# Research Ethics Board

# Guide to Completing the Application for Ethical Review Form

This document provides guidance on completing and submitting an Application for Ethical Review. For further information concerning principles and standards of ethical review, see the Tri-Council Policy Statement on Ethical Conduct for Research Involving Human Participants (TCPS2 2018). Example consent forms and other resources are available on the CapU REB Website.

**CONTENTS**

# 1. ADMINISTRATIVE INFORMATION

### 1.1 Title of Research Project

Please make your title explicit and descriptive of the project for which you are applying. Avoid using acronyms in the title.

Note that the Project Title, Principal Investigator name, and funding may be listed in an annual public report provided to the Capilano University Board of Governors or funding agencies. The title given in the application form must correspond to the title on all study documents, including the consent form. If the study is supported by research grant or contract funding, the title should correspond to the title on the grant or contract.

### 1.2 Is this project being completed in partial fulfillment of the requirements of a graduate degree?

This question is to be answered if a student will be earning credit as a result of their involvement in the research, even if the student's supervising faculty is the Principal Investigator.

### 1.3 Is this research subject to the ethical review of another university or organization (e.g. school board, First Nation, etc.)? If 'yes', indicate whether ethical approval has or will be sought, and attach as Appendices details of approval where applicable.

Research can be subject to the jurisdiction of multiple ethical review process. For example:

- Research involving personnel from more than one university is often subject to review by the REBs of multiple universities;
- Research taking place on elementary or secondary school property is often subject to ethical review of School Districts;
- Research conducted in hospitals or medical clinics is often subject to review of regional health authorities; and
- Research conducted on First Nations, Inuit or Métis lands, or involving Indigenous people or communities, may be subject to First Nations, Inuit or Métis review processes.

Researchers should be aware that institutions, communities, organizations, or other groups may have requirements for accessing their sites and for conducting research involving participants with which they are associated. Some organizations – e.g. school districts, Indigenous communities, and correctional services – often have established guidelines for the conduct of research that researchers must follow. The intent of this question is to inform the REB whether the project might be subject to multiple review processes, whether approval from other processes has been sought, and whether approval from other process has been granted. If approval from another review process has been granted, please provide documentation of approval.

**1.4 Is the research funded or otherwise supported by a financial award or in-kind contribution other than personal contributions of the Principal Investigator(s)?** If so, please describe the contribution, including the monetary or in-kind value of the contribution, and how the funding will be spent.

Please indicate if there is funding associated with the project, and if so describe the source(s) of funds and how the funding will be spent.

**1.5 Project Personnel. Please list all project personnel who will interact with participants or haveaccess to data derived from participants.**

**Principal Investigator/s** —The Principal Investigator is typically the leader of a research team who is responsible for the ethical conduct of the research. In the case of student research, and unless the student would be using data collected by their supervisor, the student is to be named as the Principal Investigator.

**Supervising Faculty** – In the case of student research, this section is to indicate the name of the faculty member who will be supervising the student. The REB will not approve student applications unless the Supervising Faculty has been identified.

**Co-investigator/s** – This section is to indicate all other personnel who will be involved in data collection involving human participants.

**Other team member/s** – This section is to indicate anyone else who will interact with participants, or access to the data, including people who would transcribe and/or analyze data.

**1.6 Describe the role of each team member in the research. Include all personnel listed in 1.6, above.**

Describe the role of each of the personnel listed in section 1.5, how they will contribute to the research, and, if applicable, how they will interact with research participants.

**1.7 What steps has/have the Investigator/s taken to prepare for this research?**

Describe the steps you have taken to familiarize yourself with the research topic and methods. For example, describe relevant experience and any preliminary research or community engagement youhave completed to prepare for the project.

## 2. PROJECT DESCRIPTION

**2.1 Using plain language, provide a brief summary of the project purpose, research question/s, methods, and participant population (maximum 500 words).**

This section is to provide a concise summary of the research, particularly aspects involving human participants. The summary should describe *why* the research is being conducted, the research

question/to be answered, *how* the research will be conducted, and *who* will be involved.

**2.2 The following questions are intended to generally describe participants involved in the research.**

The intent of the section is to indicate, in a general way, whether some or all of the participants involved in the research may comprise persons or groups in vulnerable circumstances and/or whether the secondary use of data is proposed. Notes:

- The ability of a person to provide consent is based on their cognitive ability, not their age.
- 'Impaired or diminished capacity' refers to persons with impaired or diminished capacity for self-determination.
- "Secondary use" refers to the use in research of information originally collected for a purpose other than the current research purpose, such as the use of student assignments originally collected for teaching and assessment purposes (see TCPS Articles 5.5A and 5.5B).

## 3. PURPOSE, RESEARCH QUESTION/S, AND KNOWLEDGE TRANSFER

**3.1 What is the purpose of the research?**

Describe why the research is worth doing. What knowledge will be produced? How will the research contribute to the advancement of knowledge?

**3.2 What are the research goals and questions?**

Describe what the research is intended to accomplish. State the research question(s) the project is intended to answer. If the project involves multiple goals, please describe each. If the data generated by this project is to be used as part of a larger research project, please describe.

