse to answer questions to the right to withdraw altogether from the research

without any negative consequences for the participants. This will be included in the informed consent form that will be completed by the participant before the commencement of the data collection.

7.9. In addition, a risk assessment must consider the following aspects:

7.9.1. The level of human participant involvement (no involvement, indirect or direct involvement);

7.9.2. The perceived sensitivity of the research area (not sensitive at all, probability of being sensitive is related to the context of the study, and research that is usually categorised as sensitive in nature, i.e., controversial, contentious, embarrassing, or upsetting);

7.9.3. The type of research, invasiveness of the recruitment and data collection procedures (deceptive practices, coercion, or incentives to participate, approaching participants in a public space);

7.9.4. Confidentiality issues arising from covert observation of participants, recording, filming, or photography, potential breaches and limitations of confidentiality, lack of anonymity, and issues related to the security of personal data;

7.9.5. Participation is not voluntary, or there is undue pressure or bribery of participants;

7.9.6. Inappropriate financial interests of the researcher and/or the institution; and

7.9.7. Health and safety issues, including equipment hazards, and chemical or biological hazards.

8. RISK ASSESSMENT TOOL

8.1. To assess the ethical risk of a proposed research project, the researcher engages in a systematic and comprehensive assessment of the project. For the researcher, student researchers, and their supervisor complete a risk assessment to balance consideration of the benefits of research on sensitive topics against the risks; the ethical principles of autonomy, justice, and non-maleficence; and the strengths, resiliency, and vulnerability of participants.

8.2. Annexure A contains risk-level category definitions and examples.

8.3. Annexure B contains the risk assessment tool with reference made to distress protocol requirements where appropriate.

9. REFERENCE DOCUMENTS

- College Research Ethics Committee (CREC), 2016.
- Department of Health. (2015). *Ethics in health research: Principles, processes, and structures* (2nd ed.).
- Medical Research Council. (2002). *Guidelines in ethics for medical research: General principles including research on children, vulnerable groups, international collaboration, and epidemiology*. http://www.sahealthinfo.org/ethics/book1.htm
- University of Stellenbosch. (2012). Standard Operating Procedure. *Research Ethics Committee: Human research* (Humanities).

ANNEXURE A: RISK LEVEL CATEGORY DEFINITIONS AND EXAMPLES

This table identifies broad categories of risk with examples of these categories or the types of data collection methods or participant groups that are most common in Social Science research. A glossary of terms is included after the table defying and explaining risk, vulnerability, and distress protocol.

Risk category	Definition	Explanation and Examples	Notes
Category 1: Negligible risk	**No contact with human participants, or research where the likelihood and magnitude of possible harm are no greater than those imposed by daily life.** (The concept of 'daily life' used as a benchmark should be that of daily life as experienced by the average person in the country the participants are living in).	Research that involves non-invasive procedures and no apparent risk to participants (institutions and researchers) above the everyday norm related to NO or INDIRECT involvement of participants, a research topic that is not sensitive and de-identified data collection procedures. **Examples:** ● Document analysis or literature review in the public domain, for example in public libraries, public archives, websites, newspapers, or newsletters, as well as data relating to natural persons who have been dead for more than 20 years (The above research is generally not considered 'research on human participants.'), ● Studies based on theoretical analysis alone, ● Studies based on secondary analysis alone, ○ Use of non-human, quantitative datasets (e.g., economic data), ○ Use of previously collected human datasets (where permission from previous participants have been explicitly granted, and where a permission letter from the principal researcher. of the previous study has been obtained), and ○ Use of anonymized and aggregated human datasets (e.g., census data).	**NB:** Not all research involving material in the public domain is 'negligible risk,' e.g., research involving data extraction from social media. The latter research would fall in the low, medium, and high-risk categories dependent on the type of study.

