**Guidance Notes**

**For the Behavioural Research Ethics Board Application Form**

The following Guidance Notes (GNs) are intended to ensure that applicants have the necessary information to be able to fill out the Application for Research Ethics Review correctly and to construct consent forms that meet REB standards. The Behavioural REB procedures comply with the pertinent Tri-Council Policy Statement (TCPS 2, 2018).

In accordance with TCPS 2 Article 2.1, the research study cannot begin until the REB issues its written approval of the research proposal. All investigators are responsible for understanding and adhering to the TCPS 2 and other relevant guidelines. These Guidance Notes are not intended to be a substitute for this responsibility. Refer to the original documents for complete information.

The matters of greatest concern to the REB are the issues of informed consent of participants, voluntary participation, protection of individual privacy (confidentiality and anonymity), and safeguarding participants from any harmful results due to participation or non-participation in the proposed investigation or research project.  Our evaluation of an application is based on the degree to which each of these concerns are satisfied; when filling out the application, researchers are urged to consider these points, and to explain to the committee the steps they will take to address the concerns.  Researchers are also urged to consult the TCPS 2, 2018 ([https://ethics.gc.ca/eng/policy-politique\_TCPS 2-eptc2\_2018.html](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)) for more information.

The board acknowledges the variety of paradigms and methodologies currently available to researchers, and that each of these paradigms entails its own particular ethical issues.  Thus, there may be more than one way to address an ethical issue.  Researchers should feel free to suggest alternative approaches to those outlined below, or to explain why a particular requirement is not appropriate in the context of a given project.

**How to Use the Guidance Notes with the Application Form:**

The GN's are numbered and correspond to the same numbered box in the Application Form. It is the responsibility of the researcher(s) to ensure that the information contained in each GN is applied in a manner appropriate to each individual study for both the Application Form and any accompanying documentation.**The REB requires a complete response to each question in the Application Form.**

**PART 1: IDENTIFICATION**

**GUIDANCE NOTE 1.1:****PROJECT TITLE**

The title given in Part 1 of the Application Form should be the same and correspond to the title of any consent form(s) also submitted.  The title of the study should accurately reflect the nature of the study.

**GUIDANCE NOTE 1.2: PRINCIPAL INVESTIGATOR**The principal investigator (PI) is the individual who is ultimately responsible for the actions of those acting with delegated authority. He/she is the person responsible for the conduct of the study at a research site or the responsible leader of the team.  
  
The Principal Investigator for a study must notify the REB in writing when this responsibility is going to be assumed by a different researcher. PIs must also ensure that a process is put into place to ensure the ongoing safety of research participants in the event that the PI leaves or retires from their University or Health Region affiliated position and the study remains ongoing. 

Unless noted otherwise in Section 1.6, the REB will send all correspondence to the address provided for the PI.

**University of Regina:**Students, post-doctoral fellows, and visiting professors may serve as the PI on the ethics protocol. In these cases, a faculty member must sign as the project supervisor.

**University of Saskatchewan:**The PI must be a faculty member.

**Saskatchewan Health Authority:**  
For research being conducted within the Saskatchewan Health Authority (SHA), the Principal Investigator (PI) of the project must hold a staff appointment within a SHA affiliated institution. Projects being conducted by residents, students, or Out-of-Region investigators must appoint a local PI Investigator who will be responsible for the conduct of the project at that institution. SHA will consider Out-of-Region PIs on a case by case basis depending on the level of risk to participants and when PIs have the appropriate institutional affiliations and all required certifications and training to conduct research in Canada.

**GUIDANCE NOTE 1.4: THESIS/PROJECT SUPERVISOR**

Include the name and contact information for the project or research supervisor.  The supervisor takes responsibility for ensuring that the PI, student or Resident conducts the research project ethically, in accordance with the REB approved protocol.**GUIDANCE NOTE 1.5:PROJECT PERSONNEL**All persons assuming a formal role within the study that are to be listed on the Certificate of Approval must be noted on the application. This includes, but is not limited to co-principal investigators, co-investigators, residents, student investigators, and faculty advisors.All personnel who are associated with a research project and will have contact with research participants are required to complete the TCPS 2 Course on Research Ethics (CORE), online tutorial, before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, postdoctoral fellows research assistants, research coordinators, etc. The TCPS 2 CORE is free and can be completed in about two to three hours in either a single session or series of sessions and can be found here: <https://tcps2core.ca/welcome>

Principal investigators and all study staff accessing personal health information for studies must complete the McMaster Chart Audit Tutorial, available at <http://ethics.mcmaster.ca/chart/>, prior to submission to the Board.   
  **GUIDANCE NOTE 1.6: PRIMARY CONTACT PERSON**If another contact besides the PI will be handling all paperwork and correspondence related to this file, please indicate here.  
**GUIDANCE NOTE 1.7: LOCATIONS WHERE THE RESEARCH WILL BE CARRIED OUT**

Enter the names of locations/institutions/sites where the research will be carried out under this Research Ethics Board approval. Research outside of Canada normally requires ethics review by a board or committee within that jurisdiction.   *(TCPS 2 Chapter 8, Multi-jurisdictional research)*

The project cannot begin until you receive approval from the institutions selected.  It remains the PIs responsibility, however, to confirm and/or obtain necessary approvals from these sites.

