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).

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 Principle Investigator.

1.3 Is this research associated with a university other than Capilano University, or another institution or organization such as a school, agency or First Nation/s? If yes, describe the institution or organization and the nature of the association

This question is to be answered if the research will involve another university in any way, such when the research involves faculty or students associated with another university. This question also to be answered if the research is associated with another intuition or organization, such as a school or First Nation. If this question is answered in the affirmative, then the answer to question 1.4 is likely "yes".

1.4 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 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 Aboriginal 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, Aboriginal 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.

1.5 Is this research funded? If 'yes', indicate the source(s) and expected duration of the funding (specific agency, institution, corporation, etc.).

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

1.6 Project Personnel. Please list all project personnel who will interact with participants or have access to data derived from participants.

> **Principal Investigator/s** — While it is possible to have multiple Principal Investigators, the Principle 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 utilizing data collected by their supervisor, the student is to be named as the Principle Investigator.
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> **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.

1.7 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 1.6, how they will contribute to the research, and, if applicable, how they will interact with research participants.

1.8 What steps has/have the Investigator/s taken to prepare for this research? Describe relevant experience, courses, and any preliminary research and/or community engagement completed to prepare for this project.

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 you have completed to prepare for the project.

2. PROJECT DESCRIPTION

2.1 Using lay language, provide a brief summary of the project purpose, research question/s, methods, and participant population (maximum 200 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.

2.3 Describe, listing major all steps and procedures, how the research will be conducted. Number the steps in chronological order.

Use this section to describe the research process, particularly aspects of the research involving participants. Please number the "steps" in chronological order to the extent possible (there will likely be some overlap between steps).

If applicable, please provide details of peer review, including names of committees or individuals who have reviewed the methodology. If your study involves deception or withholding of information, please describe (and submit a deception form, located on the REB website).

2.4 Indicate the research techniques and instruments proposed (please submit the recruitment instrument, consent instrument, and research instrument as appendices to this application).

Check off any and all methods of data collection. Note that different research techniques raise different ethical risks and issues, and the consent mechanism must be tailored to the research technique. If different techniques are to be used with different participant populations, please distinguish which techniques will apply to which participant populations.

See, e.g., example consent forms on the REB website. See, also, section 7.8 below, for information on use of third party service providers such as online survey platforms.

2.5 Where will research activities involving participants take place? Indicate whether this space will be private or public.

Describe the community(s) and 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 (participants' homes, business offices) or public spaces (e.g. public libraries, streets, parks), etc. Describe in as much detail as possible (e.g., institution, campus, room) where you will recruit participants and collect data. If surveying online with no face-to-face interaction please enter "Online only."

2.6 Project Period (enter "upon REB approval" for immediate start after REB approval is granted)

Specifically, when do you plan to recruit participants and collect data? If there will be no delay following approval, enter "upon approval" under Start Date. REB approval is valid for one year following approval. If your data collection is anticipated to end earlier or extend longer than one year, enter your estimated last day to collect data under Estimated End Date.

2.7 How will the research findings be presented and distributed? (e.g. graduate thesis, conference, journal article/s, report, course paper, etc.)

Please include all methods/ways the results of the research may be published and shared, such as a scientific journal, conference paper, conference or other presentation, Masters thesis, masters project, 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 distributed and how it is intended to be used. If research findings will not be make publically available, describe who will receive the products of the research.

3. STUDY POPULATION AND PARTICIPANT RECRUITMENT

3.1 Describe the study population. Describe any inclusionary or exclusionary criteria, such as age range, vocation, community of practice, or ethnicity. If you are sampling more than one population, please describe each.

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.

3.2 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).

3.3 If applicable, how many participants are expected to be in the control group?

3.4 Describe the recruitment process. How and by whom will participants be recruited?

Describe who and how contact with prospective participants will be intimated, the relationship between the recruiter and participants, if any, and by what means this will be done.

If the initial contact is by letter, email, posted recruitment notice, or verbal script, attach the recruitment instrument as an appendix. If by email, describe how you have accessed the email addresses of people you propose to contact.