**3.3 How will the research findings be presented and distributed?**

Please include all methods/ways the results of the research may be published or otherwise shared, such as scientific journal/s, conference paper, conference or other presentation, website, eportfolio, etc.). List all that may apply. If the results of the research will not be published – e.g. "an internal report" – please indicate to whom the report will be provided and how it is intended to be used. Note that all known potential uses of research data collected from participants must be disclosed to participants in the consent process (e.g., consent form).

## 4. STUDY POPULATION AND PARTICIPANT RECRUITMENT

**4.1 Describe the study population/s. Identify any inclusion or exclusion criteria. If the study involves multiple groups, describe each group.**

Please describe the study population, including details such as age range and vocation. If applicable (i.e. if used as a variable in the analysis), please also describe the ethnicity and sex/gender of the study population.

Consider inclusion based on ability rather than arbitrary or historic data (e.g., age of majority). Consult TCPS2 article 4.1 for more information: "Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion."

If you plan to sample from more than one distinct population, please describe each population, including an estimation of each population size.

**4.2 How many people are expected to participate in the study?**
Provide a realistic estimate of the total number of study participants that you expect will be involved in the research. If applicable, indicate the number of participants in each study population, and the number of participants expected to engage with each research technique (e.g., a survey of 50 people, interviews with 20 people, and a focus group of ten people).

**4.3 Will you employ a control group? If so, please describe the control group, including how many participants would be involved in the control group.**

**4.4 Describe the participant recruitment procedure. Include a description of who will initiate contact with prospective participants, where, and how. If recruitment would employ email, please explain how you have or will acquire email addresses of prospective participants.**

Describe how you plan to recruit participants to your study. Describe the recruitment techniques you will use to make potential participants aware of the research and what would be involved. Generally, participants should be made aware of the purpose of the study, the kind of information sought, what participants would be asked to do, the amount of time required to participate, and what would be done with the information collected. Recruitment instruments may include, for example, emails, social media posts, flyers, posters, or verbal scripts detailing how the project will be described to prospective participants verbally. Please submit all recruitment documents as attachments.

Generally, recruitment instruments should describe the purpose of the study, the type of information sought, what participants would be asked to do, what would be done with the information collected, time required to participate, and any inducements involved. Please submit all recruitment instruments with your application. Recruitment instruments may include, for example, emails, social media posts, flyers, posters, or scripts detailing how the project will be described to potential participants verbally.

## 5. STUDY DESIGN AND METHODS

**5.1 Describe in detail exactly what participants will be asked to do. Number steps in order.**

Describe all research activities from the participants' perspective, including any disruption of regular activities, as well as time taken for recruitment, consent, debriefing, and review of data. Indicate whether and how participants might opt out of some aspects of the research while participating in others (e.g., to fill out a survey but decline to participate in a follow-up interview). If multiple activities are being conducted with different groups, explain what each group would be asked to do.

**5.2 Describe the research method(s) you will use to collect and interpret data, including all data collection strategies, techniques, and instruments proposed. Number steps in order.**

Describe all proposed techniques and instruments, such as interviews, survey, focus groups, observation, questionnaire, and data processing techniques leading to production of results. Please attach copies of all research instruments (e.g., interview questions, focus group script/guide, questionnaire, etc.).

**5.3 Indicate the research instruments proposed.**

**5.4 How will data be recorded?**

Describe how data will be recorded, such as by audio recording, video recording, interview notes taken by the researcher, questionnaire answers written by participant, clinical charts, research journal of researcher, etc.

**5.5 Describe the nature of the data to be collected**.

Please describe the nature of the information expected to be collected from participants (e.g. personal opinions/perceptions of participants concerning the subject of inquiry).

**5.6 Are you proposing to collect demographic data, such as participant's age, gender, income, ethnicity, etc.?** If so, describe the nature of the demographic data that would be collected and *why collection of such demographic data is necessary* to address your research purpose and questions.

Please be aware that the collection of the demographic data often raises risk for participants, such as a risk of participants being indirectly identifiable.

**5.7 Where will research activities involving participants take place? Indicate whether this space will be private or public. In employing online tools, indicate the anticipated location where participants would access the online tools.**

Describe the specific locale(s) where research activities involving participants will take place. Indicate the city or town, and precisely where activities involving participants will take place, whether in private space(s) or public spaces, such as public libraries, streets, parks, etc. Be as specific as possible.

**5.8 Indicate the amount of time required of participants to participate in the research. If the study involves multiple stages and/or techniques, please estimate the time required for each.**

Please provide a realistic estimate of the time required of participants to participate in the study. Note that data routinely collected for purposes other than research (e.g. student assignments, patient charts, etc.) would not require additional time from participants in order for them to participate in the research, although their consent to the use of the data may still be required for use of the data collected for other purposes (e.g., secondary use for research purposes). If the study involves multiple stages and/or techniques, please estimate the time required for each stage/technique. Please include in your estimate the time required for participants to read consent information and, if applicable, time required for participants to review transcripts.

**5.9 When do you plan to begin collecting primary data using techniques involving human participants? (Indicate "upon REB approval" for immediate start after REB approval is granted).**

Please indicate the date at which you plan to begin collecting primary data using techniques involving human participants. If applicable, please also indicate when, in relation to engaging with or gaining support of organizations or third parties, you plan to begin collecting primary data.