SHA has a Research Approval process for projects occurring in SHA affiliated institutions and any research that involves SHA patients, staff or other resources. Please see the following link for information on the Operational Approval process: Add Link to OA page.

**GUIDANCE NOTE 1.8:****PROPOSED PROJECT PERIOD**

Include the planned start and end date of the project. Completion of the project can be defined as the point in which data analysis has been completed in order to answer the original research question(s). The end date can be an estimate of when you expect to have the analysis complete and can be extended by submission of the annual renewal form.  *(TCPS 2 Article 2.8, continuing review throughout the life of the project)*

**GUIDANCE NOTE 1.9:****STUDIES BEING SUBMITTED FOR REB APPROVAL AT OTHER SITES**

Indicate whether this study is under review OR has received approval from another REB in Saskatchewan and/or a REB outside of Saskatchewan. *(TCPS 2 Chapter 8, multi-jurisdictional research)*

REB approval at a specific institution is required when the project will be using institutional resources, a member of the research team is a student, faculty member, researcher, etc with primary affiliation at the institution, the project involves collecting data or recruiting participants from within that institution or funding for the project may be administered by that institution.

 The University of Regina REB, University of Saskatchewan Biomedical and Behavioural REBs and the SHA REB currently have a reciprocity agreement in place before starting the application process please contact your institutional REB to confirm which REB you should be applying to: ADD Link to **General Instructions for Submission page**

**GUIDANCE NOTE 1.9.2: OTHER APPROVALS**

Some organizations, such as school districts, health regions, etc, may require approval prior for researchers to recruit participants or conduct research through their organization.  The researcher is responsible for ensuring awareness of requirements, and coordinating logistical and operational aspects of the research within the organization.

Field research outside Canada normally requires ethics review by a board or committee within that jurisdiction.  Please see *TCPS 2 Chapter 8, multi-jurisdictional research.*

**Justification for not seeking permission from an organization**:  Permission from an organization is not required in order to conduct research on that organization. Individuals that may be approached to participate in a research project about their organization should be fully informed if permission has not been obtained.  The REB will consider the welfare of participants, the level of confidentiality committed by the researchers and the security of collected research materials when organizational approval is not sought. (TCPS 2 Article 3.6 critical inquiry)

**GUIDANCE NOTE 1.10:****FUNDING INFORMATION**

Indicate the name of the source of funds and whether or not the funds have been awarded yet. If funding changes, e.g. addition, deletion or change of sponsor, during the course of research, an amendment should be submitted. *(Tri-Council MOU Schedule 2, TCPS 2 Chapter 7 Conflicts of Interest)*

**PART 2: CONFLICT OF INTEREST****GUIDANCE NOTE 2.1: CONFLICT OF INTEREST**

The TCPS 2 Chapter 7 discusses ethical issues that can arise when research activities and other activities are in conflict.  A conflict of interest may arise when activities or situations place an individual(s) in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. Note that “immediate family members” includes a person related by blood, adoption, marriage or common-law marriage to the principal investigator or project personnel. It may also include an individual that they previously had such a relationship. *(TCPS 2 Article 7.4, researchers and conflicts of interest)*

Any real, potential or perceived conflict of interest must be identified and disclosed to the REB.

**GUIDANCE NOTE 2.2: CONFLICT OF INTEREST MANAGEMENT**

The disclosure of any real, potential or perceived conflict of interest should also be made to any research participants. It may also be appropriate to disclose the conflict of interest to the sponsor, the institution, and any relevant professional body as well.  If there is a need for a researcher with a conflict of interest in a research project to be involved in some aspect of the project, the extent of the involvement should be described.  When disclosure to the REB is not enough to manage the conflict of interest, the REB, guided by established institutional policies, may require that the researcher withdraw from the research, or that others on the research team, who are not in conflict of interest, make research-related decisions. Where appropriate, disclosure to the sponsor, the institution and any relevant professional body may also be necessary. In exceptional cases, the REB has the discretion to refuse approval of a research project where the REB decides that the conflict of interest has not been avoided or cannot be appropriately managed.  (*TCPS 2 Article 7.4, researchers and conflicts of interest*)

**PART 3: OVERVIEW OF RESEARCH PROJECT**

**GUIDANCE NOTE 3.1: SUMMARY OF RESEARCH PROPOSAL**

Provide a short summary of the research project written in lay language and suitable for non-scientific REB members. It should include a brief description of the research being proposed and the potential significance.