Category 2: **Low-risk**	**Research involving human participants directly in which the only foreseeable risk is that of discomfort** or where there may be some sensitivity involved in terms of the questions asked.	● The participants are adults and not considered to be a vulnerable research population. ● The researcher will collect information that would generally be regarded as non-sensitive. For example, questions about people's everyday lives, activities, and opinions, rather than detailed biographical information. However, potential participants may experience some level of potential discomfort and where there may be some sensitivity involved in terms of the questions asked. ● Research in which the investigation of largely uncontroversial topics is undertaken through interviews, and surveys. ● The information can generally be collected anonymously, or participants may not insist on keeping the collected information strictly confidential. **Examples:** ● Use of questionnaires/surveys (that do not involve sensitive questions) sent to non-vulnerable adult participants and returned anonymously so that participants cannot be identified. ● Recording information from groups of participants (rather than individual participants) in an educational setting where participants are not identified.	**Where the only foreseeable risk is that of discomfort**, e.g., uneasiness, disturbance, mild pain, or where there may be some sensitivity involved in terms of the questions asked. **Applications deemed low-risk are reviewed by the SACAP REC (if appropriate).** A distress protocol **might be necessary depending** on the level of potential discomfort and sensitivity of the questions. Information about free, accessible, and appropriate support/ counselling services must be provided for participants on the information sheet if required. ***Research proposals must include a statement on the risk of mild discomfort due to certain questions in the Participant information sheet.***

Category 3: Medium-risk	**Research where there is a likely risk of some harm for participants and/or the researcher,** but where appropriate steps can be taken to mitigate or reduce risk. It is not expected that the research will cause severe risk or negative physical, emotional, social, cultural, or political consequences.	One or more of the following apply: ● Participants are directly involved as part of fieldwork activities. ● May include some vulnerable participants or marginalised groups, and/or contexts. ● The research topic is 'sensitive' and/or questions that may have the potential for trauma and emotional distress. ● Questions about people's everyday lives, activities, and opinions – may include biographical information and some potentially sensitive questions and/or topics. ● Information gathered is personal rather than relating to participants' opinions, attitudes, or a combination of all three. ● The information needs to be collected with personal identifiers. . ● Research studies involving social media, e.g., 'Tweets' or 'Facebook profiles, could be medium-risk, depending on the research question under investigation. ● Research locality itself may contain potential risks to the participants and/or researcher. ● There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks. **Examples**: ● Interviews for the purpose of gathering biographical data, which may elicit embarrassing or intimate personal details whose publication may not result in serious legal or social consequences but could lead to a moderate loss of status or damage to public image. ● Research, where participants are in a dependent relationship to any of the researchers and this, may affect their decision to	Where there is **a likely risk of some harm** that refers to damage incurred (which may include physical, psychological/emotional, social, economic, or legal harm as an outcome of an action, or through emotional distress) for participants and/or the researcher, **but where appropriate steps can be taken to mitigate or reduce risk.** **Applications deemed medium-risk are reviewed by the SACAP REC. Support/counselling services must be provided in the participant information sheet. A distress protocol should be given, if appropriate.** **A distress protocol and/or researcher debriefing strategy should be submitted to the SACAP REC if the risk includes psychological/ emotional harm or distress.** Information about free, accessible, and appropriate support/ counselling services must be provided for participants on the information sheet. ***Research proposals must include a statement on the risk of likely emotional distress due to certain questions in the Participant information sheet.***