**5.10 If applicable, describe the transcription process, including who will be involved in the transcription process.**

Describe the transcription processes, such as how and when audio, video, or paper forms would be converted to electronic text. If appropriate, indicate the type of transcription to be used, such as full- or partial-transcription, verbatim transcription, 'intelligent verbatim', etc. Please also indicate who will complete the transcription. Note that if someone other than a study team member will complete the transcription, the REB requires such third-parties to enter into a confidentiality agreement, a copy of which needs to be included with the application for ethical review. If using an online transcription service, please address section 9 and communicate associated risks in the consent form.

**5.11 Does the study involve partial disclosure, withholding of information from participants, or deception? If so, discuss why withholding of information or partial disclosure to participants may be warranted, and how you will debrief participants.**

Some research questions can only be properly answered using a research design that involves partial disclosure or deception. Partial disclosure in research refers to when the nature and intent of the research is only partially disclosed to participants during the consent procedure. Deception in research

refers to when participants are given misinformation about the true nature and intent of the research during the consent procedure. If applicable, use this section of the form to discuss why deception is necessary and describe the information that will be withheld from, or misrepresented to, participants during the consent process. Partial disclosure or deception should only be used when necessary, and where potential benefits of the research outweigh potential harms associated with partial disclosure or deception (see, e.g., TCPS section 3B). If the study involves partial disclosure or deception, a debriefing form is required, a copy of which should be submitted with the application ethical review.

## 6. BENEFITS, RISK, AND RISK MITIGATION

"The principle of Concern for Welfare imposes an ethical obligation to design, assess and conduct research in a way that protects participants from any unnecessary or avoidable risks" (TCPS section 2.B). The TCPS defines "risk" as the possibility of the occurrence of harm. "Harm" refers to any negative effects on welfare, which may relate to the quality of a person's life in all its aspects, including physical, economic, social and emotional health "The level of foreseeable risk posed to participants by their involvement in research is assessed by considering the magnitude or seriousness of the harm and the probability that it will occur…" (section 2.B).

The perspective of participants regarding risk of harm may be different from that of the researcher. Researchers should attempt to assess risk of harm from the perspective of the participants to the extent possible. Some research may present risks that go beyond the individual participant, and may involve risk to the interests of communities or other defined groups (see, e.g. TCPS Chapter 9).

The balance and distribution of risks and potential benefits are critical to the ethics of research involving people (TCPS Section 2.B). The intent of this section is for the applicant to provide the REB with information sufficient to allow the REB to determine whether "the potential research outcomes and potential benefits merit the risks" (TCPS Section 2.B).

**6.1 Will participants directly benefit from participating in the research?** If so, please describe the nature of the benefit/s. Note that the intent of this question is to describe the direct benefit/s to participants, and not to describe indirect benefits such as the development of knowledge that benefits a broader population.

The intent of this section is to indicate whether participants will directly benefit from participating in the research and, if so, how. Note that incentives and inducements are to be described in question 5.6. Answer this question *only if participants themselves* will directly benefit from participating in the research.

For example, research may be designed collaboratively with participants with the intent of identifying and furthering participants' goals (often called "participatory action research"). In these kinds of situations, participants may directly benefit from research that supports these goals.

If there are no benefits, state this explicitly (e.g., "There are no known benefits associated with this research"). If specific benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.

**6.2 Will participants receive financial or other inducement for their participation? If so, discuss the monetary value of the incentive/inducement, and how and when it would be provided to participants.**

The TCPS (2014) defines incentives as "anything offered to participants, monetary or otherwise, for participation in research … Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be large or attractive as to encourage reckless disregard of risks. [Significant] incentives may amount to undue inducement and thus negate the voluntariness of participants' consent" (TCPS Article 3.1).

If applicable, describe and justify the use of incentives, and include a description of the value of the incentive to participants (e.g. monetary value relative to economic standard of living). In considering the possibility of undue influence, researchers are encouraged to consider the economic circumstances of the study population, the age and decision-making capacity of participants, the customs and practices ofthe community, and the magnitude and probability of harms (TCPS Section 4.B).

Researchers frequently offer participants a chance at a prize in a draw. If such a draw does not include those who withdraw from the study, technically it becomes a lottery and is illegal in British Columbia without a license. Consequently, researchers must ensure that participation in the draw is not contingent on participation in the research, and any participants who withdraw must also have the opportunity to have their names included in such draws.

Special care should be taken when offering compensation or prizes in a draw that the method of collecting the prize or entering the draw does not compromise the anonymity of the participant (i.e., if survey data are anonymous then entry into the draw should be through a separate page or by separate email and communication regarding winning the draw should be direct and NOT as a group announcement).

It is unacceptable to have payment depend on completion of the project. However, in some cases it would be acceptable to pro-rate the amount of compensation given to participants who withdraw before completion or to divide the research into stages, with an honorarium attached to each stage.

**6.3 Does the study involve physical invasion of the body, physical distress, or risk of physical distress? If so, please explain and indicate how these will be minimized and managed.**

Answer this question if the research involves having participants engage in physical activity they would

not otherwise be doing, or if the research involves measuring aspects of participants' physicality (e.g. heart rate, BMI, etc.).