**GUIDANCE NOTE 3.2: RESEARCH DESIGN AND METHODS**

Some specific methods are identified as they represent possible alterations or further considerations to the processes of obtaining free and informed consent.

**Action Research**

Action research involves researchers investigating their own practice where dual relationships exist between the researcher and participant. When the relationship involves individuals of lesser power or status than the researcher, such as the researcher’s students, employees, inmates or clients, there is a potential for coercion.

**Autobiography**

Autobiographical research should consider the personal information of second or third parties that may be mentioned in the narrative.  The researcher should consider methods to maintain other individual’s confidentiality such as coding or the use of pseudonyms. If there are no other people interviewed or named in the narrative, ethical review is not required.

**Ethnography**

Researchers who plan to work with First Nations, Inuit or Métis participants should read TCPS 2 Chapter 9. Researchers applying to the REB must be clear about the approach they are taking and the contacts they have already made with the communities or people. Please note that researchers should be aware of OCAP principals in designing studies in Indigenous communities and all appropriate letters of endorsement from communities need to be submitted to the REB prior to study initiation.

 The people being studied have a right to know that they are being studied, what the research is about, what is required of them, and that they have a right not to be researched. Participant observation studies that do not meet the above standard are still possible as long as the relevant group approves the project. For example, spending a year in a remote indigenous community may require the approval of the community council or appropriate authority rather than the approval of each individual. The REB also acknowledges that in some cases it may not be possible to obtain the appropriate approvals prior to arriving at the research site and establishing relationships with members of the community. Fieldworkers need to be specific in their application by outlining their approach to obtaining approval either prior to, or once in, the field.

 The REB recognizes that some anthropological fieldwork is necessarily exploratory in nature. Research methods may need to be altered in the field and information gathered may fundamentally alter the focus of the research. Much anthropological research is based upon long-term relationships developed between researcher and the community being studied, and will therefore evolve over time. Also, the demands of the collaborative research model are such that researchers planning to undertake this type of research cannot have a defined agenda before establishing relationships with the people with whom they intend to work.

 The researcher should describe the type of consent process he/she intends to use and explain why it is the most appropriate method. For example, an oral consent process is clearly necessary in non-literate cultures, with illiterate participants, or where participants perceive a request to sign a formal document as a risk, a lack of trust, or an insult. In the application for ethical review the researcher must, where possible, demonstrate knowledge of the community and its expectations regarding consent and the behaviour of the researcher. If this is not possible, the researcher should outline how he/she plans to determine the appropriate form of consent once in the field.

**Focus Groups**

The investigators should note in the consent process that only limited confidentiality can be offered in focus groups, as they cannot control what other participants do with the information discussed. For example, include a sentence on the consent form that says something like, “We encourage all participants to refrain from disclosing the contents of the discussion outside of the focus group; however, we cannot control what other participants do with the information discussed.”  Please refer to the consent template guidelines for further information.

**Naturalistic Observation**

Naturalistic observation is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the subjects do not know that they are being observed, and hence cannot have given their free and informed consent. As noted in the ‘Studies exempt from review’ section, naturalistic observation studies in public places where there is no expectation of privacy are exempt from REB review. However, due to the need for respect for privacy naturalistic observation in other settings can raise concerns of the privacy and dignity of those being observed.

If your study does not meet the exemption requirements, describe the nature of the activities, the environment, and the method of recording the activities to be observed. If the observation does not allow for the identification of the subjects, it will be regarded as minimal risk. If individuals will be identified you must justify the need for this. For further advice on studies involving naturalistic observation please consult TCPS 2, Article 10.3.

**Photography, Video / Audio Recording**

If there are any plans to use photography (including digital photographs), video or audio recording in the research, those who will have access to the recordings and the methods used to protect the participant’s identity must be described in the consent form. The eventual fate of the records must also be disclosed (i.e. where and for how long they will be stored and whether they will be destroyed, any plans for secondary uses of the recordings). If there are plans to use these materials for any other purpose than the research project (e.g. for teaching purposes) and the participant could be identified, separate consent is required.

If the research includes both audio/visual recording and other methods (e.g., paper-and-pencil questionnaires, interviews), the consent form must specify to which method(s) the respondent is consenting; e.g., some participants may consent to give an interview, but not to having it recorded.

**Photovoice**

Photovoice is a participatory action research method that employs photography and group dialogue as means for marginalized individuals to deepen their understanding of a community issue or concern.  The researcher should describe plans to establish community relationships, educate participants about camera use, obtaining third party consent, limits to confidentiality, participant involvement in data analysis and the planned use of these materials.  The consent and information provided to participants should clearly articulate their roles and responsibilities. Participants will take the role of photographer so they have the responsibility for capturing photos and third party consent of individuals in photos.

**GUIDANCE NOTE 3.3: DATA COLLECTION DURATION AND LOCATION**

Provide details on the planned location of each data collection event and the estimated length of time for each data collection event.

