



Research Ethics Board

## WHEN TO APPLY

BCIT maintains its eligibility to receive federal funds from the Tri-Council Agencies (NSERC, SSHRC, CIHR) through application of the Tri-Council Policy Statement (TCPS2) "Ethical Conduct for Research Involving Humans." The application of these guidelines at BCIT is described in detail in BCIT Policy 6500 and its procedures (<https://www.bcit.ca/about/administration/policies.shtml>).

Whether or not the research is funded by BCIT or Tri-Council Agencies, BCIT is required to review and approve research "under its auspices" involving living human participants or involving human biological materials (from living and deceased individuals) if:

- (a) any of the researchers are associated with BCIT,
- (b) any of the participants are associated with BCIT,
- (c) any BCIT resources are used in the study.

If your study is designed to answer a research question and not primarily for internal BCIT use (e.g., curriculum development, program evaluation, or to improve quality), then it is probably defined as research under TCPS2 and should be reviewed by the REB before you start to collect data. "Human participants" include human biological materials.

It is much more difficult to get consent from participants after the data has been collected and therefore important to apply for REB approval if you anticipate that data from curriculum development, program evaluation, or quality studies might be used in the future to answer a research question or published in a journal that requires documentation of ethics approval. In such cases, only data that was collected anonymously and can not be traced back to a participant is exempt from review. All other secondary use of data requires REB review and may involve consent (<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1d>).

## Exemptions

- Ethics review is not required for research that relies exclusively on publicly available information when: the information is legally accessible to the public and appropriately protected by law; or the information is publicly accessible and there is no reasonable expectation of privacy ([http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2\\_en\\_a2.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.2)).
- REB review is not required for research involving the observation of people in public places where: it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; individuals or groups targeted for observation have no reasonable expectation of privacy; and any dissemination of research results does not allow identification of specific individuals. ([http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2\\_en\\_a2.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.3)).
- REB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information

([http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2\\_en\\_a2.4](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.4)).

- Quality assurance and quality improvement studies, program evaluation activities and performance reviews, or testing within normal education requirements are also exempt from review. These activities are within the mandate of such organizations and are generally administered in the ordinary course of their operations. Although QA/QI activities often look research-like, and may contain methods used in research studies (e.g., surveys, interviews, etc.), because the purpose of such activities differs from the intent of research, they are outside the scope of REB review. Although QA/QI studies may raise ethical issues that benefit careful consideration by the project team, the consent procedures for such studies generally depart from those required for research. However, where one of the goals of such QA/QI activities is to “extend knowledge,” they may fall under the TCPS definition of research and therefore require review ([http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2\\_en\\_a2.5](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.5)).

See Dalhousie REB guidelines for differentiating among research, program evaluation and quality improvement (FAQ #4, <https://www.dal.ca/dept/research-services/responsible-conduct-research-ethics/faqs.html>).

## HOW TO APPLY

Some of your questions may be answered by the FAQ posted on our website. If you have any other questions, email the REB chair at [research\\_ethics@bcit.ca](mailto:research_ethics@bcit.ca).

Step 1: Complete the TCPS2 CORE tutorial and save a copy of the certificate if you don't have a certificate. Email the copy with your application. The tutorial can be found at: <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

Step 2: Download the application form (PDF) and fill out each section. You can use the “APPLICATION SECTION” boxes below to edit your text if you have MS Word or compatible software, then copy and paste the text into the PDF application form. We update the application form periodically so download the latest version if you are starting a new project. If you have any questions, email the chair of the REB at [research\\_ethics@bcit.ca](mailto:research_ethics@bcit.ca).

**If your research involves other researchers or institutions in BC you can submit a single (harmonized) application online through UBC's RISE system and select BCIT as a primary affiliation or site of research:**

<https://www.rise.ubc.ca/>

**Contact the REB Chair for more information.**

Step 3: Write the attachments including the consent form and invitation letter based on templates found on our website or from other Canadian REB websites. Name the attachments to make them easy to recognize and if possible include the suggested attachment letter given in the application (e.g., “Appendix F” for surveys and data forms).

Step 4: Email the completed application and all attachments to the REB chair. **If you have completed a harmonized application through UBC RISE please email the REB Chair with the title and study number so that they can initiate the review process.** The chair will acknowledge receipt and let you know if they have everything they need for review. Minimal-risk studies are reviewed on an ongoing basis. Minimal risk research is defined in TCPS2 as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” (See information section for application Box 13 below for more information). If your study is above minimal-risk it will be reviewed by the full board and should be sent 2-3 weeks before the next scheduled meeting.

Check the FAQ on the ethics website for meeting dates: <https://www.bcit.ca/appliedresearch/ethics/faq.shtml>.

## WHAT HAPPENS AFTER YOU APPLY

1. Your application will be reviewed for completeness, usually within 3-5 days, and the chair will let you know if anything else is required.
2. Your application will be assigned a study number (e.g., 2018-01) reviewed over 10 business days by members of the board, and if additional expertise is required, reviewed by outside consultants.
3. The chair will summarize the reviewers comments (provisos), usually within 3-5 days of receiving the reviews, and send you a list of suggested revisions (provisos).
4. Once you return the list of changes and revised documents the chair will compare to the provisos.
5. If the provisos are satisfied then the chair will send you a letter of approval by email with the approval date and instructions for post-approval activities.
6. You will receive a certificate of approval from the administrator at a later date. Contact them if for any reason the approval email isn't sufficient for a publisher or other REB and the administrator can expedite creation of the certificate.

## POST-APPROVAL ACTIVITIES

- Your study will be approved for one year from the approval date
- Should you need more time or make any changes to your study (e.g, recruitment documents, study design, forms, co-investigators) please file an amendment form (Post-Approval Form and instructions here: <https://www.bcit.ca/appliedresearch/ethics/>).
- You will need to apply for continuation or amendments within the year, or you will need to reapply.
- If there are any unanticipated problems during your study, complete an Unanticipated Problems/Adverse Event report using the Post-Approval Form.
- When your study is complete please complete an End-of-Study report using the using the Post-Approval Form.

## DETAILED INSTRUCTIONS FOR THE APPLICATION

The following table can be used as a template to write and edit your ethics application form in Microsoft Word or compatible word processing application. Note that the majority of the sections of this application should be summarized in the consent form. When appearing in the consent form the answers to these questions should be directed towards the participant rather than the REB (i.e., “you” vs. “they”).