**6.4 Does the study involve participants who may be in potentially vulnerable circumstances, or who may be placed in a vulnerable circumstance because of the research? If 'Yes', explain why, and how such vulnerability would be minimized and managed.**

The TCPS (Glossary) defines vulnerability as a "diminished ability to fully safeguard one's own interests in the context of a specific research project." Researchers should seek to understand how vulnerability may arise as a result for participants as a result of their involvement in the research. As stated in the TCPS (Article 4.7), "…individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the groups to which they belong. Their particular circumstances shall be considered in the context of the proposed research project."

**6.5 Is there a professional and/or personal relationship of any kind between any member of the research personnel and any of the participants, such as a relationship between a teacher and student, employer and employee, care provider and care receiver, colleague and colleague, etc.? If so, please describe the nature of the relationship/s.**

Describe any pre-existing relationship between the project personnel and participants. For instance, if the researcher is a teacher conducting research involving their own students, describe the class or course (e.g. grade, subject), and whether and for how long the relationship would continue, or potentially could continue, after the research has been completed (e.g. perhaps the teacher/research teaches multiple grades, or coaches sports teams, and thus the relationship may continue after the research is completed).

**6.6 From the perspective of participants, could there be a real, potential, or perceived conflict of interest any research team personnel with respect to their relationship with research participants? If 'Yes', discuss the nature of the conflict(s) of interest and how it would be minimized and managed.**

Researchers hold trust relationships with participants, research sponsors, institutions, their professional bodies and society. These trust relationships can be put at risk by conflicts of interest that may compromise independence, objectivity, or ethical duties of loyalty. Conflicts of interest may arise from interpersonal relationships – e.g. caregiver-care receiver, teacher-student, employer-employee), economic interests, academic interests, or any other incentives that may compromise integrity or respect for the core principles of the TCPS. In some contexts, researchers may manage a conflict of interest by disclosing it to participants, or by removing themselves or a particular study population from the research. The intent of the section is for the applicant to indicate whether a conflict of interest exists and, if so, describe how the conflict would be minimized and managed.

**6.7 From the perspective of participants, is there a risk that participants might be subject to undue influence to participate in the research? If so, discuss potential sources of undue influence, why it might be warranted, and strategies you propose to minimize and manage it.**

The principle of Respect for Persons poses a duty on researchers to respect the autonomy of individuals to choose whether to participate in research. Undue influence is "the impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority (e.g. doctor/patient, teacher/student, employer/employee)" (TCPS glossary). Researchers who have pre-existing relationships with research participants often occupy dual role positions that may create conflicts, undue influence, and power imbalances that may affect the autonomy of participants to freely consent to participate. It is preferable for researchers to avoid putting themselves in positions in which they may be perceived as exerting undue influence on participants. Where avoidance is not practicable, researchers who occupy such dual role positions – e.g. researcher-therapist, researcher-teacher, researcher-advisor, researcher-employer, etc. – must employ strategies to minimize undue influence.

**6.8 Would the research take place during regular activities such as in a classroom or during a recreational activity, in which some participants in the regular activity might not be research participants? If so, describe how disruption of regular activities will be minimized both for participants and non-participants.**

**6.9 Does the study involve risk of mental/emotional distress, loss of privacy, loss of status, loss of reputation, or loss of professional/employment opportunities? If so, describe the risk/s, why risks might be warranted, and strategies you propose to minimize and manage these risks.**

This section is intended to discuss how the research may negatively affect participants. For example, some research may:

- Prompt (trigger) participants to remember traumatizing events, and thus may impact their emotional well-being;
- Encourage participants to share personally sensitive information about themselves, which may cause participants to worry that the information may be disclosed in the products of the research; or
- Invite participants to provide information that may reflect poorly on people with significant influence on their professional/employment opportunities, such as on their current or potential future employer.

Risk of harm does not necessarily preclude research, provided that there are compelling reasons that warrant the risks involved. Even when warranted, risks need to be acknowledged and communicated to participants, and strategies that minimize risk must be employed wherever possible.

**6.10 Does the research involve potential risk of harm to a community or identifiable social group? If so, describe the potential risks to the community/social group and the strategies you propose to minimize such risks.**

Research may involve risk of harm to a community and/or a defined social group. In some situations, researchers are required to engage with a community's governance structures, such as when engaging with an identifiable Indigenous community. This is particularly the case where research is intended to articulate the views or position of a community concerning particular issues (see, e.g., TCPS Chapter 9).

For example, if the purpose of the research is to ascertain and articulate the position of a First Nations community on, say, land development, the researcher would be required to engage with the governance structure of the First Nation, and would in some cases need to gain the consent of First Nation. This would always be the case if the research was to be conducted on the First Nation's land, such as an Indian Reserve (see TCPS Chapter 9).

A related consideration concerns critical inquiry: that is, where research is intended to analyze perceived shortcomings associated with the institution on which the research is focused. "Where the goal of the research is to adopt a critical perspective with respect to an institution, organization or other group, the fact that the institution, organization or group under study may not endorse the research project should not be a bar to the research receiving ethics approval" (TCPS Article 3.6). In such cases, the consent of the institution may not be required. However, if a researcher engages the participation of people associated with any such institution or group without the institution's or group's permission, the researcher shall inform participants of any foreseeable risks that may be created or exacerbated by their participation (TCPS Article 3.6). Specific requirements pertaining to Aboriginal organizations are discussed in TCPS Chapter 9.