		participate e.g., research on inmates in a prison by a prison officer or on students by a lecturer.	
Category 4: High-risk	**Research in which there is a real foreseeable risk of harm**, which may lead to serious adverse consequences, if not managed in a responsible manner.	Research that may reveal information that requires action on the part of the researcher that could place the participant or others at risk. One or more of the following apply: ● Research involving highly sensitive topics, e.g., experiences of violence, rape, illegal activities. ● Research involving vulnerable and marginalised individuals or communities, or where multiple vulnerabilities exist. ● Research involving the deception of research participants (e.g., covert observation). ● Research involving serious illegal and criminalised activities, such as violence, and fraud. ● Where the participants place themselves at risk of harm if they participate. ● Where the researcher may place themselves at risk of physical and/or psychological harm. ● Information revealed during the course of the research may place the researcher at risk of breaking the law. ● Where the researcher may place themselves at risk of breaking the law ● Where the research may reveal information that may place the participant or others at risk (e.g., victims of abuse, violence), requiring intervention from government, SACAP, or other institutions. ● There is a clear justification to undertake the research using this participant group and/or using the proposed instruments, despite the potential risks. **Examples:** ● Research investigating gang activities and possession of illegal firearms.	Where there is **a real and foreseeable risk of harm** that refers to damage incurred (which may include physical, psychological/emotional, social, economic, or legal harm) as an outcome of an action, or through emotional distress, which may lead to **serious adverse consequences if not managed in a responsible manner**. **Applications deemed high-risk must be reviewed by the SACAP REC. Remedial interventions by external professionals are strongly recommended should harm occur. Support/counselling services must be provided for participants and/or for the researcher. A distress protocol and debriefing strategy should be given, if appropriate.** **A distress protocol and/or researcher debriefing strategy must be submitted to the SACAP REC if the risk includes psychological/ emotional harm or distress.** Information about free, accessible, and appropriate support/ counselling services must be provided for participants and/or the researcher on the information sheet and in the application form. ***Research proposals must include a statement of the risk of real and***

		● Research involving child victims of physical or sexual abuse, victims of domestic violence or research dealing with HIV/AIDS.	***foreseeable emotional distress in the Participant Information Sheet.***

GLOSSARY OF TERMS:

(1) Definitions of terms

- Discomfort refers to a sensation of uneasiness, disturbance, or mild pain.
- Harm refers to damage incurred (which may include physical, psychological/emotional, social, economic, or legal harm) as an outcome of an action, or through emotional distress.
- Risk refers to (i) the likelihood of exposure to a particular negative consequence, and/or (ii) the magnitude of the possible consequences of exposure, and/or (iii) the possibility that research could result in harm.

(2) Discussion of risk: Individuals that may be at increased risk include:

- Those who are dependent/reliant on the institution/person who provides/mediates access to researchers;
- Those who are involved in illegal activities or who are criminalized by the state, e.g., drug dealers, sex workers, undocumented migrants.
  NB: it is essential to consider the individual – not an aggregated group – when assessing risk.

(3) Discussion of vulnerability: Vulnerability can originate from a lack of capacity or impaired ability to provide voluntary informed consent. For example, health status; social pressures that may impact on the ability to make a free and informed decision about participating in research; an inability to protect one's rights as a participant in research. Vulnerability needs to be considered as dynamic and specific to a particular context and

may occur with or as a result of power asymmetries between participants and researchers/institutions. There may be layers of vulnerability surrounding a participant's circumstances. Being vulnerable does not necessarily imply that harm or exploitation will occur, but it does increase the risk of harm or exploitation through research. In addition to those in vulnerable categories, vulnerability may also include individuals whose ability to provide informed consent may be reduced where:

- Their decision-making capacity is limited due to individual mental health status;
- Their decision-making capacity is limited due to the environment in which they live/work, e.g. prisoners/detainees, residents of drug rehabilitation centres;
- They are under 18 years of age;
- They are dependent on the state to maintain legal status, e.g., documented asylum seekers and documented refugees.

NB: it is essential to consider the individual – not an aggregated group – when assessing vulnerability.

The researcher needs to minimise the risk of harm, ensure that the consent process supports a truly informed decision, and put in place additional measures to ensure the ethical involvement of vulnerable groups. i.e., include details of steps to be taken to facilitate data collection across language barriers (e.g., interpretation or translation) and/or in cases of illiteracy.