The form and additional instructions incorporate wording from TCPS2 and the UBC Office of Research Ethics guidelines and application forms for Behavioral (BREB) and Clinical REBs (CREB), with their permission, found at:

- <https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes/guidance-notes-behavioural-application>
- <https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes>
- <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

APPLICATION SECTION	INFORMATION AND ADDITIONAL INSTRUCTIONS
1. Principal Investigator (or primary contact if student project)	The Principal Investigator of a research project is the person who has overall responsibility for the conduct of the research. The duties of a Principal Investigator are outlined (in part) in the BCIT “Integrity in Research” Policy 6600 ( <a href="https://www.bcit.ca/files/pdf/policies/6600.pdf">https://www.bcit.ca/files/pdf/policies/6600.pdf</a> ). If the project is

	intended to fulfill a course or degree requirement then enter your name as the primary contact for correspondence. Your faculty advisor will be responsible for ensuring that you, as a student, conduct your study to the same standards.
2. Direct Supervisor (serves as Principal Investigator if student project)	The Supervisor of the Principal Investigator is the person to whom the Principal Investigator reports as an employee of BCIT or another agency, or the faculty advisor (or equivalent) if the researcher is a student.
3. BCIT Contact (if investigator external to BCIT)	A BCIT contact is required only if the Principal Investigator is external to BCIT. The BCIT contact is a BCIT employee or manager (e.g., a Dean or Associate Dean) who will provide access to BCIT's facilities or resources (e.g., distribute invitations, book space, etc.).
Signatures	<p>Your email submission will serve as your signature and agreement to act within Policy 6600 (or equivalent), and the guidelines of TCPS2 (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/</a>). The PI named in Box 1 is required to submit a Certificate of Completion for TCPS2: CORE or equivalent (<a href="http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/">http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/</a>).</p> <p>Please have the supervisor named in Box 2 send an email directly to the REB chair (<a href="mailto:research_ethics@bcit.ca">research_ethics@bcit.ca</a>) to attest that you have the expertise and resources to carry out the study.</p> <p>Please have the BCIT contact (if external to BCIT) send an email directly to the REB chair (<a href="mailto:research_ethics@bcit.ca">research_ethics@bcit.ca</a>) to attest that they will provide access to the resources necessary for you to carry out your study.</p> <p>Alternatively, print this page, collect signatures, then scan and email. NOTE: Using Adobe digital signature feature for PDFs will lock your application from editing and make revisions more difficult. Use a separate copy, named and marked "signatures" for digital signatures if you choose to use this PDF feature.</p>
4. Title of project	Title, PI name and institution, and funding may be listed in an annual public report made to the BCIT Board of Governors or provided to 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.
5. Research is: <input type="checkbox"/> Behavioural <input type="checkbox"/> Clinical	<p>The BCIT REB reviews both behavioral and clinical studies and uses the same application form so this question directs you and the reviewers to the questions in Box 20 of the form.</p> <p>The REB defines behavioural research as involving interviews, focus groups, observations, or the administration of questionnaires or tests, which may or may not take place in a clinical setting. The REB defines clinical research as the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques and analysis of blood or other samples. It also includes</p>

	the analysis of laboratory, physiological, kinesiological or biological data obtained from physical interventions, medical records or clinical studies involving the linkage of data from existing databases.
6. Source of Funds	Enter the source of funds for the study, or “self” if self-funded. Attach budget in Appendix A. Appendix letters given here and elsewhere in the application are not required but are suggestions to keep files organized.
7. Is there an Industry Service Agreement (ISA) in place? Attach ISA in Appendix B <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	Applies primarily to BCIT Applied Research. Enter “not applicable” otherwise.
8. Project Period (enter “approval” for start if no delay) Start Collection Estimated End Date	Specifically, when do you plan to collect data? If there will be no delay following approval, enter “approval” under <b>Start Collection</b> . 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 <b>Estimated End Date</b> .
9. Indicate the institutions where the research will be carried out <input type="checkbox"/> BCIT campus <input type="checkbox"/> Other:	If your study involves surveying only BCIT students/faculty/staff, select “BCIT Campus.” If you plan to conduct your study at or recruit participants from other institutions, please enter the names or acronyms of the institutions here and below in Box 10. If you plan on conducting your study in public areas, enter “public spaces.” Please include documentation of REB approval from the other institutions as an attachment.
10. Where will the project be conducted (room or area)? Please provide documentation of approval if outside BCIT.	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.”
11. Research for graduate or undergraduate degree? <input type="checkbox"/> Yes <input type="checkbox"/> No	The REB requires documentation that your study design has been reviewed and approved by your advisor or committee <b>prior to submission</b> . If yes, submit dissertation/thesis acceptance letter or equivalent in Appendix D. If no, please have your study reviewed before submitting this application.
12 Commercialization, conflict of interest or financial interest? <input type="checkbox"/> Yes <input type="checkbox"/> No	If the results of this research are anticipated to lead to financial gain for the PI (and/or family) or the sponsor, or they may benefit in any other way from the results of the study, the REB needs to be satisfied that participants are informed of conflict of interest in the consent process.  Please see Chapter 7 of TCPS2 for more information ( <a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/</a> ) “Researchers’ conflicts of interest may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy. Conflicts may arise from an individual’s involvement in dual and multiple roles within or outside an institution. While it may not be possible to eliminate all conflicts of interest,

	<p>researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.”</p> <p>If you answer yes to this question please complete Box 23.1.</p>
<p>13. Minimal risk?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>TCPS2 defines minimal risk research as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.” Minimal risk research is normally eligible for review on an ongoing basis by a subset of REB members (i.e., “delegated review”). Applications are reviewed as they are received.</p> <p>Research considered above-minimal risk will be reviewed at a meeting of the full board. Please submit your application at least two weeks in advance of the next meeting (see FAQ on our website for meeting dates:  <a href="https://www.bcit.ca/appliedresearch/ethics/faq.shtml">https://www.bcit.ca/appliedresearch/ethics/faq.shtml</a>)</p> <p>Risks of research include physical risk (harm through bodily contact or administration of any substance, device or other intervention), psychological or emotional harm (harm due to feeling embarrassed, uncomfortable, anxious or upset), social risk (harm due to loss of status, privacy, or reputation, and includes legal, financial or employment risk).</p> <p>Vulnerability to harm exists along a continuum and is influenced by many factors such as participant capacity (mental, emotional, cognitive), age, wellness or health status, institutionalization, power relationships, gender and gender identity, setting and recruitment, dependency). Please consider participant vulnerability and include justification for your choice in research plan (Appendix E).</p> <p>Common examples of above minimal risk studies include:</p> <ul style="list-style-type: none"> <li>• Projects involving any moderate to serious physical, emotional, psychological, legal, social, or economic risk to participants.</li> <li>• Potential disadvantage due to experimental design (e.g., randomization in an intervention study).</li> <li>• Projects involving sensitive questions or invasive procedures.</li> <li>• Projects involving vulnerable populations where participants’ capacity to consent may be affected (e.g., infants and young children, individuals with cognitive or intellectual disabilities).</li> <li>• Projects where there is a possibility of coercion (e.g., studies involving "captive" groups such as employees, students, members of the military, prisoners).</li> <li>• Projects involving partial disclosure or deception (e.g., some information which may affect participants’ decision to participate is withheld at time of initial consent).</li> </ul> <p>(From <a href="https://research.uottawa.ca/ethics/submission-and-review/types-review">https://research.uottawa.ca/ethics/submission-and-review/types-review</a>)</p>
<p>14. Coordinated or harmonized review?</p>	<p>If your study involves multiple institutions, we may be able to</p>