Research involving identified groups often has impacts (both positive and negative) that go beyond individual participants. The REB cautions against analyses that may contribute to stereotyping of groups on the basis of age, gender, ethnic or cultural background, sexual orientation, etc. Therefore, when the study includes specific groups or a range of groups and asks participants to categorize themselves according to age, gender, ethnicity, colour, etc., the researcher must describe the nature of the analysis to be undertaken. Groupings in surveys should be inclusive and at minim allow for a choice of "other."

If the research may be critical of an identified group, participants should be made aware of this risk during the consent process.

**6.11 Is the research likely to reveal information that the researcher has a duty to report in accordance with law and/or profession codes of conduct? If yes, describe the nature of such information and your plan for managing such information should it be discovered.**

The promise made by researchers to maintain participant confidentiality is critical. However, "the ethical duty of confidentiality must, at times, be balanced against competing ethical considerations or legal or professional requirements that call for disclosure of information obtained or created in a research context. For example, in exceptional and compelling circumstances, researchers may be subject to obligations to report information to authorities to protect the health, life or safety of a participant or a third party. Researchers are expected to be aware of ethical codes (such as professional codes of conduct) and laws that may require disclosure of information they obtain in a research context" (e.g., those requiring the reporting of children in need of protection) (see, e.g., TCPS Article

5.1).

For example, all researchers are legally-required to report child abuse to the authorities. Professional codes of conduct may also require reporting of other material incidental findings —for example, health practitioners may be required to report suicidal or homicidal ideation or behaviour to third- parties. In these cases, the well-being of a participant or third-party may be at risk.

Research data may be requested by third-parties, such as law enforcement authorities. If a researcher chooses to protect participant confidentiality, this may put the researcher at odds with legal proceedings.

A famous example of research ethics abutting against legal interests is found in the Russel Ogden case involving Simon Fraser University (http://www.sfu.ca/~palys/OgdenPge.htm). This case demonstrated:

- Researcher-participant confidentiality can be protected in the face of legal proceedings; and
- Research institutions have a duty to support their researchers in maintaining confidentiality, including paying for legal costs.

Limits to confidentiality are to be assessed by the researcher and need to be considered on a case-by-case basis (see TCPS2 Article 5.1 for discussion). Researchers should consider the likelihood of material incidental findings being revealed in the conduct of the research and how they plan to management such information should it be revealed. In research where incidental findings are more likely, researchers should submit a plan to the REB explaining how they will deal with such findings.

## 7. CONSENT/ASSENT PROCESS

**7.1 From whom will you be seeking consent? (e.g., participants themselves, authorized third parties such parents and/or guardians.**

While an authorized third party may grant consent for an individual under their guardianship to participate in research, where practicable and appropriate the researcher is also required to obtain and document participants' assent to participate in research (see, e.g., TCPS Section 3C). In such cases, it may be appropriate for researchers to administer the authorized third-party consent process and the assent process separately, particularly where disclosure of a participant's decision to assent or decline to participate may involve risk of harm.

**7.2 Have you engaged with, or will you be engaging with, communities and/or governance structures with which participants are associated, such as a School District or Ingenious Community/s?** If so, explain how you have or will engage with such organizations and governance structures.

Researchers may be required to engage with the community governance structure/s with which participants are associated (see, e.g., TCPS Article 9.2). If you do not intend to engage or seek permission from a relevant entity, please explain why (see, e.g., TCPS Article 9.10).

**7.3 How will you ensure participants (and/or authorized third parties) are fully informed of the research prior to providing consent/assent?** If different techniques and/or populations require different approaches to ensuring consent is fully informed, please distinguish approaches and indicate how consent will be informed for each population and/or research technique.

Explain how you will communicate the details of the research to participants. Methods for communicating the information would depend on the design of the research. For example, interview-based research typically employs a written consent form. Online surveys typically employ a "consent section" at the beginning of the survey. For in-person surveys, the researcher may in some contexts communicate the details of consent verbally. To some extent the nature of the information to be communicated to potential participants depends on the research methods employed. Generally, and as outlined by TCPS Article 3.2, "the information generally required for informed consent includes:

- a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
- a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
- an assurance that prospective participants:
    - are under no obligation to participate; are free to withdraw at any time without prejudice to pre-existing entitlements;
    - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
    - will be given information on the participant's right to request the withdrawal of data …, including any limitations on the feasibility of that withdrawal;
- information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
- the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
- the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
- an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected,… a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
- information about any payments, including incentives for participants, reimbursement for participation-related expenses …; and

- a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm…"

For consent to be informed, prospective participants must be provided with adequate time and opportunity to understand the information provided, pose any questions they may have, and consider whether they will participate. As stated in TCPS Article 3.2, "the time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed, and the setting where the information is given." Critical to informed consent is that prospective participants understand the information being conveyed to them by researchers. Methods for communicating consent information will depend on the nature of the research, the study population, and other contextual variables, such as the location where participants are engaged, prior relationships of researchers and participants (if any), and considerations related to language and culture of participants.

**7.4 How will consent (and assent, if appropriate) be documented?** If not using a consent form, explain why. If different techniques and/or populations require different approaches to the documentation of consent, please distinguish these different approaches and indicate how consent will be documented for each population and/or research technique.