Generally, participants should be made aware of the purpose of the study, the kind of information sought, what participants would be asked to do, and what would be done with the information collected. 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.

Privacy legislation prohibits third parties from providing contact information of others without their consent. Recruitment invitations may be forwarded by others to prevent sharing of private information, and snowball-type recruitment ideally involves participants passing on the invitation to other potential participants.

Note that the REB discourages initial contact by telephone. However, surveys which use random digit dialling may be allowed. If your study involves such contact, you must also complete the 'Telephone Contact' form.

Please submit all recruitment instruments with your application.

4. CONSENT/ASSENT PROCESS

4.1 Consent mechanism

a) How will consent be sought and documented

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:

- information that the individual is being invited to participate in a research project;
- 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 of 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.

Consent must be documented (see TCPS Articles 3.13 and 10.2). Methods for documenting consent will depend of 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. Please provide details of each consent processes you plan to use.

b) From whom will consent be sought (e.g. from participants themselves, from a legal guardian, or both)?

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 record participants' assent to participate in the research. 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.

c) 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 sections 8.3 and 8.4, above should be applied to ensure the informed and documented assent of participants. In some cases, such as those involving young children, the approach should be age-appropriate, and adjusted to suit the maturity of participants.

d) If applicable, will you modify the consent mechanism to accommodate participants who lack or have diminished capacity to consent (e.g. age appropriate language in consent form)?

e) Who will seek consent?

Identify the Research Personnel who will manage the consent process, or describe if the consent of participants will be managed by a third party.

4.2 Have you engaged with, or will you be engaging with, organizations or institutions with which participants are associated, such as a schools, businesses, or First Nations? If so, explain how you have or will engage with such organizations and institutions.

In some cases the researcher may be required to engage with and, in some cases, acquire the consent of a company, institution, or community's governance structure (see, e.g. TCPS Article 2.11 and Chapter 9.

4.3 Will participants be provided an opportunity to review, make changes to, and/or withdraw data they provide (e.g. transcript of their interview)? If "yes", describe the process of participant checking, including how and when will the data will be provided to participants?). If "no", 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 to an opportunity to review near-complete drafts of the products of the research, which allows them 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 approves protocol in which participants are provided:

1. An opportunity to choose whether their interview is audio or video recorded;
2. An opportunity to choose whether their personal identity will be associated with the data they provide;
3. A opportunity to choose whether they can be directly quoted in the products of the research; and
4. If participants agree to any of the above, they have an opportunity to review the transcript of their interview, and an opportunity to revise, add, or remove any of their statements from their interview transcript.

Whether the fourth component (above) is required is assessed with reference to degree of risk and vulnerability of circumstance: the greater the risk and vulnerability, the more likely it is that the REB will require the fourth component (above).

4.4 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?

Ongoing consent refers to participants' right to be informed of changes to the research as they arise, and to be provided an opportunity to withdraw throughout the course of the research where practicable, for any reason. As stated in TCPS Article 3.1, "to maintain the element of voluntariness, participants shall be free to withdraw their consent to participate, and 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."

For instance, where participation is anonymous or anonymized (see definitions in section 10.2), it would be impossible to withdraw a particular participant's data. Once an anonymous online survey is submitted, for example, it is impossible for a participant to withdraw their data because there would be no way to identify the data was provided by the participant.

Other circumstances provoke questions concerning when, in the course of a study, withdrawal may become impractical. Generally, such issues are judged with reference to the likelihood and potential magnitude of risk of harm to participants. The higher the risk to participants, the greater the extent to which consent needs to be ongoing. For instance, in cases where the research creates circumstances in which participants are highly vulnerable, it may be appropriate to provide participants an opportunity to withdraw from the study right up to immediately prior to publication of the study results. Some research protocol require that participants have an opportunity to review a near-complete draft of the products of the research, which allows them to judge for themselves the risks associated with their participation. In other circumstances, where the perceived risk of harm to participants may be low, a research protocol may only require that participants have an opportunity to withdraw until two weeks after they have provided research information. The suitability of a proposed approach to ensuring ongoing consent is relative to the risk of harm involved. Regardless of the approach taken, the informed consent process needs to explain to participants any limits to their withdrawal.