<input type="checkbox"/> Yes <input type="checkbox"/> No	coordinate our review with review by other REBs. If possible, we will review application forms from other REBs and may coordinate feedback to minimize rounds of revision before approval. If you have already submitted an application to any other REB please attach details or approval letter. If your research involves other researchers or institutions in BC you can submit a single (harmonized) application online through UBC's RISE system and select BCIT as a primary affiliation or site of research: <a href="https://www.rise.ubc.ca/">https://www.rise.ubc.ca/</a>
15. CO-INVESTIGATORS AND STUDENTS	List any others who will assist in collecting or analyzing data. If there are more than three please include these same details for each in Box 15.4, followed by their research qualifications.
15.4 What are the research qualifications of all those conducting the study?	Explain in brief what each person will do on the research team and what experience they bring to it. Describe relevant training, experience, degrees, and/or courses.
16.1 Summary of purpose and objectives of project.	Summarize the purpose in lay language suitable for non-scientific REB members. Include the research question and/or hypothesis (if applicable) and the study population. Submissions should include a more complete research plan or protocol in Appendix E.
16.2 How will you accomplish the purpose and objectives described previously?	Summarize the study methods, how the study aims will be achieved and how the analysis will be undertaken. The summary should have enough detail for the REB to assess any potential risks to the participants and how the researcher will handle them. Include definitions of jargon, technical terms, and acronyms.  If applicable, please provide details of peer review, including names of committees or individuals who have reviewed the methodology. If your study involves deception, you must also complete Box 27 in this application titled 'Deception Form.'
16.3 Will your project use? <input type="checkbox"/> Questionnaires/surveys <input type="checkbox"/> Interviews <input type="checkbox"/> Observations <input type="checkbox"/> Tests <input type="checkbox"/> Other screening or data collection forms	Check off any and all methods of data collection and attach <b>final</b> versions of the documents in Appendix F. Interviews should be accompanied by a script and observations by a description of anticipated observations and a collection form.  Online surveys should be preceded or continuous with the consent form or letter (provided it includes essentially the same information as a standard consent form) and ends with the statement "Having read the above, I understand that by clicking the "Yes" button below, I agree to take part in this study under the terms and conditions outlined in the letter above. Yes: I agree to participate. No: I do not agree to participate." (The "No" button should link to the statement "Thank you. You have decided not to participate in this survey. No data has been collected from you.")  If it is not practical to have Yes and No buttons, you may end the consent letter with the statement "If the questionnaire is completed, it will be assumed that consent has been given."
18. DESCRIPTION OF POPULATION 18.1 How many participants will be invited in total? 18.2 How many in the control group (if	The minimum number of participants may be based on your own best estimate or, for clinical trials, on sample size calculations.

<p>applicable)?</p> <p>18.3 Minimum number of participants required for the study?</p>	
<p>18.4. Inclusion criteria. Who is being recruited and what are the criteria for their selection?</p>	<p>Please enter as an itemized list. Provide justification if you wish to exclude any group based on age, gender, or other characteristics (<i>see below</i>). Consider inclusion based on ability rather than arbitrary or historic data (e.g., age of majority). Consult TCPS2 article 4.1 for more information (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#ch4_en_a4.1">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#ch4_en_a4.1</a>) “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.”</p>
<p>18.5 Exclusion criteria. Who will be excluded from the study and what are the criteria for their exclusion?</p>	<p>If not applicable, write "N/A". Please enter as an itemized list. Provide justification if you wish to exclude any group based on age, gender, or other characteristics. See TCPS2 article 4B, Inappropriate Exclusion based on gender, age, and decision-making capacity (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#toc04-1b">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#toc04-1b</a>)</p>
<p>18.6 How are the participants being recruited?</p>	<p>Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and the relationship between them and the participants, and by what means this will be done. If the initial contact is by letter, email, or posted recruitment notice, attach a copy in Appendix C. If by email, please describe who will send emails and the number and timing of any reminder emails.</p> <p>Third parties cannot provide contact information for others without their consent unless researchers have obtained permission from the Provincial Privacy Commissioner. Recruitment invitations should usually be forwarded by others (e.g., Program Assistant) to prevent sharing of private information and snowball-type recruitment ideally involves participants passing on the invitation to other potential participants.</p> <p>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.</p>
<p>18.7 If a control group is involved, and their selection and/or recruitment differs from the above, provide details</p>	<p>Enter “N/A” if none or “No difference in recruitment” if they will be recruited in the same way as the experimental/intervention group. See TCPS2 Chapter 11 for more information on clinical trials (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/</a>).</p>
<p>19. PROJECT DETAILS</p> <p>19.1 Will the study use any of the following? (Note: May involve modifications of consent process)</p> <p><input type="checkbox"/> Action Research</p>	<p>These methods are included here because they represent possible departures from established processes for obtaining free and informed consent. Please ensure you have included a detailed description of any of the procedures or methods selected here in Box 16 and your project plan as an attachment. See TCPS2 Chapter 3B for more information</p>



- Autobiography/Auto-Ethnography
- Data Linkage
- Deception
- Ethnographic Fieldwork
- Expert Interviews (conducted by someone of authority/power)
- Focus Groups
- Naturalistic Observation
- Random Digit Dialing
- Secondary Use of Data
- Participant Pools
- Use of Medical/Clinical Records
- Videotaping
- None of these methods

(<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1b>)

- **Action research** involves researchers investigating their own practice where dual relationships exist between the researcher and participant. When the relationship involves individuals of lesser power or status than the researcher, such as the researcher's students, employees, inmates or clients, there is a potential for coercion. Please refer to the UBC [Action Research guidelines](#) for more information.
- **Autobiography** is when a researcher retrospectively and selectively writes about his or her past experiences. **Auto-ethnography**, on the other hand, is an approach to research and writing that seeks to systematically explore the researcher's subjective experience and connects it to wider cultural, political, and social meanings and understandings. If you are interviewing other people or engaging in prospective data collection at a particular fieldsite (i.e. your study leans heavily on ethnographic as well as auto-biographical approaches), research ethics approval is required.
- Research involving **deception** occurs when participants do not know the true purpose of the research in advance. A simple test for possible deception is to ask yourself: "Is there any information in the procedures section of the ethics application that I would not be willing to tell the participant in the study prior to their participation?" Complete Box 27 in this application titled 'Deception Form.'
- **Fieldwork:** Researchers who plan to work with First Nations, Inuit or Métis participants must read TCPS2 Chapter 9. Researchers applying to the REB must be clear about the approach they are taking and the contacts they have already made with the communities or people.
- **Expert interviews** are defined here as those that involve an interview with an expert in a similar position to the researcher (e.g., an academic, politician, owner or executive of a company, head of an NGO, or president of an association or union) and which are designed to obtain factual accounts of an event, a procedure, a process, history, and so forth, where there is minimal or no risk to the interviewee. If the person being interviewed is someone authorized to release information or data about their organization and its policies, the research does not require review and the person does not need to complete a consent form, although professional interview procedures should be observed. If the expert is being asked to proffer a personal opinion, then an ethics application must be submitted, and consent (written or oral), to the extent appropriate to the situation is required.
- **Focus groups:** The investigators should note in the consent process that only limited confidentiality can be offered in focus groups, as they cannot control what other participants do with the information discussed. For example, include a sentence on the consent form that says something like, "We encourage all participants to refrain from disclosing the

contents of the discussion outside of the focus group; however, we cannot control what other participants do with the information discussed."