Consent must be documented (TCPS Article 3.12). Methods for documenting consent will depend on the design of the research. In some contexts it may be appropriate to seek the informed consent of participants for particular aspects of the research, such as for the audio or video recording of interviews, taking pictures, or for the use of quotations in the products of the research. Verbal consent may be appropriate in some situations, such as where culture or custom make a written consent inappropriate. If you are planning to obtain verbal consent, please describe how you will record who has provided consent, when, and where. If you are proposing to use more than one research instrument – e.g. interviews and a focus groups – you will likely need to employ different consent processes for each.

**7.5 If consent will be sought from third parties (e.g. guardian of child/children), will you also seek and document assent of participants themselves? If yes, explain how informed assent will be ensured. If not, explain why assent will not be sought.**

The principles discussed in relation to questions 7.3 and 7.4, above, should be applied to ensure the informed and documented assent of participants who do not have the cognitive capacity to consent for themselves. In some cases, such as those involving young children, the approach should be age-appropriate, and adjusted to suit the cognitive capacity of participants (e.g., an assent form may be less formal and written at a grade 4 level).

**7.6 Will participants and/or authorized third parties be provided a copy of a Consent/Assent Form to keep and, if so, how? If not, explain why not.**

Information on the research should be made readily accessible to participants even after they have provided consent. This can be accomplished by providing a copy of a consent form to participants, or, for example, by providing the information on a publicly accessible website. Please be aware that some online surveys do not allow participants to return to the survey once it has been completed. In such instances, the researcher will need to employ a method for ensuring that participants have access to a copy of the consent information after an online survey has been submitted.

**7.7 How will you ensure informed consent/assent is ongoing, and up until what point in the research will participants be able to withdraw from the study? Please be specific concerning the point in time after which withdrawal would not be possible.**

Ongoing consent refers to participants' right to be provided an opportunity to withdraw throughout the course of the research where practicable, for any reason, and to be informed of changes to the research as they arise (see TCPS Articles 3.1 and 3.3). In some cases, however, the physical practicalities of the research may prevent withdrawal of participants' data. For instance, once submitted, withdrawal from an anonymous online survey would not be possible. The suitability of a proposed approach to ensure consent is ongoing and is relative to the risk of harm involved. If there is a practicable limit to withdrawal, the consent instrument needs to ***explain to participants the point in time after which withdrawal would not be possible***.

**7.8 Will participants be provided an opportunity to review and make changes to the information they provide? If yes, explain the process of participant checking. If not, explain why not.**

When and to what extent participants should be able to review and withdraw information provided will depend on the risks and vulnerability involved. As stated by the TCPS Article 3.1, "to maintain the element of voluntariness, participants shall be free to withdraw … the data they provided, from the research at any time, and need not offer any reason for doing do. In some cases, however, the physical practicalities of the project may prevent the actual withdrawal of the participant."

REBs employ a proportional approach to the assessment of such issues. The higher the risk to participants, the greater the extent to which participants should be provided opportunities to withdraw. Research that places participants in highly vulnerable circumstances may require participants be provided an opportunity to review near-complete drafts of the products of the research, which allows participants to judge for themselves the risks associated with affirming their continued consent. Where the perceived risk of harm to participants is low, providing an opportunity for participants to withdraw up until two weeks after they have provided research information *may* be acceptable.

Concerning matters related to the management of interview data, REBs generally approve protocol in which participants are provided:

- Choice of whether their interview is audio or video recorded;
- Choice of whether their personal identity will be associated with the data they provide;

- Choice of whether they may be directly quoted in the products of the research; and
- An opportunity to review, revise, add, or remove any of their statements from a transcript of their interview such that only the reviewed transcript is used in the research.

Whether transcript review is required is assessed with reference to the degree of risk and vulnerability. The greater the risk and vulnerability, the more likely it is that the REB will require that participants be provided an opportunity to review transcripts.

**7.9 Will the results of the study be made available to participants? If yes, explain how. If not, explain why not.**

The REB encourages researchers to provide the results of their study to participants. For example, study results can be supplied to participants as printed documents, emails, or posted on a website. If participants are anonymous or anonymized, however, the method by which results are provided must maintain anonymity (e.g., website).

## 8. PRIVACY, ANONYMITY, AND ONGOING DATA MANAGEMENT

**8.1 Will information collected from participants, or parts of the information, be treated as confidential?** If applicable, describe the information that would be kept confidential (e.g., personal identity of participants).

Note that 'confidential' means that the information will not be disclosed in the products of the research. Please identify the types of information you will collect from participants that you will not disclose in the products of the research (e.g., the personally identifiable information, such as name). If your consent mechanism allows for participants to choose whether to be identified in the products of the research, please describe (e.g., consent form includes a checkbox for participants to explicitly consent to be identified). Please also consider how the identification of one participant may change the level of risk for other participants

**8.2 Will information provided by participants be anonymous, anonymized, coded, or contain indirectly or directly identifiable information**? If employing multiple research techniques with different levels of anonymity, check all that apply:

Use the checkboxes to indicate how and the extent to which personally identifiable information would be collected and managed. Research employing multiple techniques will likely involve multiple levels of anonymity.

"Anonymous Information" refers only to techniques in which the personal identity of participant is not known to the researcher, such as with an anonymous survey.

