Full UBC Behavioral Research Ethics Board (BREB) Guidance Notes

This information is also available in the online version of the ethics application in RISe by clicking on the question marks ?

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Page 1. Principal Investigator & Study Team - Human Ethics

1.1. Principal Investigator

Please select the Principal Investigator (PI) for the study. Once you hit "Select", you can enter the PI's name, or enter the first few letters of their name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.

The PI bears the overall responsibility for the conduct of the study and is required to act within the guidelines of the TCPS2.

UBC affiliated PIs must have a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Assistant Professor, Associate Professor, Professor or BCCA Investigator) OR is deemed a PI by an affiliated institution or by a Dean. Non-UBC affiliated PIs will be present here, if allowed by your institution, e.g., harmonized applications being processed through Research Ethics BC (REBC).

If you cannot find the PI's name in the list, have it added into the RISe system by emailing the following information to <u>RISe Support</u>: Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher number via email.

1.2. Primary Contact

Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application.

Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the application boxes below if they are part of the study team. Graduate students should also be listed in box 1.3.A so their names appear on the approval certificate. Note that the PI may change the Primary Contact anytime without an amendment.

1.3A. Co- Investigators - Online Access	List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section. If you cannot find your name or any of your study team members' names in the list, please have them visit https://www.rise.ubc.ca/access-rise to proceed with obtaining a RISe account. Once an account is created, new users will receive their researcher numbers via email. If you are applying to the BC Cancer, co-investigators will not be listed on the certificates of approval; however, all participating BC Cancer centre PIs will be listed. You will be asked to enter the BC Cancer centre PI's names in View 11. For further information click here for the BC Cancer Research Ethics Board policy.
1.4A. Additional Study Team Members - Online Access	Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application. Examples of additional study team members who you may wish to have online access to the application include Clinical Trial Coordinators and Research Assistants. The study team members listed in this section do not have online access to RISe.
Study Team Members - No Online Access	Please print off the application and ensure that each member listed in this section has read and understood the objectives and procedures of this study.

1.6. Tri Council	All research personnel who are associated with a research project are required		
Policy Statement	to complete the TCPS2 online tutorial (CORE) and enter their date of completion		
(TCPS) Tutorial	in their RISe profile before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, medical residents, research assistants, research coordinators and faculty, whether they are the Principal Investigator or not.		
	The TCPS CORE Tutorial is free and can be completed in about four hours. CORE Certificates do not need to be attached. Copies should be retained and available on request.		
	Click <u>here</u> for the TCPS 2 Document .		
	Click here for the TCPS 2 'CORE' Tutorial.		
	This tutorial provides an essential orientation to Canadian human research ethics guidelines.		
	CORE-2022 is now available, please contact the REB for your institution to inquire about CORE-2022, as completion requirements may differ.		
1.7. Project Title	The title given in the application form must correspond to the title on all study documents, including the consent form.		
1.8. Project Nickname	The nickname will not be printed on the certificate. It will be used throughout the online application and review process to serve as a quick reference to identify the project.		

Page 2. Study D	ates and Funding - Human Ethics		
2.1.A. Estimated start date	In multi-phase projects, include the period that involves research with human participants.		
2.1.B. Estimated end date	Note that the study closure date does not activate an ethics application closure. All ethics applications need to be closed by the PI at the appropriate time by submitting a Post Approval Activity (PAA) for a Completion. At the time of closure, the data retention and destruction plans may need to be updated if available data storage methods or locations have become outdated. In multi-phase projects, include the period that involves research with human participants. You will need to close your application in RISe once all research activity has		
	concluded by submitting a PAA Request for Completion of Research. Note that the closure steps require you to include details about storage of data as laid out in Box 8.5.		
2.2.A. Types of Funds	"Source of Funds" refers to the funder, sponsor, grantor, or agency (government, industry, and non-profit) that is providing the funds needed to undertake the project. Note that you should not indicate that your study is "For Profit" if a sponsor is only collaborating and not funding the study, e.g., they are providing the study drug or laboratory space only.		
2.3.A. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Ethics	Question 2.3 lists the research funding applications/awards that have been submitted to the UBC Office of Research Services and entered into our database. Identifying the associated research funding application/award will ensure that awarded research funds will be made available to you once this ethics application receives approval. Please ensure you select the correct application. Note that the first two digits of the application number indicate the year the application was submitted (e.g., Application #F25-00001 was submitted in 2025).		
	Selecting "Add" will list the sources of all UBC research funding applications that have been submitted by the PI. If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.		
2.5.A. Is this a DHHS grant?	Please see <u>here</u> for list of HHS agencies and offices		

2.6. Study Related
Conflict of Interest

If you answer YES to this question (2.6), you will be asked to provide more detail on page 3 of the application.

Page 3. Study Conflict of Interest - Human Ethics		
This page only appears if you select "yes" in Box 2.6.		
3.1. Personal Interest	All investigators: Click here for TCPS 2, Chapter 7 - Conflicts of Interest UBC Investigators & Faculty: Click here for information on Policy SC3 (formerly Policy 97) Conflict of Interest and Conflict of Commitment. Reminder: receiving a recruitment or finder's fee for each participant enrolled is not permitted, and for physicians, is considered unethical practice by the Canadian Medical Association. Please click here or search for CMA Policy "Guidelines for Physicians in Interactions with Industry".	
3.2. Multiple Roles	Please refer to <u>TCPS 2</u> , <u>Article 7.4</u> for more information on Researchers & Conflicts of Interest.	
3.3. Management	The REB needs to be satisfied that conflicts of interest are appropriately managed. This can include disclosing the conflict of interest in the consent process. It also requires that any conflicts of interest be minimized to the extent possible. Some conflicts of interest will need to be managed further than disclosure, e.g., having someone arms length review the data to ensure objectivity, and/ or additional measures.	
3.4. Are all COI declarations for the Principal Investigator and Co-Investigators up to date?	It is the individual investigators' responsibility to ensure they comply with all relevant and applicable COI policies. Researchers who are also UBC Faculty must renew their Conflict of Interest (COI) declaration annually and update it if things change. Information provided in this view will not be reflected in UBC COI declarations. Click here for information on UBC's Conflict of Interest policy.	