- **Naturalistic observation** is used to study behaviour in a natural environment. Because knowledge of the research can be expected to influence behaviour, naturalistic observation generally implies that the subjects do not know that they are being observed, and hence cannot have given their free and informed consent. As noted in the 'Studies exempt from review' section, naturalistic observation studies in public places where there is no expectation of privacy are exempt from REB review. However, due to the need for respect for privacy, naturalistic observation in other settings can raise concerns of the privacy and dignity of those being observed.
- TCPS2 Article 5.5 defines **secondary use of data** as, "the use in research of information originally collected for a purpose other than the current research purpose. Common examples are social science or health survey datasets that are collected for specific research or statistical purposes, but then re-used to answer other research questions. Another common example is the use of data collected for non-research purposes to answer a research question. Secondary use of data (including data linkage) for research purposes requires review and approval by the Research Ethics Board unless the data was collected anonymously or is in the public domain.
- **Data linkage** is when you are linking two or more separate datasets. If the datasets you plan to link contain identifiable information, please be aware that the BC Personal Information Protection Act states that "An organization may disclose, without the consent of the individual, personal information for a research purpose, including statistical research, only if linkage of the personal information to other information is not harmful to the individuals identified by the personal information and the benefits to be derived from the linkage are clearly in the public interest".
- **Video recording:** If any individuals present in an experimental setting that is being video-recorded decline to participate, researchers must take extra care to protect their rights. On the one hand, it is unfair to require non-participants sit outside camera range if this also excludes them from participating in any activity that is not part of the research project or marginalizes them in some other way. On the other hand, participants' rights not to take part in the research must be respected. Electronically distorting the facial features of non-participants does not honour the participant's wish not to participate. It is not a matter of non-identification but a matter of non-participation.

19.2 How and where will consent be obtained?

Include:  
 1) how participants will be approached,  
 2) how much time they will have to read and consider the consent form,  
 3) who will obtain consent,

	<p>4) relationship between investigators or co-investigators obtaining consent and the participant, and</p> <p>5) whether any participants will have difficulty giving informed consent on their own behalf.</p> <p>Consider physical or mental condition, age, language, and other barriers. Please describe steps taken to obtain consent or assent in such cases, including who will provide consent for them (Note: Those under the age of 19 may provide consent in some cases). Justify any alteration or waiver to free and informed consent. See TCPS2 Chapter 3A for more information (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a</a>).</p>
<p>19.3 Where approval is required from other jurisdictions, groups or communities (e.g. institutions, school boards, indigenous communities) please describe how and from whom it was obtained and attach a copy of the research agreement in question (Appendix G).</p>	<p>Written evidence of approval (to use the premises or to access students, clients, patrons or patients) is required for projects carried out at other institutions. If agency approval cannot be obtained without prior approval of the REB, a letter of conditional approval will be issued for submission to the institution if all other aspects of the application are satisfactory. Please indicate whether a request for approval has been submitted to the institution or whether conditional approval by the REB must accompany a request to the institution for approval.</p> <p>TCPS2 (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.3">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.3</a>) states that “research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction, whether elsewhere in Canada, or outside Canada, shall undergo prior research ethics review by both: the REB at the Canadian institution under the auspices of which the research is being conducted; and the REB or other responsible review body or bodies, if any, at the research site.” Please indicate if any agencies have jurisdiction over the site of the research and whether approval has been applied for or received. If formal research ethics approval processes are not in place at the study site, please explain.</p> <p>For more information on research involving the First Nations, Inuit and Metis peoples of Canada see TCPS2 Chapter 9 (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/</a>).</p>
<p>19.4 Risks. What is known about the risks of the proposed research, including any physical, social, or psychological discomfort or incapacity the participants may experience?</p>	<p>Describe the potential risks or inconveniences to the participant associated with each procedure, test, interview, or other aspect of the study. Please also address the broader impacts of your study on individual participants and the groups to which they belong. Such impacts may include: social stigmatization, threats to reputation, the creation of unfair stereotypes, and/or psychological harms such as anxiety, regret, or guilt feelings. Describe strategies to be used to minimize or manage the study impacts for participants and other affected individuals. If you think there are no risks associated with your study, please indicate this (e.g., "There are no known risks associated with this research") rather than responding "N/A".</p>

	<p>Clinical risks should be listed as bullet points and quantified using percentages, where possible. Ensure that there is consistency between this box and study documents, especially the consent form. See UBC CREB Guidance Note #12 for a detailed discussion of required information around risks (<a href="https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes#GN12">https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes#GN12</a>).</p>
<p>19.5 Benefits. Describe any potential benefits to the participant.</p>	<p>Specify the benefits to the participants. If there are no benefits, state this explicitly (e.g., "There are no known benefits associated with this research"). If any specific therapeutic 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.</p> <p>For sample wordings around the benefits of participating in a research project, see the BC Common Clinical Informed Consent Form Template: <a href="http://bit.ly/common-clinical-informed-consent-template">http://bit.ly/common-clinical-informed-consent-template</a></p>
<p>19.6 Impact on Community or Organization. If your research may have a positive or negative impact on a specific community, group, or organization please describe. If the results may be critical of any community, organization, or group, participants should be informed of the possible consequences.</p>	<p>If the research may be critical of an identified group, participants should be made aware during consent that their participation may have an impact on the group. Consult TCPS2 Article 3.6, Critical Inquiry for more information (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.6">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.6</a>).</p> <p>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."</p> <p>For example, in the case of sex and gender see: <a href="https://www.formulate.com.au/blog/sex-and-gender">https://www.formulate.com.au/blog/sex-and-gender</a></p>
<p>19.7 How much time will participants dedicate to the project?</p>	<p>Please describe in terms of number of visits, tasks, and minutes/hours per visit/task, as applicable. Ensure that you also include this information in the consent form and that the amount of time stated is consistent in the application, recruitment letters or posters, and consent form. Approximations are acceptable but consistency is required. For naturalistic observation studies, the response would be "N/A".</p>
<p>19.8 Describe any compensation offered participants, including reimbursements for expenses, meals, parking, medication, honoraria, gift cards, course credit/marks. Provide details of amounts and compensations schedules and include a description of how the compensation will be</p>	<p>Provide details of amounts and compensations schedules and include a description of how the compensation will be pro-rated if the participant withdraws from the study.</p> <p>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</p>