**PART 4: PROJECT DETAILS**

**GUIDANCE NOTE 4.1: INTERNET-BASED RESEARCH**

Describe the venue where the inter-action, communication, etc will take place.  If the researcher is not the creator of the website location, identify the third party owner and the plans for obtaining permission to use data gathered from the site.

**GUIDANCE NOTE 4.1: SECURITY OF DATA**

Describe the security provisions of the internet interaction or website to maintain the confidentiality of participants’ responses.  This may include encryption during storage and transmission, server security, and informing participants to remove “cookies” from the computer. Researchers should check the service provider to understand the type of security provisions that they offer.  Any potential security limitations should be described to potential participants so they understand the level of privacy protection.  Unless using an encryption device, the researcher should assume mail on the internet is not secure.

A potential statement that may be used to describe associate limits to confidentiality:

It is also important for you to know that this web-survey company that is located in the USA, is the host of this on-line research. This company is subject to U.S. laws; in particular, the US Patriot Act that allows authorities access to the records of internet service providers. The web survey company servers record incoming IP addresses - including that of the computer that you use to access the survey. However, no connection is made between your data and your computer's IP address. If you choose to participate in the survey, you understand that your responses to the survey questions will be stored and accessed in the USA.

**GUIDANCE NOTE 4.2: RESEARCH INVOLVING Indigenous PEOPLE**This section should be completed if your research directly involves a community on First Nations, Inuit or Métis Lands, research involves Indigenous people who comprise a sizeable proportion of the study or community or where Indigenous-specific conclusions are intended.

First Nations, Inuit and Métis communities have unique histories, cultures and traditions. They also share some core values such as reciprocity - the obligation to give something back in return for gifts received - which they advance as the necessary basis for relationships that can benefit both Indigenous and research communities.

If the research project involved Indigenous communities or organizations, or Indigenous as an identified participant category, ensure that you are familiar with the TCPS 2 Chapter 9, Research Involving the First Nations Inuit and Métis Peoples of Canada.  The landscape of research involving Indigenous peoples is rapidly changing. Growing numbers of First Nations, Inuit and Métis scholars are contributing to research as academics and community researchers. Communities are becoming better informed about the risks and benefits of research. Technological developments allowing rapid distribution of information are presenting both opportunities and challenges regarding the governance of information.  *(TCPS 2 Chapter 9, Research Involving the First Nations, Inuit and Métis Peoples of Canada.)*

Provide justification for not seeking Indigenous community consent.  Researchers need to provide information that explains why engaging with communities or community leaders is not appropriate within the context of this research.  The researcher could consult culturally relevant regional or national Indigenous organizations for guidance.  *(TCPS 2 Article 3.6 on critical inquiry and Article 9.7 critical inquiry in research involving the First Nations, Inuit and Métis Peoples of Canada)*

Please note that OCAP training is recommended for all researchers doing research in Indigenous communities see: <https://fnigc.ca/ocap-training/>

**GUIDANCE NOTE 4.2.1: COMMUNITY ENGAGEMENT**Communities may be defined in multiple ways and the organizational structure of each community may vary.  The nature and extent of community engagement in a project will be determined jointly be the researcher and the relevant community. *(TCPS 2 Article 9.1 requirement of community engagement, nature and extent of community engagement is determined jointly, Article 9.3 respect for First Nations, Inuit and Metis governing authorities, Article 9.10 Requirement to advise the REB on plan for community engagement)*

Provide justification for not seeking community consent:   *(TCPS 2 Article 3.6 on critical inquiry.)*

**GUIDANCE NOTE 4.2.3: RESEARCH AGREEMENT**A research agreement can serve as a means of clarifying and confirming mutual expectations and understandings.  The researcher, individual participants and the community should have a clear prior understanding as to the agreed expectations with regard to the anonymity of the community and specific individuals.  The agreement should state expectations regarding intellectual priority rights of all parties involved in the research.  The agreement should also address use of the community’s cultural knowl3edge and sacred knowledge. *(TPCS2 Article 9.11 research agreement, Article 9.16 privacy and confidentiality, Article 9.18 intellectual property related to research, CIHR Guidelines for Health Research Involving Indigenous People)*

**GUIDANCE NOTE 4.3: COMMUNITY-BASED PARTICIPATORY RESEARCH**Describe the process and the nature of community engagement with the planned community.  Please see the guidance notes for community engagement for research involving Indigenous Peoples.**GUIDANCE NOTE 4.4: DECEPTION**

In some studies the quality of the data depends on the participants being unaware of the true research goal. A consent procedure that is not fully informed may be allowed as long as the tasks that the participants will be asked to perform are clearly described and the deception is revealed and explained to participants at the earliest opportunity.

