Contents for **Guidance Notes** for Behavioural Application

Guidance Notes in Application

Box	Guidance note
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1.1	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 his or her 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 TCPS 2 (2018). 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 RISe Support: 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	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. Note that the PI may change the Primary Contact anytime without an amendment.

Box	Guidance note
1.3	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. 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. If you cannot find your name or any of your study team members' names in the list, have them added or inform them to add themselves by emailing the following information to RISe Support(risesupport@ors.ubc.ca): 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 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.
1.4	List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval. Examples of additional study team members who you may wish to have online access to the application include Clinical Trial Coordinators and Research Assistants.
1.5	The study team members listed in this section do not have online access to RISe. 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	All research personnel who are associated with a research project are required to complete the TCPS 2 online tutorial (CORE) 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 two hours. CORE Certificates do not need to be attached. Copies should be retained and available on request. Click here for the **TCPS 2 2018 Document**. Click here for the **TCPS 2 'CORE' Tutorial**. This tutorial provides an essential orientation to Canadian human research ethics guidelines.
1.7	The title given in the application form must correspond to the title on all study documents, including the consent form.
1.8	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.

Box	Guidance note
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2.1A	In multi-phase projects, include the period that involves research with human participants.
2.1B	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 been updated. In multi-phase projects, include the period that involves research with human participants.
2.2A	"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.
2.3A	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 #F21-00001 was submitted in 2021). Selecting "Add" will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.
2.5A	The **Department of Health and Human Services**, DHHS (US Federal Agencies), requires the Research Ethics Board to review the actual grant application to compare it to the protocol being approved, to ensure that they are the same. Your certificate of approval will not be released until this documentation is attached. Attach DHHS Grant Application for each sponsor listed above.
2.6	If you answer YES to this question (2.6), you will be asked to provide more detail on page 3 of the application.

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3.1	All investigators: For TCPS 2, Chapter 7 – Conflicts of Interest http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter7-chapitre7.html UBC Investigators & Faculty: Click here for information on Policy SC3 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 for more information from the Canadian Medical Association on finder's fees).
3.2	Please refer to TCPS 2, Article 7.4 for more information on Researchers & Conflicts of Interest.
3.3	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 at arm's length to review the data to ensure objectivity, and/ or additional measures.
3.4	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.

Box	Guidance Notes
	Page 4A (Q4.1 to Q4.2C)
4.1	**Clinical** projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of clinical medical records, and any invasive procedure. A clinical research project that also includes questionnaires or interviews should be submitted to a Clinical Research Ethics Board. **Behavioural** projects are those that are behavioural or social scientific in nature or involve humanities research. They may involve the study of patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do include research involving interviews, observations, and the administration of questionnaires or tests.
4.2A	Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited. 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 C for Children's and Women's Health Centre of BC P for Providence Health Care V for Vancouver Coastal Health (VCHRI/VCHA) U for University of British Columbia, University of Northern British Columbia and University of Victoria S for Simon Fraser University I for Interior Health and Island Health N for Northern Health
4.2B	Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited. Add other non-UBC affiliated research sites. Ensure that the primary affiliations of all study team members are represented here. 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.

Box	Guidance Notes
	Page 4B (Q4.2D-Q4.6)
4.2D	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.
4.3B	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.
4.4A	According to Article 2.7 of the TCPS 2 (2018), "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.
4.5A	The TCPS 2 (2018) 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(2018), p. 202). 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.

Box	Guidance Notes
4.6	Examples of non-REBC institutions would be University of Toronto or Ottawa or Harvard etc. Any institution not listed below. Research Ethics BC (REBC) includes the following Institutions and Health Authorities: University of British Columbia University of Northern British Columbia University of Simon Fraser University of Victoria Fraser Health Northern Health Interior Health Island Health Providence Health Vancouver Coastal Health Children and Women's BC Cancer

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F.1.	UBC has entered into alternative review agreements with these institutions. Regardless of whether your study is minimal risk or above minimal risk, it may be eligible to be reviewed pursuant to those alternate review agreements. (Please note that the REB reserves te discretion to determine the appropriate process to be applied to the review of the study.) Click here for more information on options available for multi-jurisdictional studies.
F.2.	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.
F.3.	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.
F.4.	Click here for more detailed instruction on describing **recruitment**. Please ensure the same sites are listed on page 4 of the application.
F.5.	Article 3.12 of TCPS 2 (2018) 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 Article 10.2). 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? 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.

F.6	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 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. 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.

Box	Guidance Notes
	Page 4C (Q4.7, 4.8)
4.7A	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.