5. 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).

5.1 Benefits. Describe any potential *direct* benefits to participants.

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.

5.2 Will the results of the study be made available to participants and the organization with which participants are associated? If so, 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).

Whenever possible, an offer should be made to provide research participants with feedback on the findings/results of the research. Please provide specific details on how such feedback will be provided or an explanation of why it is not appropriate to your research. In the context of community-based research, mechanisms to disseminate results to the community should generally be demonstrated.

Please describe your communication plan such as an invitation to send participants a summary of the results when available or invitation to a seminar. If there are any restrictions imposed on disclosure of feedback or other information to participants, including publication of results, please describe.

5.3 Impact on Community or Organization. If your research may have a positive or negative impact on a specific community, group, or organization, please describe.

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

For instance, if part of the stated purpose of the research is to ascertain and articulate the position of an institution, such as a company, on, say, its hiring practices, the researcher may be required to engage with the governance structure of the company, and sometimes gain the consent of the company prior to interviewing participants of the company. This would always be the case if the research was to be conducted on the company's property.

To provide another example, if the stated 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.

5.4 Risks.

a) Please identify any known or anticipated risks to participants, such as risk of mental or emotional distress, loss of privacy, loss of status, loss of reputation, or loss of professional or employment opportunities?

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

- Prompt (trigger) participants to remember traumatizing events, and thus may impact their emotional wellbeing;
- 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;
- 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.

These are just a few ways research may inadvertently cause harm to participants. 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 need to be employed wherever possible.

b) Explain why these risks might be warranted.

c) Indicate how these risks would be minimized and managed.

Almost all research involves some risk. The intent of this question is to prompt applicants to describe the risks involved, and to propose strategies to minimize and manage these risks. For example, the following are commonly-employed strategies for minimizing risk:

- Anonymizing data, so that the products of the research do not directly or indirectly disclose the identity of participants;

- Providing participants the ability to withdraw their data, or portions of their data, if they believe that use of the data may cause negative impacts on them.

5.5 How much time will participants dedicate to the project? Please describe the time required in terms of number of visits, tasks, and minutes/hours per visit/task, as applicable.

5.6 Describe any compensation or inducement being offered to participants, such as reimbursements for expenses, medication, honoraria, gift cards, etc. Indicate the monetary value associated with any inducements.

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 of the 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 confidentiality of the participant (i.e., if survey data are anonymous then entry into the draw should be through a separate, un-linked page or by separate email and communication regarding winning the draw should be personal 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.

5.7 Is there a professional and/or personal relationship of any kind between any of the project 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.? Please explain 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).

5.8 Data collection may produce material incidental findings; that is, unanticipated discoveries having significant welfare implications for the participant or third parties. Is this study likely to produce incidental findings? If so, describe your plan to manage incidental findings (see, e.g., TCPS Article 3.3).

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. One's own professional codes of conduct may 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.

In other cases, research may produce incidental findings in the form of knowledge about illegal activities. There is no law that requires anyone to report criminal behaviour, except in the case of child abuse as noted above. However, research data may be requested by third-parties, such as the police. 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 in the context of the research on a case-by-case basis (see TCPS2 Article 5.1 for discussion). In this section of the

application form, researchers should consider what the chances are that material incidental findings may be revealed and how they anticipate dealing with such a situation.

In research where incidental findings are more likely, researchers should submit a plan to the REB explaining how they will deal with such findings, including how they will arrange for participants to consent to receiving the findings.

6. CLINICAL STUDIES (complete this section only if the research is clinical in nature)

6.1 What procedures in this project (e.g. diagnostic procedures or other treatment) involve an experimental approach differing from standard patient care or practice? Are any of the procedures, devices or diagnostic tests used in this study still in the experimental stage? If so, please specify and identify the known or anticipated risks.