"Anonymized Information" refers to techniques in which the personal identity of participants is initially associated with the data they provide but the data is later permanently de-identified. Once anonymized, it is not possible to determine the identity of participants who provided the data except potentially through

indirect identification.

"Coded Information" refers to techniques in which the personal identity of participants is associated with the data but their personal identity is not disclosed in the products of the research.

☐ Anonymous Information: the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is very low.

☐ Anonymized Information: Directly identifiable information is collected and then irrevocably removed from data (so there is no way re-identify data).

☐ Coded Information: Participant names are replaced with a number or pseudonym. A coding 'key' is kept that allows for re-identification of data.

☐ Indirectly Identifying Information: Participants can reasonably be expected to be identified in the products of the research by association.

☐ Directly Identifying Information: Participants would be directly identifiable by through their names, social insurance number, or other direct identifiers.

NOTE: "Anonymous Information" refers only to techniques in which the personal identity of participant is not known to the researcher, such as with an anonymous survey.

Research involves accessing, collecting and using different types of information about participants for which there may be a reasonable expectation of privacy. Researchers (and REBs) need to consider whether information proposed for use in research is personally identifiable. The categories above provide a framework for assessing the extent to which information may be used to identify an individual.

Ethical concerns related to privacy decrease as it becomes more difficult (or impossible) to associate information with particular participants. Ethical concerns related to privacy also vary with the sensitivity of the information and the extent to which disclosure of information may harm an individual or group (see, e.g. TCPS section 5A).

One way to protect the privacy of participants is by employing techniques that collect information anonymously (e.g., on-line survey) or to *anonymize* the information, although this is not always desirable or possible. Another technique is for a trusted third party anonymize the information so that researcher never knows the identity of participants. In some contexts it may be appropriate for personally identifiable information to be irrevocably removed from the dataset by researchers themselves.

Even using such techniques, however, it may still be possible for participants to be indirectly identified. For instance, participant identities may be indirectly identifiable if participants are drawn from a small study population, and/or if the research reveals information that identifies an individual through a combination of indirect identifiers (e.g., vocation, place of residence, unique personal characteristic, or

having particular knowledge). If such risks exist, they need to be communicated to participants as part of the informed consent mechanism.

**8.3 If you checked multiple checkboxes in question 8.2, please explain which level of anonymity would apply to which research technique** (e.g., "the online survey would be anonymous; the interviews would be coded.")

For example, if the research involves an anonymous online survey and interviews in which participants would choose whether to be identified, an appropriate answer would be as follows: "The online survey would be anonymous. The interviews would be either coded or directly identifiable, in accordance with the preference of each participant."

**8.4 Do you plan to use direct quotations from participants in the products of the research?**

The REB encourages researchers to provide an opportunity for participants to explicitly consent to be quoted in the products of the research, such as by using a checkbox on the consent form.

**8.4 Do you plan to directly quote participants in the projects of the research? If so, how will you attribute quotations? (e.g., will you use real names of participants, pseudonyms, or alphanumeric codes).** If employing multiple techniques, please explain how quotes would be attributed for each technique.

The REB encourages researchers to provide an opportunity for participants to explicitly consent to be quoted in the products of the research, such as by using a checkbox on the consent form.

**8.5) To what extent would the identity of participants be directly or indirectly identifiable in the products of the research?** Describe the information that would be disclosed that might result in participants being indirectly identifiable (e.g., geographic location, vacation, employer, etc.).

Please explain whether and how participants might be directly or indirectly identifiable in the products of the research for each research technique proposed.

For example, if the research involves an anonymous online survey and interviews in which participants would choose whether to be identified, an appropriate answer may be as follows:

"Online survey participants would be neither directly nor indirectly identifiable." Interview participants would be either coded or directly identifiable, in accordance with the preference of each participant. Participants who choose not to be directly identified may be indirectly identifiable.

**8.6 Describe where and how research data, including consent forms (if applicable), will be stored and secured, and who will have access to the data.** Describe the hardware devices that will be used for the storage of data, and how these devises will be secured (e.g. smartphones, laptops, shared computers, "cloud" storage, USB drives, etc.).

Please describe how data collected from participants will be stored and secured throughout all stages of the research. If the study involves different multiple study populations and/or techniques, and these require different approaches to data management and protection, please describe each approach. Please account for all of the different types of data collected or generated by the study. Please specify the media involved.

**8.7 Will research data be destroyed after completion of the study and, if so, how and when will the data be destroyed?** Please specify the media involved (e.g., paper or electronic data) and what will be done with each, including consent forms if applicable.

According to TCPS (Section 5.3), "...appropriate data retention periods vary depending on research discipline, research purpose and the kind of data involved... Similarly, some funding bodies, such as the Social Sciences and Humanities Research Council and the Canadian Institutes of Health Research, have specific policies on data archiving and sharing." Please specify the media involved (e.g. paper or electronic data) and what will be done with each, including consent forms if applicable.

## 9. THIRD PARTY SERVICES PROVIDERS

**9.1 If applicable, indicate which internet-based services will be used to collect, store, and/or analyze your data, and where their servers are located.**

Researchers are responsible for identifying and disclosing to participants all potential data security issues associated with the study, including those associated with the use of internet-based services. Because internet services that are based in foreign countries are subject to foreign legislation, choice of internet-based services may be a factor in assessing the risks involved. If applicable, please indicate the internet service you will use, and where its internet servers are located. Internet-based services may include, for example, automated transcription services, on-line survey platforms, video conferencing, cloud-based storage, etc.