<p>pro-rated if the participant withdraws from the study.</p>	<p>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.</p> <p>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).</p> <p>Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks. The offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement (see TCPS2 Article 3.1 <i>Incentives</i> <a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epc2/chapter3-chapitre3/#ch3_en_a3.1">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epc2/chapter3-chapitre3/#ch3_en_a3.1</a>). Account for issues such as the economic circumstances of those in the pool of prospective participants, the age and capacity of participants, the customs and practices of the community and the magnitude and probability of harms.</p> <p>It is considered unacceptable to have payment depend on completion of the project. However, in many cases it would be considered 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.</p> <p>See guidelines from University of Toronto for a more complete discussion (<a href="http://www.research.utoronto.ca/policies-and-procedures/compensation-and-reimbursement-of-research-participants/">http://www.research.utoronto.ca/policies-and-procedures/compensation-and-reimbursement-of-research-participants/</a>).</p>
<p><b>20. FOR CLINICAL RESEARCH</b>  <b>20.1 Provide details of any possible side effects resulting from the experimental treatment (if applicable).</b></p>	<p>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. For specific guidance on X-Rays, please see UBC CREB GN#17 (<a href="https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes#GN17">https://ethics.research.ubc.ca/ore/ubc-clinical-research-ethics-general-guidance-notes#GN17</a>). 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.</p> <p>Qualitative terms such as "rare", "common", "infrequent" are not acceptable unless quantitative ranges are explicitly attached to</p>

them. The use of symbols (e.g. e or d) is not acceptable. Quantifiers such as "more than 5%" are similarly not acceptable because they do not adequately define the magnitude of the risk.

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, could occur if a novel combination of drugs is being tested, even if the individual drugs are not expected to have these side effects.

20.2 For studies involving diagnostic procedures, what are your plans to report any incidental findings to the participant?

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.

See TCPS2 article 3.3 *Incidental findings* ([http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3\\_en\\_a3.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.3)) and University of Waterloo guidelines for more information ([https://uwaterloo.ca/research/sites/ca.research/files/uploads/files/guideline\\_on\\_incidental\\_findings\\_reporting\\_october\\_2014.pdf](https://uwaterloo.ca/research/sites/ca.research/files/uploads/files/guideline_on_incidental_findings_reporting_october_2014.pdf)).

20.3 What procedures in this project (e.g. diagnostic procedures or other treatment) involve an experimental approach differing from standard patient care?

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.

<p>20.4 For research involving a double-blind code, what provisions are made to break the code when needed? Who has the code?</p>	<p>N/A, if not a double blind project.</p>
<p>20.5 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.</p>	<p>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).</p>
<p>21. DATA 21.1 How and where will the data be stored (e.g., files on computer hard drive, hard copy, videotape, audio recordings, mobile phone, etc.)?</p>	<p>Study documents must be kept in a secure locked location and computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer, back up files should be stored with same level of protection. If any data or images are to be kept on the web servers, please describe privacy security measures in place such as passwords and user agreements.</p> <p>Confidential information must not be collected or exchanged via e-mail unless the information has been encrypted (e.g., documents are password-protected). Web-based questionnaires must use encryption software. Please also beware of using online storage services such as "Dropbox" to store or share your study data, especially if you are researching a sensitive topic. For example, Dropbox's user policy states that:</p> <p><i>We may disclose to parties outside Dropbox files stored in your Dropbox and information about you that we collect when we have a good faith belief that disclosure is reasonably necessary to (a) comply with a law, regulation or compulsory legal request; (b) protect the safety of any person from death or serious bodily injury... If we provide your Dropbox files to a law enforcement agency as set forth above, we will remove Dropbox's encryption from the files before providing them to law enforcement...</i></p>
<p>21.2 How will the confidentiality of the data be maintained? Include methods to protect the identity of participants such as anonymity, coding, pseudonyms, and anonymizing after collection or analysis.</p>	<p>Applicants should demonstrate how the confidentiality of the data and participant privacy will be maintained during data collection and analysis, including hard copies of participant data (e.g., interview transcripts, completed questionnaires, fieldnotes, etc.) and electronic files.</p> <p>The TCPS2 identifies 5 different categories of data collected from research participants, each with different implications for the privacy of participants (see Article 5a: <a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1a">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#toc05-1a</a>).</p> <ul style="list-style-type: none"> <li>• “Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).</li> <li>• Indirectly identifying information – the information can</li> </ul>

reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary).
- Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.”

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

“Ethical concerns about privacy decrease as it becomes more difficult to associate information with a particular individual and concerns also vary with the sensitivity of the information collected and the extent to which it might harm an individual or group. The easiest way to protect participants is through the collection and use of anonymous or anonymized data, although this is not always possible or desirable.”

#### **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."

21.3 Who will have access to the data and describe how they will be made aware of their responsibilities concerning privacy and confidentiality (e.g., attached confidentiality agreement)?

Please list their names and roles (e.g., research assistant, transcriptionist, translator). Please explain how those who will have access to the study will be made aware of their duties around maintaining confidentiality, etc. The research participants must also be told in the consent form who will have access to his/her data and what use will be made of it, either now or in the future. Temporary student assistants and clerks may be referred to by their role instead of name.

If you are using an online survey, where will the data collected by the survey be stored (e.g., Canada or U.S.)?

To use a BCIT-licensed survey tool that keeps the data in Canada, Sally McKinstry in the Learning and Teaching Centre manages the BCIT licenses for SurveyMonkey and can help you put the survey online with the necessary BCIT logo and privacy notices. She can be reached at [Sally\\_McKinstry@bcit.ca](mailto:Sally_McKinstry@bcit.ca) or 604-432-8406.

Researchers planning to use online survey companies should acquaint themselves with the relevant laws. In particular, section 30.1 of the BC Freedom of Information and Protection of Privacy Act (FIPPA) which states:

*A public body must ensure that personal information in its custody or under its control is stored only in Canada and accessed only in Canada, unless one of the following applies: if the individual the information is about has identified the information and has consented, in the prescribed manner, to it being stored in or accessed from, as applicable, another jurisdiction; if it is stored in or accessed from another jurisdiction for the purpose of disclosure allowed under this Act; if it was disclosed under section 33.1 (1) (i.1).*

See the UBC Online Survey Guidance Notes for more information ([https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/Online\\_Survey-GN.pdf](https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/Online_Survey-GN.pdf)). If you have any questions regarding FIPPA legislation and online surveys please consult BCIT's Privacy Manager (<https://www.bcit.ca/privacy/>)

Ideally, Canadian companies with servers located in Canada should be used for survey purposes instead of using online survey companies located outside of Canada. However, the REB will consider online surveys using companies located outside Canada

(e.g. United States, Australia) which involve giving the survey internet address to the potential research participant to access from any computer (i.e. the company's server may collect the IP address of the participant's computer) and which do not collect demographic data that could be used to identify the research participant.

The consent document or letter of introduction must indicate the location of the survey company's server and include a description of any associated limits to confidentiality. An example of a typical statement is, "This online survey company is hosted by a web survey company located in the USA and as such is subject to U.S. laws. In particular, the US Patriot Act which allows authorities access to the records of internet service providers. This survey or questionnaire does not ask for personal identifiers or any information that may be used to identify you. The web survey company servers record incoming IP addresses of the computer that you use to access the survey but no connection is made between your data and your computer's IP address. If you choose to participate in the survey, you understand that your responses to the survey questions will be stored and accessed in the USA. The security and privacy policy for the websurvey company can be found at the following link: \_\_\_\_\_."