Are any of the procedures, devices or diagnostic tests used in this study still in the experimental stage? If yes, please specify and identify the known or anticipated risks related specifically to these procedures, devices or diagnostic tests.

6.2 For clinical research involving medical devices, drugs, or health products, please describe the status of approval with Health Canada and attach documentation from the Health Products and Food Branch of Health Canada.

For Registration of Clinical Trials If there is any possibility of the intent to publish the results of the study in an ICMJE (International Committee of Medical Journal Editors) member journal, and it falls under their definition of a clinical trial (which includes behavioural treatments, dietary interventions and process-of-care changes), the study must be registered BEFORE it is started (but not necessarily before ethical approval is granted).

6.3 If applicable, provide details of any possible side effects resulting from the experimental treatment.

Quantify the foreseeable risks of harms (side effects) or inconveniences (discomfort to incapacity) to the participant associated with each procedure (including radiation risks from X-rays, therapy, test, interview or other aspect of the study). Quantification should include information about the seriousness and consequences of the different types of adverse events that have been observed, as well as the probability of these events occurring. Quantification of these harms should emphasize the incremental risk with the experimental intervention as compared to placebo or no treatment, wherever possible.

It is generally acceptable to provide a qualitative description of the risks associated with standard blood drawing (venipuncture). For example, the consent form should state that the side effects of blood draw include pain and/or discomfort, bruising, fainting and/or light-headedness, and the rare possibility of infection.

List risks in descending order of frequency and/or to group them according to category of risk (e.g. by magnitude, severity, organ system, etc.).

Where no percentages are available, specific discussion about risks encountered in case series/case reports, preclinical studies or studies involving similar drugs or procedures are required. If absolutely no relevant data about harms of the experimental procedures is available (e.g. a Phase 1 trial), Investigators are required to make their best effort to honestly inform participants about possible risks of participating in the research, even if they cannot be quantified. This quantification can be in the form of "for thirty participants, five experienced a particular side effect". This information must always be included in the consent form.

The consent form must include an explanation that unanticipated side effects, including severe or irreversible ones.

6.4 Diagnostic procedures may produce material incidental findings; that is, unanticipated discoveries having significant welfare implications for the participant or third parties. Is this study likely to produce incidental findings? If so, describe your plan to manage incidental findings (see, e.g., TCPS Article 3.3).

Incidental Findings can be defined as unanticipated discoveries made in the course of research but that are outside the scope of the research. Material Incidental Findings are those incidental findings that may impact the welfare of participants, e.g. health related, psychological or social. This includes perceived abnormalities found on clinical research scans and tests as well as unexpected psychological or social findings.

In research where incidental findings are more likely, researchers should submit a plan to the REB explaining how they will deal with such findings, including how they will arrange for participants to consent to receiving the findings. Researchers must disclose any material incidental findings discovered in the course of research.

6.5 What are the plans for future use of the project data or biological samples beyond that described in this protocol? Will the data or samples be kept in a database or registry for future research? How and when will the data be destroyed?

Describe any known future use of the data beyond the conclusion of this research project, and indicate whether participant consent will be obtained in the current consent procedure or the participant will be contacted later to obtain consent. Either possibility must be described in the consent process. If consent is to be obtained now, the future use of the data must be described in full in the consent form included with the current application. If consent for future use of the data is to be obtained later, full details, including the consent form, must be submitted to the REB for review and approval before the research begins.

Original data for a given study should be retained in the unit of origin for at least five years after the work is published or otherwise presented (if the form of the data permits this, and if assurances have not been given that data would be destroyed to assure anonymity).

This means original data should be stored for at least 5 years after the study results have been published or otherwise presented, but may be retained for a longer period provided that they are stored securely. If this 5 year period, destruction of the data is the best way of ensuring that confidentiality will not be breached. Please note that the responsibility for the security of the data rests with the Principal Investigator.

In some cases, data are of such value that they should not be destroyed – (for example: oral history interviews). In these cases, please describe your plans to preserve this material. The consent process should outline these plans and describe how and when it may be appropriate for others to have access to this information.