Page 4.A. Study Type - (Boxes 4.1 to 4.2C)

4.1. Application Type

The difference between Clinical or Behavioural studies is not always clear. The final decision is at the discretion of the Boards. Please reach out to your REB if you have any questions around which study type should be selected for box 4.1.

Behavioural and social sciences projects intend to study the relationship between people and their surroundings, including how people interact with each other, their communities, and institutional systems. They include psychological phenomena such as emotions, biases, and motivations etc. Psychological therapy and counselling studies fall under behavioural research. Emergent design and community-based studies are considered social science and behavioural research unless a clinical intervention is involved. Common methods include, but are not limited to, interviews, focus groups, surveys, questionnaires, behavioural therapy workshops, experimental coaching, observations, and secondary use of data.

Behavioural and social sciences studies can be about health and include health care providers and patients, where the goal is **not** to modify direct patient clinical care (e.g., diagnosis, medication, or treatment). When clinical charts are being accessed for a behavioural study full patient consent is required. Retrospective medical chart review projects should be submitted using the Clinical application form.

Clinical research intends to evaluate the effects of one or more health-related interventions on health outcomes. Investigations include, but are not restricted to, drug administration, surgical procedures, radiologic procedures, devices, genetic therapies, cells and other biological products, radiopharmaceuticals, natural health products (NHPs), process-of-care changes, preventive care, manual therapies, and psychotherapies.

Health Canada and US FDA regulated research, research evaluating human anatomy, physiological outcomes and processes, medical chart reviews, secondary analysis of clinical data, biobanks and clinical data registries should be submitted as a Clinical application.

A clinical research project that also includes questionnaires or interviews as part of its methodology should be submitted to a Clinical Research Ethics Board.

4.2.A. UBC/UBC affiliated Institutions and Sites for Study

Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited.

This Box only has UBC and UBC affiliated sites (VCH, PHC, BC Cancer, CW). For REBC sites, please add in box 4.2B.

Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology).

Include the PI's and Co-I's home institution as a site, even if data collection/recruitment is not happening there

Please click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval:

B for BC Cancer

B for BC Centre for Disease Control

B for BC Children's Hospital; BC Women's Hospital

P for Providence Health Care

V for Vancouver Coastal Health (VCHRI/VCHA)

U for University of British Columbia

4.2.B. Non-UBC Institutions and Sites for Study

Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited.

Only BC sites that are a part of the <u>REBC</u> are listed in this box. For UBC/UBC affiliated sites, please add in Box 4.2A.

Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology).

*If study site(s) cannot be found, please select "Other" which is available for each Health Authority (e.g., Interior Health - Other) then add site name & address to box 4.2.C. If you are adding more than 5 sites in a particular Health Authority, please contact that ethics board before proceeding.

Ensure that the primary affiliations of all study team members are represented here.

Please click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out:

F for Fraser Health

I for Interior Health and Island Health

N for Northern Health

S for Simon Fraser University

U for University of Northern British Columbia and University of Victoria

Institutional Approvals: Research at hospitals and in Health Authorities cannot commence until you receive local site / resource approval from the hospital(s) selected. Issuing of the certificate of ethical approval may be delayed until site approval from the hospital(s) has been obtained.

Page 4.B. Behav	vioural Study Type - (Boxes 4.2D to 4.6)		
4.2.D. Roles of Study Sites and Institutions	Sites Listed are populated based on Boxes 4.2.A & 4.2B. In order to remove/add site(s) please update boxes 4.2A & 4.2B on the previous page.		
4.3.B. Relationship to Previous Ethics Application	Indicate whether the study is an extension or a sub-study of a primary study or if the study is utilizing data collected under a previous study. A sub-study is a concurrent study on a sub-sample/population of the original study sample/population.		
4.4.A. External peer review	According to Article 2.7 of the TCPS 2, "Research in the humanities and social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed". For research posing more than minimal risk, the REB recognizes that an independent peer review may be either 'internal' or 'external'. The appropriate type of review is dependent on the nature of the study. For graduate student projects submitted, the approval of the supervisory committee is deemed to constitute sufficient peer review. If you have any peer review reports attach them to section 9.7 of the RISe application.		
4.4.B. Internal (Institution or hospital) peer review	Internal review is defined as review by a committee or peer within the PI's institution, separate from the study team. For students, review by their supervisor or supervisory committee is required.		

4.5.A. Risk and Vulnerability

The TCPS 2 defines minimal risk 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".

In considering whether your study is minimal risk you should consider **participant vulnerability** and the **research risk** itself. Vulnerability is "A diminished ability to fully safeguard one's own interests in the context of a specific research project" (TCPS 2). Research risk should factor in the type of potential harm that might result (e.g., psychological or informational), the magnitude or seriousness of the harm (e.g., transient or permanent), and the probability of occurrence of the harm (e.g., likely or remote).

The matrix provides a high level assessment of risk, which a REB administrator or REB may use to initially determine if the research to be reviewed is minimal or above minimal risk. It should be noted that this matrix uses generalized terms. A more detailed analysis of the specifics of the study will be conducted to ensure that the appropriate level of scrutiny is applied.

4.6. Other Canadian REB

Examples of non-REBC institutions would be University of Toronto or Ottawa etc.

Please see the Research Ethics BC (REBC) website for a list of institutions and health authorities: https://healthresearchbc.ca/research-ethics-bc/info-and-resources/information-for-researchers/

This page only appears if you select "yes" in Box 4.6.