(4) **A Distress Protocol** refers to a procedure to follow in emergencies where, for example, a participant becomes distressed during an interview. Under such situations, the interview is terminated, and the distress protocol is enacted. A distress protocol must include the name and contact details of an appropriate provider who can provide support, at no cost to the participant. This may include counselling services or accessible Non-Governmental Organisations (NGOs).

Researchers may need to consider:

- The possible distress experienced by the participant: e.g., questions that address issues of abuse, abandonment, previous negative sexual experiences, or traumatic memories that may induce distress.
- The possible distress experienced by the researcher: this may include provisions for how the safety of the researcher will be supported and should be discussed with the supervisor and the name and contact details for counselling services provided if needed.

RISK ASSESSMENT TOOL

QUESTION	NEGLIGIBLE RISK	LOW RISK	MEDIUM RISK	HIGH RISK
Are the participants of the study?	O No contact with human participants	O Persons 18 years older and above with the capacity to provide informed consent?	O SACAP academic and/or support staff/students? O In a dependency relationship with the principal researcher and/or research team? O to be compensated in any way (e.g., incentive, reimbursement for travel, etc) for participating in the study?	O Children or young people under the age of 18? O Children who are in the custody of the State? O Women? O People with little or no formal education? O Persons with a cognitive disability or mental impairment of any kind? O Persons who are physically disabled? O Offenders or people on parole? O Persons who are highly dependent on medical care, i.e., a sample from a hospital/clinic? O Military personnel? O Socially and/or economically disadvantaged communities? O Persons who are not usually considered to be vulnerable but would be considered vulnerable in the context of this research project

				O Persons who are unable to give consent themselves (e.g., consent through a gatekeeper/ legal representative)? O Persons aged 65 and above? O Persons with diminished physical and/or educational capacity (e.g., traumatised)? O Persons who are not competent to give participation consent (e.g., due to language challenges)?
Is the researcher administering any process and/or intervention that		O is expected to result in no foreseeable risk, harm, or discomfort to the mental and/or the physical well-being of the participants? O is expected to result in the only foreseeable discomfort being that of inconvenience (e.g., time and effort required by participants to complete questionnaire/form, participate in a street survey)?	O could be hazardous to social well-being (e.g., possibly results in damage to social networks/relationships with others, discrimination, social stigmatisation, the discovery of previously unknown paternity status) and/or result in discomfort associated with the social well-being of the participants and/or researcher?) O could be hazardous to economic well-being (e.g., possibly results in the imposition of direct and/or indirect financial commitments on participants) and/or result in discomfort associated with the economic well-being of the participants and/or researcher? O collects any articles/documents of the property, personal or cultural from participants? (e.g., medical	O involves participants undergoing psychological, physiological, or medical testing and/ or treatment? O involves the collection and use of human biological samples (e.g., skin, blood, urine, saliva, hair, bones, tumour, and other biopsy specimens) or their exhaled breath? O could be hazardous to the physical health (e.g., possibly results in illness, injury, pain) of the participants and/or researcher? O seeking disclosure of information that could be hazardous to the psychological well-being (e.g., possibly results in feelings of worthlessness, guilt, anger, fear) of the participants and/or researcher? O seeking disclosure of information that could be hazardous to the legal well-being (e.g., possibly results in the discovery and prosecution of criminal activity or civil

			records, student records, staff records? O may result in a traumatic experience for the participants and/or researcher? O may result in the disclosure of personal sensitive and/or embarrassing information about the participants and/or researcher? O involves covert observation of behaviour that is not normally in the public domain? O could result in the participants feeling humiliated, manipulated and/or in other ways treated disrespectfully and/or unjustly? O uses specialised equipment on the participants? O could result in discomfort associated with the physical health (e.g., the act of measuring blood pressure, minor side effects of taking medication) of the participants and/or researcher? O could result in discomfort associated with the psychological well-being (e.g. feelings of anxiety due to being interviewed) of the participants and/or researcher?	liability or be damaging to the financial standing, employability, personal or professional relationships) of the participants and/or researcher? O could result in the participant learning about a genetic possibility of developing an untreatable disease? O innovative therapy or intervention