21.4 What are the plans for future use of the raw data or biological samples beyond that described in this protocol? Will the data be kept in a database or registry for future research? How and when will the data be destroyed? Please consult institution, granting agency, and publisher policy and ensure that retention information is described in the consent form. Many require retention of data for at least 5 years after publication and clinical trial data for at least 25 years.

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 BREB for review and approval before the research begins.

In general, researchers have a duty to keep complete and accurate records of data, methodologies and findings, including graphs and images, in a manner that will allow verification or replication of the work by others. This includes recording all primary data in clear, adequate, original and chronological form, and retaining it in a repository from which it cannot be removed.

BCIT maintains a data repository for this purpose, managed by the library (see <http://circuit.bcit.ca/researchdata/>)

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 within BCIT after the study results have been published or

	<p>otherwise presented, but may be retained for a longer period provided that they are stored securely. BCIT has no explicit requirement for the shredding of data at the end of this period; however, 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.</p> <p>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.</p> <p>Consult Policy 6700 and procedures for more information (<a href="https://www.bcit.ca/about/administration/policies.shtml#info">https://www.bcit.ca/about/administration/policies.shtml#info</a>)</p>
<p>21.5 Will any data which identifies individuals be available to persons or agencies outside the Institute?</p>	<p>If yes, who and for what purpose will the data be released? Describe any steps you will take to ensure that data released will be maintained in the same level of confidentiality. Confidential information must not be collected or exchanged via e-mail unless the information has been encrypted. Research data that is being sent outside of Canada must be approved by the REB and clearly disclosed in the consent form. See section 16 of the BC Common Clinical Informed Consent Form Template for further information on specific disclosure requirements for clinical studies (<a href="http://bit.ly/common-clinical-informed-consent-template">http://bit.ly/common-clinical-informed-consent-template</a>).</p>
<p>21.6 Will participants have an opportunity to review and correct or withdraw their responses or sharing of audio/video recording/images?</p>	<p>If so, please describe when and how this will occur.</p>
<p>21.7 What are the plans for feedback to the participant?</p>	<p>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.</p> <p>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. If clinical, please also include in your research plan (Appendix E) procedures for consenting to disclosing material incidental findings.</p>
<p><b>22. FUNDING INFORMATION</b>  <b>22.1 Agency / Source of Funds:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Internal</li> <li><input type="checkbox"/> External</li> <li><input type="checkbox"/> Self-funded</li> </ul> <p><b>22.2 Funds Administered By:</b></p>	<p>Applied Research is allowed to release limited amounts of grant funding to researchers for "initial" research work that doesn't involve human participants. Please be aware that you will need to submit an ethics application well in advance of the component of the study involving human participants.</p>

<input type="checkbox"/> BCIT <input type="checkbox"/> Other: 22.3 BCIT Research Budget Account Number: Status <input type="checkbox"/> Awarded <input type="checkbox"/> Pending	
22.4 Was funding peer reviewed: <input type="checkbox"/> Yes <input type="checkbox"/> No If no, please explain	According to TCPS2, research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer-reviewed. For research that poses more than minimal risk, the REB recognizes that there is a range of options for obtaining peer review, dependent on the nature and funding status of the study. Given this variability, the REB requires information concerning the type of independent peer review that has been conducted and, about who conducted the review (i.e., internal or external). For student research, the approval of the advisor or supervisory committee will be deemed sufficient. Please note that any review process within a for-profit agency is not considered to be independent, and so is not sufficient. Please provide details of any in-house review processes.
22.5 Copy of funding application included in Appendix H <input type="checkbox"/> Yes <input type="checkbox"/> No 22.6 Funding Start Date (YYYY-MM-DD) 22.7 Funding Finish Date (yyyy-mm-dd):	Research grants or contracts administered by the Institute will not be established until the project has been reviewed and approved by the appropriate REB, although if you require partial access to research funds well in advance of the component of the study involving human participants you can submit a request for access to these funds.
<b>23. CONFLICT OF INTEREST DECLARATION</b> 23.1 If any of the following apply, please explain how the conflict will be avoided or managed: 1) Hold patent rights or intellectual property rights linked in any way to this study or its sponsor, 2) Receive personal benefits in connection with this study (e.g., paid by funder for consulting), 3) Non-financial relationship with the sponsor such as unpaid consultant, advisor, board member or other non-financial interest, or 4) Have direct financial involvement with the sponsor such as ownership of stock, stock options, or membership on a Board.	The REB needs to be satisfied that participants are informed of conflict of interest matters in 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). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements.
<b>24. CONSENT CHECKLISTS</b> 24.1 Who will consent? <input type="checkbox"/> Participant <input type="checkbox"/> Parent or guardian. <input type="checkbox"/> Agency officials	Written parental consent is always required for research in schools and an opportunity must be presented either verbally or in writing to the students to refuse to participate or withdraw. Submit a copy of what will be written or said to the students.  Passive Consent occurs when a parent is asked to return a consent form if they do not want their child to participate in a study, whereas active consent occurs when a parent is asked to sign a consent form indicating they are willing to allow their child to participate in the study. Regardless of the form of consent used for parents, the child must always be given the opportunity to assent or consent (depending on capacity) to participate. The REB

will consider the use of passive consent with approval from the school district for youth in grades 9-12 because the youth would generally be mature enough to consent for themselves outside of the school setting. Passive consent in younger children is not permissible unless a strong case is made justifying its use. All studies proposing passive consent in younger children will require full board review. Please note that school boards have their own requirements regarding consent. If the REB approves passive consent in a study but the school board does not agree with the decision the researchers will be asked to change their consent forms to active consent. Please ensure lay language is used in all consent forms as not all parents are able to understand the complexities of some consent forms.

Although the age of majority in British Columbia is 19, neither applicable law nor the TCPS2 relies on the age of majority to determine whether people have the capacity to consent to participate in research. According to the Interagency Advisory Panel on Research Ethics (PRE), seeking consent from minors should not be based on their age but on whether they have the capacity to understand the significance of the research and the implications of the risks and benefits to themselves. Researchers conducting studies with minors should therefore consider: the nature of the research, the research setting, the level of risk the research poses to participants, and provincial legislation.

Within BC, there is nothing that abrogates the application of the common law in relation to a minor's legal capacity to consent. The common law presumes that all persons, including minors, are legally and mentally capable of providing their own consent. There are two doctrines directly applicable to the consent of minors: the 'emancipated minor' doctrine and the 'mature minor' doctrine. The emancipated minor doctrine provides that persons under the age of majority who are 'emancipated' in the sense of living on their own, earning their own income, etc., are generally capable of consent, because they are 'emancipated from parental control and guidance'. For example, the REB considers university students under the age of majority, minors who are themselves parents, etc., to be emancipated minors.