F.3. Approval at Another Canadian REB

If you answer yes to this question, you may be able to submit a shortened application. After completion of this view, you will automatically be directed to View 9 (Documentation). In View 9, you are required to attach all relevant documentation from the other REB. This includes the application, Certificate of Approval, Informed Consent and recruitment documents and all available correspondence between the researcher and the REB, including, provisos or modifications required from the REB review of the study. Please also attach to View 9, all local/UBC site specific documents as applicable.

[if Yes in F.3] F.3.A. Activities of BC Researchers

Please specify which aspects of the study the UBC researchers will be involved in. For example, if they are only involved in data analysis, please state this. If UBC researchers will be involved in all aspects of the study, such as recruitment, data collection, and analysis, please indicate this.

[if Yes in F.3] F.4. Local Recruitment

If you intend to use REACH BC as a recruitment tool, please attach the study information to Box 9.4. This will be either the REACH BC "Add a Research Study" PDF form or the "study posting preview" generated on REACH BC. Include "REACH BC" in the title of the document. If any substantial changes are made to your study description as a result of ethics review (e.g., participant inclusion criteria, research focus), the updated REACH BC study description must be reuploaded to your ethics application before it will be approved. You will need to submit your certificate of ethics approval (which will record the addition or inclusion of REACH BC) before your study will be posted to the site.

[if Yes in F.3] F.5. Obtaining Local Consent

<u>Article 3.12</u> of TCPS 2 states that "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent" (see also <u>Article 10.2</u>).

Ethics boards recognize that written consent may not be appropriate for certain types of research. Researchers wishing to obtain oral consent should describe the alternative means of obtaining and documenting consent. A script of the oral consent process should be appended to Box 9.2.

[if Yes in F.3] F.6. Retention and Destruction of Local (UBC) Data

Please specify data retention and destruction methods for all data types to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded).

According to UBC Policy <u>SC6</u> on Scholarly Integrity, data must be retained for at least 5 years after publication within a UBC facility, but may be retained for a longer period provided they are stored securely. There is no explicit requirement for destruction of data at the end of this period.

Responsibility for security of data rests with the Principal Investigator.

In some cases, data are of such value that they should not be destroyed (e.g., 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.

4.7.A Creation of a Research Database or Registry

Research databases or registries are repositories that collect and store information about humans specifically for future unspecified research purposes. The information may or may not include personally identifying information, test results, information about ethnicity, age, or place of origin, etc., that is collected retrospectively or prospectively.

Wanting to use routinely collected teaching or program evaluation data for future unspecified research purposes would fall into this category.

When you click "Yes" to question 4.7.A you will be directed to a branch off which asks specific questions about the registry or database you are creating. If your application is exclusively to obtain approval for the creation of the database or registry, the application will truncate and you will be directed to view 9. If the creation of the database is only one component of the application, you will need to fill out views 5-8.

4.9 Survey Research

Answer yes to this question if your only mode of data collection is a survey, and if the study is minimal risk. If you are using a survey in combination with another data collection method (e.g., interviews) answer No to this question. Please note that the answer to this question cannot be changed after initial approval.

If you answer Yes, your application will be shortened. Ensure all the necessary study documents are included on page 9.

4.10 Secondary Use

Answer yes to this question if you are only conducting a secondary analysis of data and the study is minimal risk. If you are combining secondary analysis with data collection (e.g., surveys or interviews), answer No to this question. Please note that the answer to this question cannot be changed after initial approval.

If you answer Yes, your application will be shortened. Ensure any necessary documentation is included on page 9.

Page B: Creation of a Research Database			
This page only appears if you select "yes" in Box 4.7.A.			
B.1. What is the scope and purpose of the registry?	E.g., to conduct educational research that produces insights into how teaching and learning might be improved.		
B.3. Over what period of time will data be collected?	Include a clear date range for the information that will be included in the registry. Clearly indicate if data will be collected indefinitely, or until the participant withdraws, if applicable.		
B.4.A. Sources	For example, student records, program evaluation data, routinely collected classroom data, etc.		
B.5.A. Confidentiality	Personally identifying information is information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g., name, SIN, student ID number, date of birth, address, or unique personal characteristic etc.		
[if Yes in B.5.A] B.5.C. Irreversibly Anonymized data	Irreversibly Anonymized data are 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 to very low.		
B.6.A. Consent	Note: Attach a copy of the consent form to Box 9.2.		
B.7. Justification	 Refer to TCPS 2 Articles 3.7A and 5.5A for further information on the following criteria. A. Explain why inclusion in the registry involves no more than minimal risk to the participants. B. Confirm that the lack of participants' consent is unlikely to adversely affect the welfare of the participants. C. Demonstrate how the purpose or aim of the registry would be impossible or impracticable to carry out, if the prior consent of the participant is required. D. Explain why the value of conducting this research using this registry exceeds the public interest in protecting the privacy of individuals. E. Demonstrate compliance with any known preferences previously expressed by individuals about any use of the information. F. Confirm that any other necessary permissions for secondary use of information for research purposes are in place. 		

B.9. What entity or who will have custodianship of the registry?	This is the person who is responsible for overseeing the management and use of the data, including the main rules governing use of the registry, the process by which access requests will be reviewed, and the organization to whom the researcher is accountable for the proper management of the data.
B.10. What steps will be taken to ensure the security of the data?	Reference procedural measures, technical measures, and physical measures planned for the protection of data. If a coding procedure is being used, describe the procedure in detail in this box.
B.12.A. Data Transfer	If this changes in the future, an amendment must be submitted before data are transferred.
B.13.A. Data Linking	If this changes in the future, an amendment must be submitted before data are linked.
B.15.B. Future Use	Reference who will have access to the registry in the future and under what circumstances, what will happen if an individual data custodian leaves the institution, where the ongoing registry will be stored or maintained, and what security measures will be in place.