Misleading or misinforming people of the nature, objectives or consequences of research must always be explained and justified.  *(TCPS 2, Chapter 3.7 Alteration of consent)*

**Types of Deception**:

Deception by omission: Some part of the purpose of the experiment or nature of the task is not revealed to the participant. For example, a reaction time task that purportedly measures eye-hand coordination but also implicitly measures logical reasoning ability.

Deception by commission: A cover story masking the real purpose of the experiment is given to participants. For example, participants in a study that is investigating the impact of racist attitudes are told they will be involved in testing a new job interview procedure.

Minor deception: Withholding specific points of interest in an attempt to prevent a bias in the results is usually considered minor deception. For example, a study of memory may not reveal to participants that they are specifically being tested on their ability to remember something.   
  
Major deception: Leading participants to believe that they have committed a crime or failed an exam are examples of major deception. Deceptions of this magnitude must be clearly counterbalanced by the benefits of the research and participants must be carefully debriefed.

**GUIDANCE NOTE 4.5: DEBRIEFING**

Deception is considered a risk, as it can negatively impact on a participant’s feelings of trust in the study, in the researcher, and in research. Therefore, whenever deception is to be used, it is important that debriefing be done so as to provide the participant with an opportunity for **real**informed consent. The participant should also be re-consented, or asked whether they wish to have data withdrawn, after debriefing.

It is important that participants have access to study findings. For some populations, it may not be appropriate for dissemination of results to only be accessible in a scholarly journal article format. Please describe the format by which participants can access findings (newsletter, website, copy of thesis material, etc.), and how they will be notified of this.  *(TCPS 2, Article 3.7 research involving partial disclosure or deception)*

**GUIDANCE NOTE 4.6: COMPENSATION**

If compensation is offered, it should not provide undue influence in an individual’s decision to participate in the research. Participants may be duly compensated for time spent participating in the study. When participants represent a particular profession, compensation per time spent may be appropriate. Specify the form and amount of compensation as well as the justification for the amount of compensation to be offered to participants.  A suggestion, to avoid compromising the confidentiality of participants as may be required to comply with financial policies regarding individual payments, is to provide gift cards or certificates as payment.*(TCPS 2, Chapter 3.1. incentives)*

It is expected that whenever possible, participants who withdraw will receive partial compensation.

**PART 5: ESTIMATION OF RISKS AND BENEFITS**

**GUIDANCE NOTE 5.1:**

To evaluate risk for this protocol, please consider:

*Group Vulnerability - i.e.,*any pre-existing vulnerabilities associated with proposed participant groups, e.g. relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status.  *(TCPS 2 Article 4.7 participants’ vulnerability and research)*

Examples of potentially vulnerable groups or populations:

-        Young children;  
-        People in institutions, such as correctional facility;  
-        Persons dependent upon medical, psychological or other counselling;  
-        Homeless persons;  
-        Persons with intellectual, physical or other significant disabilities or impairments that could compromise their ability to give consent;  
-        Persons who may not freely be able to consent without risk of coercion.

*Research risk—i.e.,*the probability and magnitude of harms participants may experience as a result of the proposed methods to be used and types of data to be collected, e.g., relating to physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality). *(TCP2S, Chapter 2, B. Concept of Risks and Potential Benefits)*

Types of minimal risk research qualifying for delegated review:

·        Observational research where there is no intervention by the researchers  
·        Interview or filling in a questionnaire for fully competent adult participants  
·        Anonymous surveys on minimal risk topics  
·        Non-invasive tests on healthy persons

Types of research that may require additional review:

·        Research activity with greater risk to the participant;  
·        Conflict of interest situations, e.g. dual professional and research roles;  
·        Deception;  
·        Use of significant prizes, payments or incentives for participation;  
·        Research involving dependent or unequal relationships in relation to context and impact:

- Professionals researching their clients;  
- Employer or manager researching employees/subordinates;  
- Teachers researching their students;

·        Research on a sensitive personal, psychological, social, legal or professional issues in relation to the context and impact, for example:  
  
                 - Identity – sexual orientation, racial, ethnic;  
                 - Attitudes/practices – drug use, prostitution, pregnancy termination;  
                 - Business/workplace conditions and practices: OHS, workplace bullying or harassment;  
                 - Illegal or potentially illegal activities – mandatory reporting of child abuse, war crimes, terrorism;  
                 - Psychological investigation or exploration of serious conditions such as trauma, grief and loss, addictions, etc.

The point is not that research on such topics should not or cannot be raised, but the activity may require further ethical review by the REB. The TCPS 2 outlines a proportionate approach to research ethics review, the higher the level of risk, the higher the level of scrutiny. *(TCPS 2, Article 2.9 proportionate approach)*

Please consider overall assessments of group vulnerability and research risk (i.e., *low*, *medium*, *high*) and locate the protocol in the matrix, below.