7. DATA COLLECTION AND MANAGEMENT

7.1 Will you use data collected from human participants that was collected for purposes other than the research (e.g. prior studies, school records, etc.). Is this data publically available? If not, how and from where will this data be acquired? Does the data contain personally identifiable information? See, e.g., TCPS Article 5.5A.

This question refers to data that would be collected regardless of whether the research was conducted, which may include, for example, student records or grades, clinical charts, etc. While data collected primarily for purposes other than the research may be used for research in some situations, unless the data are publicly available or contain no personally identifiable information, use of such data generally requires the consent of those who provided the data where practicable. Student records or grades, for example, are collected primarily for administration and not for research. Permission to use this information for research purposes may require researchers to obtain consent from students or guardians where practicable (see, e.g., TCPS Articles 5.5-5.7).

7.2 Describe the nature of the primary data to be collected (e.g. personal opinions of participants concerning subject of inquiry, test results, product of classroom activity, observations of Investigator, etc.)

In addition to a general description based on the technique/s employed, please describe in detail the nature of the data to be collected (e.g. personal opinions/perceptions of participants concerning the subject of inquiry).

7.3 How will data be recorded?

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

7.4 Level of anonymity.

Researcher 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 following categories provide a framework for assessing the extent to which information may be used to identify an individual:

LEVELS OF ANONYMITY
Directly Identifiable Information – The information identifies a specific individual through direct identifiers, such their name or an easily identified employment position within a company.
Indirectly Identifiable Information – The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. place of employment, unique personal characteristic, specific knowledge).
Coded Information – Direct identifiers are removed from the information and replaced with an alphanumeric code or pseudonym. 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' codes with their actual name so data can be re-linked if necessary). Note that coding of information is no guarantee of anonymity where indirectly identifiable information is not also removed from products of the research.
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 from indirectly identifiable information is low or very low. To be anonymous, no one, not even the researcher, knows the identity of participants.

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 to for a trusted third party anonymize the information so that research

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.

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.

Patient Interviews

The research team should be aware that the patient as a research participant may think that they have given vital information during an interview to their health care providers, when in fact the information is not passed on by the researcher. The researcher's actions on this issue must be communicated clearly in the consent form.

Focus Groups

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."

7.5 For research involving coded information, describe how and by whom coded data will be managed. Where and how will the code be stored? Under what circumstances would the code be used to re-identify information?

7.6 Do you plan to directly quote participants? If so, will you attribute quotes to particular participants and, if so, how will you distinguish quotations belonging to different participants? (e.g. using the real names of participants, pseudonyms, or alphanumeric codes).

Please indicate if you plan to directly quote participants, if you plan to associate particular quotes with particular participants and, if so, how. Please refer to section 7.4, above, concerning level of anonymity.

7.7 Who will have access to the data at each stage of the research? How they will be made aware of their responsibilities concerning privacy and confidentiality (e.g., confidentiality agreement)?

Please list personnel, their roles, and at what stage of the research they will access the data (e.g., Investigator, research assistant, transcriptionist, translator, etc.). Research participants must also be informed in the consent process who will have access to the data they provide and what use will be made of it, either now or in the future.

7.7 How and where will research data and consent forms be stored (e.g., files on computer hard drive, hard copy, videotape, audio recordings, mobile phone, etc.)?

Please describe how data collected from participants will be stored and secured throughout all stages of the research. If the study involves different research population and/or techniques, and these require different approaches to the storage and protection of information, please describe for each population and/or technique. According to TCPS Article 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.

7.9 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 and privacy 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.

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 with the use of third-party service providers. In the case of 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 is being 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 than two 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 be accessed by foreign government/s in accordance with its/their laws."

8. 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).

9. ATTACHMENTS

Please see REB website for example consent forms.

SUBMISSION

Please be aware that submission of an application to the REB constitutes a commitment of the Principal Investigator to adhere to the ethical protocol described herein. 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. These are examples of issues that would 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;
- Failure to acknowledge and manage risks;
- 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”.