Page D: C	lass-Based	l Proj	jects
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This page only appears if you select "yes" in Box 4.8.	
D.1. Additional Risk Mitigation	The BREB encourages instructors to ensure that student projects are conducted with low vulnerability populations and that the research itself involves a low level of risk, although exceptions that still fit within the minimal risk parameters are allowable. If the student projects will be low risk and with low vulnerability populations, please answer 'not applicable' to D.1. Important note: Final responsibility for the conduct of the student projects rests with the course instructor. If any student proposes to conduct research that does not meet the minimal risk criteria (e.g., they involve a medium or high vulnerability population AND medium or high research risk), and you are willing to allow the project to proceed, a separate application for the project must be submitted to the BREB (using the normal BREB application form and channels), with the instructor as the PI and the student as the co-Investigator.
D.2. Assignment Purpose	Please attach a course outline and any assignment materials to question 9.1 of the application.
D.3.A. Methods	If the students will potentially be using a range of methodologies, all should be listed here.
D.4. Recruitment	What types of recruitment methods will students be using in the course? Study advertisements? Direct approach? List the types of recruitment strategies students will use.
D.5. Consent	Please ensure that a template consent document is attached to question 9.2 of the application.
D.6. Withdrawal	This information should generally be outlined in consent documents.
D.7. Feedback for Participants	For some types of student projects it may be appropriate to provide feedback to participants (e.g., if students are doing a mini-ethnography). Otherwise answer 'not applicable'.
D.8. Assessing and Minimizing Risk	Although the student projects will involve minimal risk, students should have an awareness of how any risks will be mitigated (e.g., confidentiality risks, potential for minor upset, etc.).
D.9. Ethics Training	This might take the form of a lecture on ethics, assigned readings, class discussions, etc.

D.10. TCPS 2 CORE	Students who are conducting research with human participants are expected to be familiar with the Tri Council Policy Statement and are required to complete the TCPS tutorial 'CORE'.
D.11. Instructor	This might take the form of a research proposal that students are required to
Review	submit, or individual meetings with the course instructor, etc.
D.12. Data Storage	Please note that you are required to keep these materials for at least 6 months beyond the end of the semester, but they can be destroyed after this period.
D.13. Instructor Responsibilities	Please check each box to indicate your awareness of your responsibilities as the course convenor/instructor.

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Page K: Survey Research	
This page only appea	rs if you select "yes" in Box 4.9.
K.1. Project Description	Describe the purpose of your project in lay language. Briefly summarize your research questions and hypotheses and methods for data analysis. Do not cut and paste directly from your study proposal, which should be attached in Box 9.1. Indicate how long the survey is expected to take participants to complete.
K.2.A. Participation Criteria	Provide an itemized list of the inclusion and exclusion criteria for participation. The selection of participants must take TCPS 2 Article 4.1 into consideration, which states that "Taking into account the scope and objectives of their research, researchers should be inclusive in selecting research participants." The TCPS 2 (2018) cautions against recruiting participants into research studies solely because they are easy to access or manipulate. Article 4.1 also states that "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." Provide justification for excluding participants on the basis of such attributes.
K.2.B. Number of Participants	Specify the number of expected participants for this study. If different study sites are being used, and you are able, specify the number of participants per site (e.g. UBC=100, MTurk = 300, SFU=50).

K.3. Recruitment Methods	Describe how you will gain access to names and contact details. Attach copies of all recruitment materials such as letters, advertisements, flyers, radio or television scripts, or Internet messages to Box 9.4/9.6 of the application. Potential participants should not be asked to write their name and/or contact information on an advertisement posted in a public place. Researchers should treat this information as confidential and not encourage public posting of lists of personal information. Indicate from where participants will be recruited (e.g., hospital, clinic, school). Snowball sampling involves contacts or participants known to the researcher facilitating the recruitment of other potential participants. Researchers are not allowed to use contact information received from a third party unless the contact has provided prior permission to have their information shared. If multiple sites/platforms are being used, please describe the recruitment process for each, if they differ.
K.4.A. Personal Identifier Collection	Personal identifiers are those that when used alone, or in combination with other information, can lead to the identification of participants. These include: name, address, social insurance number, personal health number, date of birth, postal code. If any of these variables are being collected, answer Yes to this question. If you are collecting personal information from respondents, then survey tools hosted and serviced in Canada should ideally be used for survey purposes.
[if Yes in K.4.A] K.4.B. Identifiers Collected	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.

[if Yes in K.4.A] K.4.C. Data Security Safeguards	Data collection is "Anonymous" if no personal identifiers are collected within the survey. Data is "Anonymized" if all personal identifiers are permanently removed and no method of linking the data to the original source is possible. Data is "De-identified" if direct personal identifiers have been removed and coded but the original identifiers can be traced back to the source through the use of a list linking codes to identifiers. Describe how security of the data will be maintained. Study documents must be kept in a secure locked location and computer files will need to be encrypted as well as password protected. Data cannot be stored or downloaded onto an unsecured computer and back up files must be stored appropriately. Researchers may be required to make their data publicly available at the time of publication. Please see the guidance notes for full details and ensure the consent
	form is consistent with this information.
K.5.A. Survey Distribution	Select all options that apply regarding survey distribution.
[if Web-based in K.5.A] Distribution Platform	Specify which online survey platform will be used for data collection. If you are collecting personal information from respondents, then survey tools hosted and serviced in Canada should ideally be used for survey purposes. For studies involving UBC, UBC strongly recommends that you use the UBC-hosted version of Qualtrics. The version of Qualtrics licensed to UBC is hosted in Canada and is fully compliant with FIPPA. UBC faculty, staff and students can use this tool without charge. It is available at https://it.ubc.ca/services/teaching-learning-tools/survey-tool
[if Paper forms in K.5.A] Paper Based Distribution	Specify whether surveys will be delivered via email, handed out in person, or distributed by a third party, etc., and indicate who will oversee distribution.
[if Other in K.5.A] Other Distribution Methods	If you are using a method other than an online or paper-based survey, describe how the survey will be administered in this section.

K.5.B. Data Storage Countries

Please select all that apply.