**RISK MATRIX: Review Type by Group Vulnerability and Research Risk:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Research Risk** | | |
| **Group Vulnerability** | **Low** | **Medium** | **High** |
| **Low** | Minimal Risk | Minimal Risk | Above Minimal Risk |
| **Medium** | Minimal Risk | Above Minimal Risk | Above Minimal Risk |
| **High** | Above Minimal Risk | Above Minimal Risk | Above Minimal Risk |

A variety of additional factors might also lead to a project’s being escalated to being assessed as above minimal risk–for instance, if the project is unusual, complex, or large scale, there could be an increased probability of harm and need for close review.  *(TCPS 2 Chapter 2, concepts of risk and potential benefits)*

**GUIDANCE NOTE 5.1.3: MANAGEMENT OF RISKS**

Describe the precautions that have been taken to manage/minimize the risk: Are the risks reasonable in relation to the benefits?  If the protocol has the potential to upset, distress or harm individuals, arrangements to mitigate such effects and the provision for support must be described.

The researcher must, at the outset, advise the participant what support services are available (e.g. University Counseling Services, referral to an appropriate agency or medical clinic).   Whenever possible, the researcher is urged to determine optional services that may be voluntary (e.g. the family physician, other appropriate government/community based agencies) versus fee-for-service options.

**GUIDANCE NOTE 5.1.4: BENEFITS**

Specify the potential benefits to the participants.  If there are no benefits, states this clearly to participants.  If benefits at a community or society level are expected, these should be mentioned. The proportionate approach to ethical review requires that a project have favourable balance of risks and benefits in order to receive REB approval.  (*TCPS 2, Ch 2 Concepts of risk and potential benefits, Ch4, fairness and equity in research participation)*

**PART 6: PARTICIPANT RECRUITMENT**

**GUIDANCE NOTE 6.1: DESCRIPTION OF PARTICIPANTS**

Indicate what the study’s total enrollment will be (i.e., globally across all sites) and how many participants are expected to be recruited at the local site.  Provide the criteria for inclusion and exclusion of participants from the research. *(TCPS 2 Chapter 4, Fairness and Equity in Research Participation)*

Ensure that a justification is provided if subjects are included or excluded on the basis of such attributes as culture, language, religion, race, mental or physical disability, sexual orientation, ethnicity, gender or age. *(TCPS 2 Chapter 4, Appropriate Inclusion and inappropriate exclusion)*

**GUIDANCE NOTE 6.2: EXCLUSION**

Provide a description of any potential participants that may be excluded from participating.  Provide a justification for any exclusion criteria. (*TCPS 2 Articles 4.2-4.7 inappropriate exclusions from participation in research)*

**GUIDANCE NOTE 6.3: METHOD OF RECRUITMENT OF POTENTIAL SUBJECTS**

Provide a detailed description of the planned methods of recruitment. Describe how potential participants will be identified, who will contact them and the manner in which it will be done. *(TCPS 2 Article3.1 the approach to recruitment is an important element in assuring voluntariness)*

Specifically, the REB requires information on how participants are identified and initially contacted to participate in a research study. In particular, this information should include a description of:

a.     the source (i.e. its original purpose, if relevant) of the contact information and an explanation of who you will obtain permission from in order to access this information ;   
b.     who will make the initial contact with the prospective participant;   
c.     how the prospective participant will be initially contacted;   
d.      when the prospective participant will be initially contacted

**GUIDANCE NOTE 6.4: PRINCIPAL INVESTIGATOR EXPERIENCE AND TRAINING**

Who will actually conduct the study and what are their qualifications to conduct this kind of research?  If the research is to involve methods that pose greater than minimal risk, collection of sensitive data, and/or recruiting a vulnerable population, a brief description of the research team’s experiences and/or ability to conduct the research is required.  This could include your familiarity with the proposed methods, the population(s) and the research topic or issues.  If the researcher is a student, the degree of supervision, by the faculty supervisor and/or on-site supervisor should be included.

 The Research Ethics Board requires that all PIs and study team members interacting with participants have TCPS 2 tutorial certification. The TCPS tutorial, Course on Research Ethics (CORE) provides an applied approach to the guidance provides in the TCPS 2 and takes about 4 hours to complete, it does not have to be completed in one sitting and is free.

The TCPS 2 Core can be accessed at:  <https://tcps2core.ca/welcome>

*(TCPS 2 Chapter 2 Balancing risk and potential benefits, Article 4.7 participants’ vulnerability and researchers familiarity with cultural, social and economic circumstances of prospective participants)*

**GUIDANCE NOTE 6.5: RELATIONSHIPS**

Dual roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures.  The relationship, whether pre-existing, current or future, should be described. *(TCPS 2 Article 3.1. undue influence and coercion)*

**PART 7: CONSENT PROCESS**

**GUIDANCE NOTE 7.1: CONSENT REQUIREMENTS**

*(TCPS 2, Article 3.1. voluntary consent, Article 3.3 consent shall be an ongoing process, 3.5 consent shall precede collection and/or access to research data, Article 3.12 consent shall be documented)*

The purpose of a consent process is to provide adequate information of the sort to enable a person to make a rational, informed decision as to whether he/she wishes to participate in the research study, or not.   Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues through study completion/subject withdrawal, and beyond. Any verbal exchange about the study, the written informed consent form and any other written documentation given to participants should provide adequate information for the participant to make an informed decision about his/her participation

 In certain circumstances, written evidence of informed consent is not appropriate. Some examples when it may not be appropriate to use written consent are: (a) when it is culturally inappropriate, (b) when the participant is illiterate, (c) there is a potential risk to the participant.