			O could result in discomfort associated with the legal well-being of the participants and/or researcher? O could result in the identification and/or re-identification of a participant from a resulting report? O could result in risks to non-participants (e.g., distress to relatives upon discovering that a participant suffers from a serious genetic disorder, infectious disease risks to a community, social/economic discrimination of subgroup populations)?	
Is the researcher administering a questionnaire/survey/ interview/focus group/observation practice that		O occurs in public spaces and natural environments where the researcher does NOT interact directly with participants? O occurs in public spaces and natural environments where the researcher does NOT stage any intervention? O occurs in public spaces and natural environments where the participants do NOT have a reasonable expectation of privacy? O occurs in public spaces and natural environments and dissemination of research findings does NOT identify individuals or groups of participants?	O collects sensitive data from the participants (e.g., personal data that is not normally in the public domain)? O does not guarantee the anonymity of the participant? O occurs in public spaces and natural environments and dissemination of research findings does identify individuals or groups of participants? O occurs in public spaces and natural environments where the	

			researcher interacts directly with participants? O occurs in public spaces and natural environments where the researcher stages an intervention? O occurs in public spaces and natural environments where the participants have a reasonable expectation of privacy? O does not guarantee the confidentiality of data collected from the participants	
Is the researcher intending to access participant data from an existing stored repository (e.g., school, institutional, university records or data collected from another previously completed or ongoing research study) that	O relies exclusively on publicly available information or is accessible through legislation or regulation, (where permission from previous participants has been explicitly granted, and where a permission letter from the principal investigator of the previous study has been obtained) O relies exclusively on secondary use of anonymous information (i.e., no	O requires access to participant information (in a non-identifiable form, e.g., summarised form) as part of an existing published or unpublished source or database	O requires access to participant information (in individually identifiable or re-identifiable form) as part of an existing published or unpublished source or database?	

	identifiable information is generated or inferred, e.g., anonymised aggregated datasets, e.g., census data.			
Does the researcher intend to publish the findings of the study in a publication that..	O requires no evidence of human ethics approval/acknowledgement?	O requires evidence of human ethics approval/acknowledgement?	requires evidence of human ethics approval/acknowledgement?	requires evidence of human ethics approval/acknowledgement?
Does any sponsor of the study/the researcher have a vested interest in any possible findings of the study	O No		O Yes	
Are there any restrictions/conditions attached to the publication and/or presentation of the study results?	O No		O Yes	
	Number of ticks in this column: ___	**Number of ticks in this column: ___**	**Number of ticks in this column: ___**	**Number of ticks in this column: ___**
		If the number of ticks in this column is more than 0 and the number of ticks in Medium risk column is 0 and number of ticks in High-risk column is 0, then the application would qualify for an expedited review by the Scientific Review Committee who will review for scientific rigour and then refer their recommendation to the SACAP REC who will review the safety of the research tools and procedures for approving	If the sum of the number of ticks in Medium and High-risk columns is more than 0, irrespective of whether ticks appear in other columns, then the application would require full review by the SACAP REC after the proposal has been approved by the Scientific Review Committee.	

		ethical clearance of research involving human participants	

RISK LEVEL OF STUDY	
Guided by the information above, classify your research project based on the anticipated degree of risk.	
Category 1: Negligible	
Category 2: Low-risk	
Category 3: Medium-risk	
Category 4: High-risk	
In medium and high-risk level research, given a brief outline of the potential benefits of the study for the research participant group/and/or using the proposed data collection methods, despite the potential risks.	
In medium and high-risk level research, given a brief outline of the support/counselling services that will be provided for participants and/or for the researcher. A distress protocol and debriefing strategy should also be outlined, if appropriate	