To select the country from the dropdown, you can type the first letter or full county name in the text field, and the country or countries (if using the first letter) will appear below for selection.

Will the data be stored in Canada or another country? If you select a country other than Canada, the consent form must include, if applicable, any laws within that country that could compromise the confidentiality of participants.

K.6. Obtaining Consent

<u>Article 3.12</u> of TCPS 2 states that "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent" (see also <u>Article 10.2</u>).

Include the following details:

- 1. Who would approach the participant to obtain consent?
- 2. Who would inform and take the consent from the participant?
- 3. What is the relationship of the person obtaining consent to the participant?

For most surveys, a signed consent is not required. Instead, ensure the relevant consent form details are provided to invitees before they are asked to complete the survey. This could take the form of a cover letter/consent form that participants are required to read before completing the survey. See Online Survey Guidance Note for further information.

K.7. Remuneration

Describe what expenses will be covered (e.g., meals, parking, medications) and how payments or gifts will be made (e.g., honoraria, gifts-in-kind, prizes, credits). Specify the amounts, payment schedules, and values of gifts-in-kind.

In accordance with TCPS 2, ethics boards take a neutral stance on the use of incentives. However, "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." (Article 3.1)

As an incentive to participate in studies, 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 in a draw that the method of distributing the prize does not compromise the confidentiality of the participant.

K.8.A. Data Storage

Specify data retention methods for all data types to ensure confidentiality. All electronic files and devices containing personal information about an identifiable individual collected for research purposes must be encrypted. For further information around UBC's encryption requirements (Security Standard #5) go to https://cio.ubc.ca/information-security/policy-standards-resources.

According to UBC Policy <u>SC6</u> on Scholarly Integrity, data must be retained for at least 5 years after publication within a UBC facility, but may be retained for a longer period provided they are stored securely. There is no explicit requirement for destruction of data at the end of this period.

Responsibility for security of data rests with the Principal Investigator.

Researchers may be required to make their data publicly available at the time of publication. Please see the <u>guidance notes</u> for full details and ensure the consent form is consistent with this information.

K.8.B. Data Destruction Process

Specify the data destruction method for each data format (e.g., files will be deleted, paper copies shredded, hard drives re-formatted)

K.9. Future Data Use	Indicate if there is any known future use of the data after this research project concludes.
[if Yes in K.9] Future Data Use Access	If you answered yes to K.9, describe how the data will be used; e.g., will participant consent be obtained in the current consent procedure or at a later date? Either possibility must be described in the consent materials. If consent is to be obtained now for future use of the data, it must be described in full to the participant and must be included with the current application. If consent for future use will be sought later, an amendment or new application must be submitted for review and approval before the research begins. If the future use of the data is known, please specify who will have access to this data and for what purpose (e.g., graduate student will have access for a dissertation).

Page L: Secondary Use of Data		
This page only appear	This page only appears if you select "yes" in Box 4.10.	
L.1.A. Project Statement	Describe the purpose of your project in lay language. Briefly summarize your research questions and hypotheses and methods for data analysis. Do not cut and paste directly from your study proposal, which should be attached in Box 9.1.	
L.1.B. Dataset Details	Provide detail regarding what the datasets entail and what variables are included within the datasets that will be used.	
L.1.C. Data Custodian	A data custodian is the individual who has administrative and/or operational responsibility over the data which is being requested (e.g., PopData BC).	
L.1.D. Data Access Permission Required	Answer Yes if you need permission to access the data.	
Data Access Permissions	Specify what type of permission you require to access the data (e.g., a letter from the organization you are working with, a formal contract).	
Data Access Permission Received	If you have received permission to use this data for your intended purpose, respond Yes to this question.	
[if No above] Data Access Request Status	What is the status of your approval? Has it been requested and is awaiting approval or has it not been requested yet?	
L.1.E. Data Set Identifiers	Personal identifiers are those that when used alone, or in combination with other information, can lead to the identification of participants. These include: name, address, social insurance number, personal health number, date of birth, postal code. If any of these variables are included in the data, answer Yes to this question.	
[if Yes in L.1.E] Identifiers Included	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.	

[if Yes in L.1.E] Identity Protection	Was the data collected anonymously, or will the data be anonymized or deidentified by the data custodian?
	Data collection is "Anonymous" if no personal identifiers were ever associated with the data.
	Data is "Anonymized" if all personal identifiers are permanently removed and no method of linking the data to the original source is possible.
	Data is "De-identified" if direct personal identifiers have been removed and coded but the original identifiers can be traced back to the source through the use of a list linking codes to identifiers.
L.1.F. Data Linkage	Answer Yes if multiple data sets will be consolidated into one file using a linking code within each file.
[if Yes in L.1.F] Data Linkage Identifiable Information	By linking the data, explain whether any potential exists for participants who were not identifiable in the original datasets to now be identifiable, due to the variables that have been combined into one dataset.
[if Yes above] Identifiers Generated by Data Linkage	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.
L.2. Consent for Secondary Use of Data	Answer Yes if participants consented to the use of the data for the manner in which it is being used in this study, or for any future use of their data.
[if No in Box L.2 AND Yes in Box L.1.E] Consent Conditions	According to the TCPS 2 <u>Article 5.5A</u> , researchers must satisfy all the listed criteria for the secondary use of identifiable information in order for the study to be approved. If this criteria cannot be met, an explanation will need to be provided in the text box.