**9.2 If applicable, indicate how you will ensure that participants are made aware of any privacy and/or confidentiality issues related to use of internet-based services.**

As part of the consent process, researchers are required to inform participants of how research data will be managed, and this includes informing participants of data security and privacy issues associated withthe use of third-party service providers. In the case of an on-line survey, for example, one way to communicate the necessary information is to include it at the beginning of the on-line survey. For example, consent information may include a statement to the effect that:

"[Company name] will be used to collect your survey responses. Survey data will be stored on [company name] servers located in [country/s where located], and thus is subject to [company name] data privacy

policies and foreign legislation. For information on [company name] privacy policy, see [URL link to company's privacy policy]. I will download and delete all survey data from [company name's] servers not more thantwo weeks after completion of data collection, which I expect will be [date]. I will not collect any personally identifiable information, including Internet Protocol (IP) addresses. Please note that because [company name] stores data on servers located outside of Canada, data you provide will not be protected by Canadian privacy legislation, may beaccessed by foreign government/s in accordance with its/their laws."

Describe the proposed strategy to inform participants of risks associated with all proposed online service providers.

**9.3 If using on on-line survey instrument, provide the URL (website link) to the survey.**

If using an online survey platform, please provide a URL to the fully develop research instrument (e.g. online-survey). Tips for developing an on-line survey:

- Include a consent question at the beginning of the survey - a question that asks participants whether they have read and understood the consent information, and whether they agree to participate under those terms;
- Provide participants with the option of declining to answer any specific questions (i.e., no mandatory questions);
- Be aware that collection of IP addresses undermines anonymity. If the survey is advertised as "anonymous", no IP address should be collected. Similarly, the use of "tokens" negates anonymity; and
- Be aware that some service providers retain data even after the researcher "deletes" the data. Read the data retention and privacy policies of the service provider you are using, and ensure that the information you communicate to participants is accurate.

## 10 SECONDARY USE

**Complete this section only if you propose to use data that was originally collected for a purpose other than the research for which you are applying for ethical review (see TCPS Articles 5.5A and 5.5B for information on secondary use).**

**10.1 For what purpose was the 'secondary use data' originally collected?**

Describe the purpose for which the data was originally collected, such as program evaluation, teaching and learning, or other activity not related to the research for which you are applying for ethical review.

**10.2 Describe the 'secondary use data' for which you are applying to use in accordance with TCPS Articles 5.5A and/or 5.5B on secondary use.**

Please describe the data that was originally collected for a purpose other than the research for which

you are applying for ethical review, such as comments submitted anonymously by an employee during a program review, former student assignments, etc. (see, e.g., TCPS Articles 5.5A and 5.5B).

**10.3 Describe the population of people from whom the 'secondary use data' was collected.**

Describe the population from whom the data was originally collected (e.g., patients enrolled in a program supervised by the researcher; students who attended a class taught by the researcher, etc.).

**10.4 When was the 'secondary use data' collected?**

Describe the time period in which data was collected.

**10.5 Did the people who provided the 'secondary use data' consent to the data being used for research purposes?**

Indicate whether the people who provided the data provided their informed consent to use the data for research purposes.

**10.6 If the answer to question #10.5 is 'yes', please describe the mechanism by which consent was informed and documented.**

If a consent form was used, please attach a copy of the consent form that was used.

**10.7 If the answer to question #10.5 is 'no', please indicate whether you propose to seek consent to use the data for research purposes, and, if so, how. If you propose not to seek consent, please explain why not.**

If you are proposing to use a consent form, please attach a copy of the consent form.

## 11. CONFLICT OF INTEREST DECLARATION

Participants must be informed of any potential, perceived or actual conflict of interest as part of the consent process. Note that patent/property rights or holdings of immediate family members also constitute a conflict of interest for the PI and/or other members of the study team. "Immediate family members" includes partners and children (whether living in the household or not).

## 12. ATTACHMENTS

Please be aware that almost all research projects require at least three instruments: 1) a recruitment instrument; a consent instrument; and 3) a research instrument. Please see REB website for example consent forms.

## SUBMISSION

Submission of an application to the REB constitutes a commitment of the Principal Investigator to adhere to the ethical protocol described therein. Once approved, the application, including all appendices, becomes the ethical protocol with which the research must comply.

If any significant aspect of the research changes, the Principal Investigator must apply to the REB to amend the protocol. Significant changes include, but are not limited to:

- Change of project personnel;
- Change in study population;
- Change in methods;
- Change in documented consent procedure; and
- Change in data management procedures.

**TIPS**

**Please carefully review your application for completeness and consistency prior to submission. The following issues often delay REB approval:**

- Missing appendices, such as recruitment instruments (emails, flyers, scripts), interview questions, and consent forms;
- Inconsistency among the application form and appendices (e.g., the application acknowledges risks but the consent form does not;
- Missing information on how and when (up until what point in times) participants can withdraw; and
- Inconsistent or inaccurate use of key terms, such as “confidential”, “anonymous”, “anonymized”, and “coded”.