 Renewal of consent may be appropriate in the context of ethnographic research, community-based research or those studies where participants are interviewed or surveyed on multiple occasions.

**Telephone Surveys:**

If a researcher is conducting a telephone survey, informed consent should take the form of a verbal explanation of the same points covered by written consent. The researcher’s University affiliation, the purpose of the study, the fact that participation is voluntary, the time commitment being requested, and the manner in which confidentiality or anonymity will be guaranteed should be described.

Any combination of the other items on the consent form that might be relevant should also be included. Respondents can give verbal indication of their consent to participate; this should be documented in the researcher’s research records.

For telephone surveys of this type, the "script" that provides the above information must be submitted in your application package.

**Implied consent:**

Implied consent is sometimes used in circumstances where the research risk is low and the researcher does not physically interact with the participant.  This is commonly used in survey research, either internet or paper based.   An information section should precede the survey outlining the elements of consent.

**GUIDANCE NOTE 7.2: COMPETENCE**

In Canada, there is no definitive age below which parental/guardian consent is required in order to participate in research. The age of majority in Saskatchewan is age 18.  Whenever children (under 18 years of age) are to be included as participants, the researcher must consider the risk of the research, the maturity level of the children, and any potential risks versus benefits associated with parental knowledge of the research (e.g. research looking at drug use in youth).

Adolescents that do not live with their parents can consent for themselves. Similarly, university students are considered to be adults, whether or not they live out of the home.

If an adult participant is not competent to formally consent, a surrogate decision maker can do so. However, the research should be explained to the participant, and given the opportunity to provide assent or dissent.

Assent:   Assent means to concur with the decision of another, whereas “consent means to provide permission".  Assent, from children or those individuals who lack the capacity to consent for themselves, should also be obtained, as even very young children can be made to understand simple explanations of what the research involves and determine whether they want to participate or not.

*(TCPS 2 Article 3.9 Capacity, Article 3.10 authorized third party consent and ascertaining wishes of individual, Article 3.11 research directives)*

**GUIDANCE NOTE 7.3: PROJECT RESULTS**

Whenever possible, an offer should be made to provide research participants with feedback on the findings or results of the research.  For community based research, mechanisms to disseminate results to the community are expected.  Provide details on the plan for feedback or explain why it is not appropriate to your research. *(TCPS 2 Article 3.2.f informed consent for dissemination, Article 3.4 incidental findings)*

**GUIDANCE NOTE 7.4: WITHDRAWAL**

What actions constitute withdrawal should be listed. This may include actions of non-compliance by the participant, leading the researcher to withdraw the participant from the study. If participants cannot withdraw after a certain point for any reason (e.g. de-linking of data), this should be explained. *(TCPS 2 Chapter 3.1 consent can be withdrawn)*

**PART 8: DATA SECURITY AND STORAGE**

**GUIDANCE NOTE 8.1: DATA COLLECTION**

Identify both the researcher(s) and their role for anyone who will be collecting data from participants.

**GUIDANCE NOTE 8.2: ACCESS TO ORIGINAL DATA**

Identify all research personnel that will have access to the raw data, which may include information that would identify participants.

**GUIDANCE NOTE 8.3: CONFIDENTIALITY OF DATA***(TCPS 2 Articles 5.1 safeguard information, 5.2 describe measures for meeting confidentiality obligations, 5.3 safeguarding information over the full life cycle of information)*

The TCPS 2 identifies 5 different categories of data collected from research participants, each with different implications for the privacy of participants (see TCPS 2, Chapter 5, P. 56):

* Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
* Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
* Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).
* Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
* Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

**IMPORTANT NOTE:** Unless your data fits the definition of ‘anonymity’ provided in the TCPS, it is usually more appropriate to promise confidentiality than anonymity.

Specify where, how, and for how long the data will be stored.  Documents or files that link de-identified data to their primary source must be stored separately from the study data.

**1)** The principal investigator or the project supervisor should be responsible for the data storage.

**2)** Describe how data security will be maintained during the transportation of confidential information from the site of data collection to the data storage location. Standard measures include password protecting electronic files and storing hard copies of project materials in a locked filing cabinet. Web-based questionnaires must use encryption software.