L.3.A. Data	Specify data retention methods for all data types to ensure confidentiality. All
Retention	electronic files and devices containing personal information about an identifiable individual collected for research purposes must be encrypted. For further information around UBC's encryption requirements (Security Standard #5) go to https://cio.ubc.ca/information-security/policy-standards-resources . According to UBC Policy SC6 on Scholarly Integrity, data must be retained for at least 5 years after publication within a UBC facility, but may be retained for a longer period provided they are stored securely. There is no explicit requirement for destruction of data at the end of this period. Responsibility for security of data rests with the Principal Investigator. Researchers may be required to make their data publicly available at the time of publication. Please see the guidance notes for full details and ensure the consent form is consistent with this information.
L.3.B. Data Destruction	Specify the data destruction method (e.g., files will be deleted, hard drives reformatted).
L.4. Future Use of Data	Indicate if there is any known future use of the data after this research project concludes.
[if Yes in L.4] Future Access to Data	Describe any known future use of the data beyond the conclusion of this research project, and indicate whether participant consent will be obtained, if necessary. If the future use of the data is known, please specify who will have access to this data and for what purpose (e.g., graduate student will have access for a dissertation).

Page 5. Summary of Study and Recruitment - Behavioural Study	
5.1.B. Summarize the research proposal	Attach a detailed proposal (if available) to Section 9.1.
	The REB will review the study proposal attached for the expanded description of how the study aims will be achieved and how the analysis will be undertaken. Provide a brief summary of the methods here.
	Describe the purpose in lay language or include definitions of jargon or technical terms.
	All acronyms must be written out in full the first time they appear in the application, recruiting and consent materials.
5.2. Inclusion	Please enter the inclusion criteria as an itemized list.
Criteria	The selection of participants must take TCPS 2 <u>article 4.1</u> into consideration, which states that "Taking into account the scope and objectives of their research, researchers should be inclusive in selecting research participants". The TCPS 2 cautions against recruiting participants into research studies solely because they are easy to access or manipulate.
5.3. Exclusion	If applicable, provide all exclusion criteria. If not applicable, write "N/A".
Criteria	Article 4.1 of the TCPS 2 states that "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". Provide justification for excluding participants on the basis of such attributes.
	Please enter the exclusion criteria as an itemized list.
5.4. Recruitment	If you intend to use REACH BC as a recruitment tool, please attach the study information to Box 9.4. This will be either the REACH BC "Add a Research Study" PDF form or the "study posting preview" generated on REACH BC. Include "REACH BC" in the title of the document. If any substantial changes are made to your study description as a result of ethics review (e.g. participant inclusion criteria, research focus), the updated REACH BC study description must be reuploaded to your ethics application before it will be approved. You will need to submit your certificate of ethics approval (which will record the addition or inclusion of REACH BC) before your study will be posted to the site.

5.5. Use of Records	For example, where the investigator has access to records they intend to use for research purposes, assurance needs to be provided that the use has been authorized
5.6. Summary of	The summary should include activity locations, event type, who will be
Procedures	facilitating, who will be involved in each activity, recording methods and measures being used.
	The research methods checked in the following box should be reflected in the description here.
	If the study involves an experimental approach to curriculum or therapy, specify how the procedures differ from normal practice.
	If Deception is involved, please click <u>here</u> to complete the Deception Form, then save and attach the form to question 9.7.

Page 6. Particip	ant Information and Consent Process - Behavioural Study
6.1. Time to Participate	Indicate how much time participants will be asked to dedicate to each procedure/activity/phase and provide the total time required.
	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. If your study involves no direct interaction with participants (e.g., naturalistic observation) you would respond "N/A".
	Ensure that the information provided is consistent in the application, recruitment materials, and consent documents.
6.2. Risks and Mitigation	Describe the potential risks of the proposed research for participants and how each will be mitigated.
	Include information about any physical, social, or psychological risks that the participants are likely to experience as a result of taking part in the study. Click here for further information on risks.
6.3. Potential Benefits	Specify the benefits to the participants. State explicitly if there are no benefits. If 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.
6.4. Impacts on Community	If your research involves an identified group or "community," outline the likely impacts of the research on the community.
	Research involving identified groups often has impacts (both positive and negative) that go beyond individual participants.
	Analyses that may contribute to stereotyping of groups on the basis of ethnic or cultural background, sexual orientation, etc., are generally cautioned against.
	Therefore, when the study includes specific groups or a range of groups and asks participants to categorize themselves according to ethnicity, colour, etc., the researcher must describe the nature of the analysis to be undertaken.
	If Indigenous communities are the focus of analysis then the REB takes direction from Chapter 9 of TCPS 2.

6.5. Reimbursement and Incentives

Describe any reimbursement for expenses (e.g., meals, parking, medications) or payments/gifts-in-kind (e.g., honoraria, gifts, prizes, credits) to be offered to participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.

In accordance with TCPS 2, ethics boards take a neutral stance on the use of incentives. However, "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 TCPS 2 Article 3.1)

Click <u>here</u> for further information on reimbursement and payments.

6.6. Obtaining Consent

<u>Article 3.12</u> of TCPS 2 states that "Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent" (see also <u>Article 10.2</u>).

Ethics boards recognize that written consent may not be appropriate for certain types of research. Researchers wishing to obtain oral consent should describe the alternative means of obtaining and documenting consent. A script of the oral consent process should be appended to Box 9.2.

6.6.A. Waiver of Consent

If the nature of the research requires an alteration to consent requirements and if the potential benefits outweigh the foreseeable risks, please provide your justification for the waiver or alteration. You will need to demonstrate that the study meets the below criteria. Please address each criterion individually in your response.

Per TCPS 2, Article 3.7A

- (impossible or impracticable to carry out the research if consent were required)
- a) the research involves no more than minimal risk to the participants;
- b) the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
- c) it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
- d) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
- e) the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

Per TCPS 2, Article 5.5A

(secondary use of identifiable data):

- a) identifiable information is essential to the research;
- b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
- c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
- d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
- f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

6.7. Time to Decide	How long after being provided with detailed information about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given. TCPS 2, Article 3.2 states, "For consent to be informed, prospective participants should have adequate time and opportunity to assimilate the information provided, pose any questions they may have and discuss and consider whether they will participate. 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."
6.8. Capacity to Consent	Click <u>here</u> for information on individuals who lack the capacity either temporarily or permanently to consent for themselves.
	Please note that not having attained the legal age of majority in BC (19 years) does not necessarily mean that the participants are unable to provide their own consent.
6.9. Ongoing Consent	Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.
	TCPS 2, Article 3.3 states, "Consent shall be maintained throughout the research project."
	Renewal of consent might be particularly appropriate in the context of longitudinal, ethnographic or other research methods involving multiple contacts with participants.
6.10. Provisions for Consent	What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g., consent forms in Braille, or in languages other than English).
	Attach copies of translated documents to page 9.
6.11. Restrictions on Disclosure	Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the funder/sponsor has placed on investigators, including those related to the publication of results.