The mature minor doctrine recognizes that if a minor has reached a level of intellectual and emotional maturity such that he or she is capable of understanding and appreciating the nature and consequences of a particular decision, together with its alternatives, they can be considered capable of providing his/her own legal consent. The REB therefore will consider requests for obtaining consent from minors on a case-by-case basis based on the nature of the research, the research setting and the level of risk the research poses to participants. However, please be aware that in some settings you may be required to obtain parental consent regardless of whether you deem the minors to be capable of providing their own consent. For example, written parental

consent (as well as authorization from appropriate school authorities) is normally required for research in the schools whenever students under 19 are involved.

Please note that if parental consent is required due to agency or institutional requirements you must also present an opportunity to the minor (either orally or in writing) to refuse to participate or withdraw at any time. A copy of what is written or said to the parents/guardians and to the minor must be included for review by the REB.

**Assent**

"Assent" means to concur with the decision of another, whereas "consent" means to provide permission. If parental consent is necessary for research with children due to their lack of capacity to consent, assent is required from the child. Children old enough to understand the concepts described in a consent form should be provided with an assent form to sign. Regardless of capacity due to age or ability, and in spite of authorized third party or parental consent, the investigator is not permitted to compel a participant to take part if it is clearly against his/her will.

24.2 In the case of projects carried out at other institutions, the REB requires written proof that agency consent has been received. Please specify below:

- Research carried out at a hospital – approval of hospital REB.
- Research carried out at a school – approval of school board and/or principal. Exact requirements depend on individual school boards. Check with school boards for details.
- Research carried out in a provincial health agency – approval of Deputy Minister.
- Other – specify:

Written evidence of approval (to use the premises or to access students, clients, patrons or patients) is required for projects carried out at other institutions. If agency approval cannot be obtained without prior approval of the REB, a letter of conditional approval will be issued for submission to the institution if all other aspects of the application are satisfactory. Whenever possible, applications should be submitted concurrently to the REB and the other institution. Please indicate whether a request for approval has been submitted to the institution or whether conditional approval by the REB must accompany a request to the institution for approval.

If you are conducting research internationally you may be required to obtain a research permit to conduct research in that country. It is your responsibility to find out what permits are required.

24.3 The REB requires signed consent in most cases other than those limited to questionnaires. See consent information for surveys below.

- BCIT letterhead.
- Title of the project.
- Identification of investigators, including a telephone number. Research for a course or graduate thesis should be identified as such and the name and telephone number of the faculty advisor included.

Please check each item in the following list before submission of the consent form in Appendix G to ensure that the written consent form that you attach to your application contains all necessary items. Please see posted guidelines for more detailed information and a template

[https://www.bcit.ca/files/appliedresearch/pdf/reb\\_informed\\_consent\\_guidelines.pdf](https://www.bcit.ca/files/appliedresearch/pdf/reb_informed_consent_guidelines.pdf).

For other useful information you may give to participants see <http://pre.ethics.gc.ca/eng/education/participation/>

- Brief but complete description of the purpose of the project and of all procedures to be carried out in which the participants are involved. Indicate if the project involves a new or non-traditional procedure, device, therapy, or therapeutic. Your description should be written at a level of language and detail that someone with a Grade 8 education and no prior knowledge of your project could understand.
- Explanation of why they are being invited to participate including inclusion and exclusion criteria (in list form)
- A description of the risks and benefits of participation in the project. State explicitly if none are known.
- Assurance that the identity of the participant will be kept confidential and description of how this will be accomplished, i.e. describe how records in the principal investigator's possession will be coded, kept in a locked filing cabinet, or encrypted and password-protected if kept on a computer hard drive. In the case of printed questionnaires, a statement discouraging participants from writing their name or other identifying information.
- Statement of the total amount of time that will be required of a participant.
- Details of compensation to be offered to participants, including any pro-ration for partial participation.
- An offer to answer any inquiries concerning the procedures to ensure that they are fully understood by the participant and to provide debriefing, if appropriate.
- A statement that if they have any concerns about their rights or treatment as research participants, they may contact the REB Chair, (insert name), at (insert phone number) or [research\\_ethics@bcit.ca](mailto:research_ethics@bcit.ca).
- A statement that they have read and understood the information in the consent

form dated [include date of REB approved ethics form] and have had the opportunity to ask questions.

A statement of the participant's right to refuse to participate or withdraw at any time (e.g., "It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign this consent form. After signing the consent form and after starting participation you are still free to leave the study at any time without any consequences and without giving any reason.").

A statement that withdrawal or refusal to participate will not jeopardize further treatment, medical care or influence class standing, as applicable.

Note: This statement must also appear on letters of initial contact. For research done in the schools, indicate what happens to children whose parents do not consent.

A statement acknowledging that the participant has received a copy of the consent form including all attachments for the participant's own records.

A statement that the participant is consenting to participate (by signing).

A place for printed name and signature of participant and a place for the date of the signature.

If applicable, a place for the signature, printed name and date for each of these people (where participant requires additional assistance): legal guardian/ representative, person reading or translating, witness, investigator.

Consent forms that include parental consent contain a statement of choice providing an option for refusal to participate, e.g. "I consent / I do not consent to my child's participation in this study." Also, written or verbal consent (or assent) must be obtained from the child, after the parent has consented.