**3)**Data security refers to the physical, administrative and technical safeguards to safeguard information. Standard measures include password protecting electronic files and storing hard copies of project materials in a locked filing cabinet. Web-based questionnaires must use encryption software.  Data should be stored within a University facility.  Long term storage of student research data after data analysis is complete, should be undertaken by the project supervisor.  Normally this would be in the research office or research laboratory.

**4)**  Each discipline has guidelines for the retention of original data and materials relating to scholarly activity. In the event your discipline has no formalized policy, the **minimum**period for data retention accepted by the REB is 5 years after the work is published or otherwise presented. In some circumstances, it may be appropriate to deposit your data with an archive. This cannot be done without the permission of the participants. Take this into consideration when seeking their consent to participate in your research.

**5)**  Describe the final plans for the original data set.  In some cases, data will be preserved; plans for preservation of material should be described.  Explain whether anonymous data will be archived and the final archival location.  If data will be destroyed, explain how electronic data will be destroyed.

**GUIDANCE NOTE 8.4: DISSEMINATION OF RESEARCH RESULTS**

Describe the intended plans for dissemination of research results.  (*TCPS 2, Article 3.2.f, dissemination of research results and whether participants will be identified directly or indirectly)*  
   
**SECTION 10: APPENDICES**

**Recruitment/Advertisements:**

This includes any type of communication, e.g. flyer, posters, newspaper ad, internet message, email notice, social media post, etc. that is directed to potential participants for the purpose of recruitment.

 The minimum information that should be included in any advertisement is the official title, the principal investigator’s name, affiliation and contact information and indicates the project has REB approval.  The advertisement should not be coercive or ambiguous and should be consistent with information provided in the consent form.

**Letter of Initial Contact:**

The letter of initial contact is initiated by the researcher to provide information about the research project.

**Consent form:**

The consent form is a written, signed and dated document which provides adequate information to enable a person to make a rational and informed decision as to whether they wish to participate in the research study or not.  The consent form must be written in simple, direct language that the participant understands.  It is generally recommended that the consent form be written at a Grade 8 reading level.  The Research Ethics Board generally considers minors attending University who are 17 years of age to be emancipated adults for the purpose of minimal risk research.

 See the consent form guidelines and template.

**Assent form:**

Assent means to agree or concur with the decision of another.  The TCPS states that the assent of a participant is required in situations where free and informed consent has been obtained from an authorized third party, and where the individual substantially understands the nature and consequences of the research.  The language and level of information should be appropriate to the participant.

**Research Tools:**

Attach copies of all relevant study materials.  This includes any non-standard questionnaires, tests, focus group guides, interview scripts, etc.

**Transcript release form:**

When the confidentiality of participants could be compromised, such as using direct quotes that would make them identifiable or culturally sensitive or personally identifiable information is gathered, participants should be given an opportunity to review the final transcript.

There are a number of means to achieve this goal; the method that is chosen should be proportional to the risks entailed by a breach of anonymity and the sensitivity of the information provided.  Researchers who chose options “3”, “4” or “5” below should clarify why the chosen procedure is appropriate for their study:

1.      Participants review the final transcript and sign a transcript release form wherein they acknowledge by that the transcript accurately reflects what they said or intended to say.  A sample form can be found on the UofS website at<http://www.usask.ca/research/files/index.php?id=21>.

2.      Participants review the quotations that will appear in written or oral presentations of the material, and grant permission to the researcher to include those quotations.  This permission should be recorded in writing using a modified version of a transcript release form, a sample of which can be found on the UofS website at <http://www.usask.ca/research/files/index.php?id=21>.

3.      Participants are given the option to review their transcripts or the quotations that will appear in the presentations of the material; the decision to review or to decline to review transcripts should be recorded in writing after their interview.

4.      Participants are clearly told in the consent form that direct quotations from the interview will be reported, and that if, at some later point, they have any second thoughts about their responses; they should contact the researcher, who will remove them from the data base.

5.      Participants are not provided the opportunity to review transcripts.  Depending on the nature of the research, another procedure may be appropriate; researchers should outline this alternative and explain why it is appropriate for their project.The REB recognizes that there are circumstances under which it is not advisable to obtain a transcript release; if this is the case, researchers should explain why the procedure is not appropriate for the proposed study.    
  
**Saskatchewan Health Authority (SHA) Operational Approval form:**

All applications for projects accessing or using SHA resources will not be accepted without a completed SHA Operational/Departmental Approvals Form, available online at: <http://www.rqhealth.ca/department/research-and-performance/operational-approval> ADD SHA site instead

This form must also be completed for internally funded projects that do not involve a direct exchange of money, but rather, are funded through ‘donations-in-kind’ from various departments. It also includes projects that are recruiting potential participants through SHA clinics/departments. Signatures are necessary to ensure that prior to commencement of the investigation, department heads and unit managers have had an opportunity to assess the impact of the proposal on their area.

*(TCPS 2 Article 3.3 consent shall be an ongoing process)*