Page 7. Number	Page 7. Number of Participants - Behavioural Study	
7.1.A External Approvals	If external approvals are required for research involving other institutions or other jurisdictions, provide written proof.	
	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 an 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.	
7.1.E. Other Jurisdictions	TCPS 2 Article 8.3(b) states, "Research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction shall	
Julisaletions	undergo prior ethics review by both: (i) the REB at the Canadian institution; and (ii) the REB or other responsible review body or bodies, if any , at the host 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, explain this in 7.1 F.	
7.1.G. Does this research focus on	Click <u>here</u> for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada.	
Indigenous peoples, communities or organizations?	While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities (e.g., the Deaf community).	
	See TCPS 2 Article 2.11 Research Involving Communities.	
7.1.H. Registration	Does this study fall within the clinical/intervention trial definition?	
for Publication 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). Please click here for further details and/or check out the Guidance Notes.	
7.2. Number of Participants	Unless you are conducting a multi-sited study involving several institutions, the responses to A and B are likely to be the same.	

7.3. Principal	Who will actually conduct the study and what are their qualifications to conduct
Investigator and	this kind of research? (e.g., describe relevant training, experience, degrees,
Research Team	and/or courses).
Experience	If this is a student project, ensure that your supervisor's experience is explained.

Page 8. Confidentiality - Beha	avioural Study
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8.1. Security of Data During the Course of the Study

How will data be stored (e.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other)?

How will security of the data be maintained? Note that study documents must be kept in a secure locked location and computer files will need to be encrypted as well as password protected. Data should not be stored or downloaded onto an unsecured computer and back up files should be stored appropriately.

If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?

Click here for further information on confidentiality.

8.2. Access to Data

Provide the names or describe the roles of those who will have access to the raw data. How will those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality?

The research participants must also be told in the consent process who will have access to their data and what use will be made of it, either now or in the future. Temporary student assistants, translators, transcriptionists and clerks may be referred to by their role instead of name.

8.3. Protection of Personal Information

Describe how the identity of research participants will be protected both during and after the research study, including how participants will be identified on data collection forms.

Click <u>here</u> for further information on protection of personal information.

Data linkage studies: If your study involves the linkage of several data sources, explain how confidentiality regarding the shared information will be preserved.

8.5. Retention and Destruction of Data

Please specify data retention and destruction methods for all data types to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded).

According to UBC Policy <u>SC6</u> on Scholarly Integrity, data must be retained for at least 5 years after publication within a UBC facility, but may be retained for a longer period provided they are stored securely. There is no explicit requirement for destruction of data at the end of this period.

Responsibility for security of data rests with the Principal Investigator.

In some cases, data are of such value that they should not be destroyed (e.g., 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.

8.6. Future Use of Data

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 to the participant and included with the current application. If consent for future use of the data is to be obtained later, full details must be submitted to the REB for review and approval before the research begins.

The REB acknowledges that in the case of **ethnographic field notes** and interviews, researchers cannot be expected to know all the uses they plan to make of the data. Therefore, researchers should inform the peoples they are studying of the potential for future use of the data during the consent process.

8.7. Feedback to Participants Please provide information regarding your plans for communicating study results to participants.

Any prohibition or undue limitation on the publication or dissemination of findings from research is ethically unacceptable. Informing participants of the research results is as important as disseminating results to the research community. See TCPS 2 Chapter 4, Article 4.8.

Include the following information as applicable:

- a) Have relevant knowledge users (e.g., participants, patient or community groups, researchers, people embedded within healthcare or other systems that could affect change, etc.) been consulted regarding sharing results in a culturally appropriate, accessible, and meaningful way? See TCPS 2 Chapter 1, Ethics Framework
- b) Have you committed to developing a plan that includes sharing results in plain language?
- c) How will participants be informed about the study results, and how will they access them?
 See TCPS 2 Article 4.8 for items a, b, c
- d) Will there be consultation with community representatives/patient partners/peer researchers before finalizing publications? See $\frac{\text{TCPS 2}}{\text{Article 9.17}}$
- e) Are there any existing conflicts, barriers, limitations, or competing priorities that could impede the timely sharing of results. If so, how will these be mitigated? See TCPS 2 Article 6.24 and TCPS 2 Chapter 7, Conflicts of Interest

For additional resources see: REBC Resources

Page 9. Documentation - Behavioural Study

Each document attached must contain a version date (yyyy/mm/dd) in the footer that matches the date given on Page 9. Copyrighted questionnaires should use the date of publication. For document guidelines, see Ethical Considerations in Research Design.

9.1. Research Proposal 9.2. Documentation of Consent	 Grant application Dissertation proposal Research proposal Participant consent form Parent/guardian consent form Other consent forms Description of process for obtaining consent (e.g., oral consent script) Click here for more guidelines on behavioural informed consent forms 	
9.3. Documentation of Assent	 Participant assent form Other assent forms (e.g., oral assent script) Click here for more information on assent for the Vancouver & Okanagan UBC BREBs Click here for UBC C&W Research Ethics Board assent template and adolescent assent template * June 2024 - Please note for REBX, Children's and Women's sites have not yet been onboarded. 	
9.4. Advertisement to Recruit Participants	Advertisement to Recruit Participants This includes any type of communication (e.g., flyer, radio/television script, poster, newspaper ad, internet message) that is directed to potential participants for the purpose of recruitment. The purpose of this documentation is to ensure that the recruitment measures are appropriate and not coercive. Click here for UBC C&W Research Ethics Board policies on participant handouts and advertisements. * June 2024 - Please note for REBX, Children's and Women's sites have not yet been onboarded.	