<p>25. QUESTIONNAIRES TO BE COMPLETED BY PARTICIPANTS</p> <p>25.1 Questionnaires should contain an introductory letter which includes an abbreviated version of the same information contained in a consent form <b><u>with the addition of:</u></b></p> <p>Please check each item in the following list before submission of this form to insure that your questionnaire contains all the required elements.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Not applicable.</li> <li><input type="checkbox"/> The statement that if the questionnaire is completed it will be assumed that consent has been given. This is sufficient if the research is limited to questionnaires; any other procedures or interviews require a consent form signed by the participant.</li> <li><input type="checkbox"/> An explanation of how to return the questionnaire (if printed).</li> <li><input type="checkbox"/> For surveys circulated by mail, a copy of the explanatory letter as well as a copy of the questionnaire.</li> </ul>	<p>Online surveys should be preceded or continuous with the consent form or letter (provided it includes essentially the same information as a standard consent form) and ends with the statement “Having read the above, I understand that by clicking the “Yes” button below, I agree to take part in this study under the terms and conditions outlined in the letter above.</p> <p>Yes: I agree to participate. No: I do not agree to participate." (The “No” button should link to the statement “Thank you. You have decided not to participate in this survey. No data has been collected from you.”)</p> <p>If it is not practical to have Yes and No buttons, you may end the consent letter with the statement "If the questionnaire is completed, it will be assumed that consent has been given.”</p>
<p>26. ATTACHMENTS</p> <p>26.1 Check items attached to this submission, if applicable.</p> <ul style="list-style-type: none"> <li>.....Budget (Appendix A)</li> <li>.....Industry Service Agreement (Appendix B)</li> <li>.....Letter of initial contact (Appendix C)</li> <li>.....Advertisement for volunteer participants (Appendix C)</li> <li>.....Recruiting letters from third parties (Appendix C)</li> <li>.....Dissertation or thesis board acceptance letter (Appendix D)</li> <li>.....Research plan (Appendix E)</li> <li>.....Plan for disclosing incidental or secondary findings (Appendix E)</li> <li>.....Questionnaires, tests, interviews, etc. (Appendix F)</li> <li>.....Explanatory letter with questionnaire (Appendix F)</li> <li>.....Participant consent form (Appendix G)</li> <li>.....Control group consent form (Appendix G)</li> <li>.....Parent / guardian consent form (Appendix G)</li> <li>.....Agency consent (Appendix G)</li> <li>.....Confidentiality agreement for research assistants (Appendix G)</li> </ul>	<p>Write the attachments such as the consent in any format you choose if no template is available. Letterhead or logos from all institutions involved in the study should appear on each document presented to the participants, including surveys and questionnaires. For internal BCIT faculty/staff applicants, letterhead and logos area available on the Loop (<a href="https://loop.bcit.ca/">https://loop.bcit.ca/</a>). External applicants and students should ask their local contact/advisor to provide them with current logo and letterhead (see Boxes 2/3).</p> <p>Some templates can be found on our website or on other Canadian REB websites. Name the attachments to make them easy to recognize and if possible include the suggested attachment letter given in the application (e.g., “Appendix F” for surveys and data forms).</p> <p>Incomplete submissions will not be reviewed until complete.</p> <p>Some templates are available from: McMaster University (<a href="https://reo.mcmaster.ca/educational-resources/">https://reo.mcmaster.ca/educational-resources/</a>). University of Waterloo (<a href="https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/samples-and-other-supporting-materials">https://uwaterloo.ca/research/office-research-ethics/research-human-participants/application-process/samples-and-other-supporting-materials</a>) Western University (<a href="https://www.uwo.ca/research/services/ethics/board_guidelines.htm">https://www.uwo.ca/research/services/ethics/board_guidelines.htm</a>)</p>

<p>.....Application for funding of funded research (Appendix H)</p> <p>.....Deception form, including a copy of transcript of written or verbal debriefing (see below, attach as Appendix I)</p> <p>.....Telephone contact form (see below, attach as Appendix J)</p> <p>.....Copy of TCPS tutorial certificate for Principal Investigator (Appendix K)</p> <p>.....Other – Specify:</p>	
<p>26.2 Use this space to provide information which you feel will be helpful to the REB or to continue any item for which sufficient space was not available.</p>	
<p><b>27. DECEPTION FORM</b>  If your study involves deception, complete items 1 to 3. If not, skip to the next page.</p> <p>27.1 Deception undermines informed consent. Indicate (a) why you believe deception is necessary to achieve your research objectives; (b) whether you think the research can be done any other way; and (c) why you believe that the benefits of the research outweigh the cost to the participants.</p> <p>27.2 Outline the anticipated impacts of your deception on the participants once they have learned of it.</p> <p>27.3 Describe how you will debrief participants at the end of the study.</p>	<p>Research involving deception occurs when participants do not know the true purpose of the research in advance. A simple test for possible deception is to ask yourself "Is there any information in the procedures section of the ethics application that I would not be willing to tell the participant in the study prior to their participation?" If the answer to this is yes, then deception is involved. Only research that meets the requirements of TCPS2 Article 3.7 will be exempted from full disclosure at the time of consent (<a href="http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.7a">http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.7a</a>). If you are conducting a study involving deception you must complete the Deception Form. This information, and the rationale behind its exclusion from the initial consent process, must be provided to the participants in a debriefing procedure.</p> <p>Where partial disclosure or deception has been used, debriefing is an important mechanism in maintaining the participant's trust in the research community. The debriefing should be proportionate to the sensitivity of the issue. Often, debriefing can be a simple and straightforward candid disclosure. In sensitive cases, researchers should also provide a full explanation of why participants were temporarily led to believe that the research, or some aspect of it, had a different purpose, or why participants received less than full disclosure. The researchers should give details about the importance of the research, the necessity of having to use partial disclosure or deception, and express their concern about the welfare of the participants. They should seek to remove any misconceptions that may have arisen and to re-establish any trust that might have been lost, by explaining why these research procedures were necessary to obtain scientifically valid findings.</p> <p>Please note that participants must be able to indicate their consent or their refusal at the end of the project following the debriefing process.</p>
<p><b>28. TELEPHONE CONTACT FORM</b>  If your study involves telephone contact, complete items 1 to 4. If not, you are at the end of the forms.</p>	<p>Research that is 'limited' (i.e., no other method of gathering data on the individual participant) to a telephone interview usually requires initial contact by letter or e-mail. The letter or e-mail</p>

28.1 Telephone contact makes it impossible for a signed record of consent to be kept. Indicate why you believe that such contact is necessary to achieve your research objectives:

28.2 Include a copy of the proposed 'front end' script of your telephone interview in Appendix J. Please check each item on the following list before

submission of request for review to ensure that the front end covers as much as possible of the normal consent procedures:

- Identification of fieldwork agency, if applicable.
- Identification of researcher.
- Basic purpose of project.
- Nature of questions to be asked, especially if sensitive questions are to be asked.
- Guarantee of anonymity and confidentiality.
- Indication of right of refusal to answer any question.
- An offer to answer any questions before proceeding. (see below, item 3)
- A specific inquiry about willingness to proceed.

28.3 Indicate how interviewers will be trained to answer respondents' questions. Investigators should prepare and submit in Appendix J 'scripted replies,' which may cover, but are not necessarily limited to:

(a) The means by which respondent was selected.

(b) An indication of the estimated time required for the interview.

(c) The means by which guarantees of anonymity and confidentiality will be achieved.

(d) An offer to provide the name and telephone number of a person who can verify the authenticity of the research project. This person shall not be a principal investigator nor shall it be a co-investigator. (Note: Investigators should be prepared, should potential respondents request it, to provide the name of a person outside the

must have all of the components of a consent form. The researcher should explain to the REB the methods through which consent to the interview will be documented.

If the researcher plans to follow-up the consent document with a telephone call, the consent document should include a contact name and number for the participant to call to stop further contact.

#### **Note on Skype or cell phone interviews**

In general, these technologies are a less secure means of communication than landlines (e.g. although Skype-to-Skype calls are encrypted, Skype-to-landline calls are not; analog mobile phones are not encrypted; different mobile phone companies have different policies around encryption, etc.). Therefore, if your study involves a highly sensitive topic where there may be legal ramifications for participants if they are identified as participating in the study, more secure forms of communication should be used.

<p>research group, as required of the Social Sciences Humanities Research Council guidelines.)</p> <p>28.4 Sensitive Participant Matter: Respondents should be forewarned of questions they may find private, stressful or sacred. It is not always practical to do so as part of the interview's front end. Warnings can be placed later in the interview and can take a naturalistic form as long as their content specifically refers to the sensitive matter. Indicate how you propose to deal with sensitive items, if any, in your interview.</p>	
<b>END OF FORM</b>	