9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc.	If the study is limited to a questionnaire that is completed by the participant, a consent cover letter may be used in lieu of a standard consent form, provided it includes essentially the same information as a consent form, plus a sentence that states that "If the questionnaire is completed, it will be assumed that consent has been given". If a study involves other procedures and a consent form, a covering letter is not required, unless the questionnaire is completed or sent to the participant at a later date. If the questionnaire will be accessed online, details of the survey webhost should be provided in 9.7B.
9.6. Letter of Initial Contact	Letters of Initial Contact – This is the preferred method of recruitment when contact is initiated by the researcher rather than by the participant responding to an advertisement and includes email invitations, follow up emails, reminders, etc.
9.7. Other Documents	If applicable, please attach a transcript (the document must include a version date) of any CD, tape or audio file and send the hard copy to the office of Board of Record. Other documents regularly required include the following: • Deception form and written or verbal debriefing. Please click here to complete the form, then save and attach it to question 9.7 • Evidence of Agency approvals from other institutions If this is an application using the streamlined process as indicated in Question 4.6, please append ALL relevant documentation from the other approving REB, including the application form, all correspondence from and to the approving REB, the proposal approved, the certificate of approval, the other REB approved informed consents, etc.
9.8. Websites and Social Media	If a Web site is part of this study, enter the URL below. Since URLs may change over time or be removed, you must also attach a copy of the documentation contained on the web site to one of the sections above.

Page 11. UBC Children's and Women's Research Ethics Board		
If any hospital/health authority sites under this authority are selected in Box 4.2.A you will be asked to complete this page.		
11.1. C&W PI	If you cannot find the PI's name in the list, have it added by clicking here . Include the name, department, rank (or affiliation with the University), email, UBC employee number (if applicable), and phone number of the PI. Once added to RISe, new user will receive their researcher number by email.	
11.2. C&W UBC Appointment	Completion of this form is not required by those affiliated with a UBC academic department. This form is intended for those in professional departments (e.g., Occupational Therapy, Social Work, Nursing)	
11.3. C&W Hospital Forms	Send the applicable forms listed in Box 11.3 to the Research Ethics Board Office at the Children's and Women's Health Centre. If you have any questions, please email the Children's and Women's Research Ethics Board office at cwreb@bcchr.ubc.ca.	

Page 11. BC	Cancer A	Agency	Centre Pl
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If any hospital/health authority sites under this authority are selected in Box 4.2.A you will be asked to complete this page.

11.1. Lead PI for BC Cancer

Additional participating centre PIs listed in this section WILL be listed on the certificate of approval and WILL have online access to read, edit, and track this application. (Only the PI named in View 1 can submit an application or amendment etc. to the REB).

Click here for criteria on who can be a PI at BC Cancer.

If a centre PI is on a leave of absence longer than 6 months they should be replaced with a new centre PI. If the PI on a leave wishes to have access while they are away so they can continue to monitor the study, they should be added to Box 1.3 as a co-investigator.

11.2. BC Cancer Status of the Clinical Trial Agreement

The Certificate of Approval will not be released until BC Cancer has received a copy of the signed contract, which should be attached in Box 9.8.

All industry-related and "for-profit" sponsored studies require a Clinical Trials Agreement between the sponsor, BC Cancer and the Investigator.

Page 11. Hospital Information for Providence Health Care		
If any hospital/health complete this page.	authority sites under this authority are selected in Box 4.2.A you will be asked to	
11.1.A. Providence Health Care Hospital Services	Once each hospital service or area has granted approval for use of services or facilities, please forward a copy to the Office of Research Ethics c/o Paula Piper (Ethics Review Coordinator). Note that each letter or email must include the title of the research, the name of the principal investigator, and the UBC PHC REB ethics file number.	
11.2.A. Providence Health Care Hospital Area	Please note that the Providence Health Care Certificate of Final Approval to commence the research will not be released until the Office of Research Services receives all relevant hospital services/areas approval letters, the contract (if applicable) has been finalized, and the ethics review fee (if applicable) has been paid.	
11.3. Providence Health Care Declaration Form	Send the completed PHC declaration form to: Alex Trethewey Pre&Post Review Manager Office of Research Ethics Providence Health Care Research Institute alex.trethewey@ubc.ca (604) 682-2344 x68366	

Ensure that the form includes the REB File number for the research.

Page 11. Hospital Information for Vancouver Coastal Health Authority (VCHA)/Vancouver Coastal Health Research Institute (VCHRI)

If any hospital/health authority sites under this authority are selected in Box 4.2.A you will be asked to complete this page.

11.2.A. Vancouver Coastal Health Authority Site Investigator

In order for a research project to be undertaken at VCHA, either a VCHA employee or a member of the VCHA medical staff needs to be designated as the "Site Investigator at VCHA". This individual must have actual responsibility with respect to the project.

If you have a faculty appointment at a post-secondary institution that has a research agreement with VCHA, but <u>do not</u> have an appointment at VCHA, you must either:

- Obtain a VCHRI Affiliated Investigator Appointment. This person will assume the role of "Site Investigator at VCHA". To apply for VCHRI Affiliated Investigator Appointment, please contact the Associate Director, VCHRI at 604-875-4111 Ext 66687.
- 2. Designate a VCHA person as the "Site Investigator at VCHA". If a co-investigator on the study is a VCHA employee or is a member of VCHA medical staff, this person may assume the role of "Site Investigator at VCHA". If you choose this option, please ensure that the "Site Investigator at VCHA" is listed as a co-investigator on the UBC ethics certificate (you would still remain the Principal Investigator on the UBC Research Ethics Certificate of Approval).