Box	Guidance Notes
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B.1	E.g., to conduct educational research that produces insights into how teaching and learning might be improved.
B.3	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	For example, student records, program evaluation data, routinely collected classroom data, etc.
B.5.A	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.
B.6A	Attach a copy of the consent form to Box 9.2.
B.7	Refer to TCPS 2 (2018) Articles 3.7 and 5.5 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	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	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	If this changes in the future, an amendment must be submitted before data are transferred.
B.13A	If this changes in the future, an amendment must be submitted before data are linked.
B.15.A	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.

Box	Guidance Notes
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D.1	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:** as the course instructor, final responsibility for the conduct of the student projects rests with you to ensure that the student projects meet the minimal risk criteria. If **any** of the student projects do not meet the minimal risk criteria (e.g., they involve a medium or high vulnerability population AND medium or high risk research), and you are willing to allow the project to proceed, a separate application for this 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	Please attach a course outline and any assignment materials to question 9.1 of the application.
D.3.A	Please attach a course outline and any assignment materials to question 9.1 of the application.
D.4	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	Please ensure that a template consent document is attached to question 9.2 of the application.
D.6	This information should generally be outlined in consent documents.
D.7.	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.	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	This might take the form of a lecture on ethics, assigned readings, class discussions, etc.
D.10	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	This might take the form of a research proposal that students are required to submit, or individual meetings with the course instructor, etc.
D.12	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	Please check each box to indicate your awareness of your responsibilities as the course convenor/instructor.

Box	Guidance Notes
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K.1	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	Provide an itemized list of the inclusion and exclusion criteria for participation. The selection of participants must take TCPS 2 (2018) 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	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	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 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.
K.4.B	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.

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K.4.C	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	Select all options that apply regarding survey distribution.
K.5.A	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/qualtrics-faqs
K.5.A	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.
K.5.A	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	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 (e.g. U.S. Patriot Act).

Box	Guidance Notes
K.6	Article 3.12 of TCPS 2 (2018) 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 Article 10.2). 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	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 (2018), 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	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 http://cio.ubc.ca/security-standards-home/information-security-policy-standards-and-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.

Box	Guidance Notes
K.8.B	Specify the data destruction method for each data format (e.g. files will be deleted, paper copies shredded, hard drives re-formatted)
K.9	Indicate if there is any known future use of the data after this research project concludes.
K.9	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).

Box	Guidance Notes
	Page L
L.1.A	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	Provide detail regarding what the datasets entail and what variables are included within the datasets that will be used.
L.1.C	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	Answer Yes if you need permission to access the data.
L.1.D	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).
L.1.D	If you have received permission to use this data for your intended purpose, respond Yes to this question.
L.1.D	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	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.
L.1.E	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.
L.1.E	Was the data collected anonymously, or will the data be anonymized or de-identified by the data custodian? 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.
L.1.F	Answer Yes if multiple data sets will be consolidated into one file using a linking code within each file.
L.1.F	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.
L.1.F	Personal identifiers include, e.g.: name, address, social insurance number, personal health number, date of birth, postal code.
L.2	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.

Box	Guidance Notes
L.2	According to the TCPS 2 (2018) Article 5.5A, 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	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 http://cio.ubc.ca/security-standards-home/information-security-policy-standards-and-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	Specify the data destruction method (e.g. files will be deleted, hard drives re-formatted).
L.4	Indicate if there is any known future use of the data after this research project concludes.
L.4	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).

Box	Guidance Notes
	Page 5
5.1B	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. 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	Please enter the inclusion criteria as an itemized list. The selection of participants must take TCPS 2 (2018) 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.
5.3	If applicable, provide all exclusion criteria. If not applicable, write "N/A". Article 4.1 of the TCPS 2 (2018) 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	Click here for more detailed instruction on describing **recruitment**. Please ensure the same sites are listed on page 4 of the application.
5.5	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	The summary should include activity locations, event type, who will be 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 here to complete the Deception Form, then save and attach the form to question 9.7.

Box	Guidance Notes
	Page 6
6.1	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	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	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	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 Aboriginal groups are the focus of analysis then the REB takes direction from Chapter 9 of TCPS 2 (2018).

Box	Guidance Notes
6.5	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 (2018), 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 (2018) Article 3.1) Click here for further information on reimbursement and payments.
6.6	Article 3.12 of TCPS 2 (2018) 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 Article 10.2). 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? 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.
6.6A	Please justify the waiver or alteration and confirm that the study meets the below criteria. Please address each criterion individually. Conditions for waiver/alteration of consent: 1) The research involves no more than minimal risk to participants. 2) The lack of consent is unlikely to adversely affect the welfare of the participant. 3) It is impossible or impracticable to carry out the research and to answer the research question properly without the waiver or alteration. 4) Whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation. 5) The waivered or altered consent does not involve a therapeutic intervention.
6.7	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 (2018), 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."

Box	Guidance Notes
6.8	Click here 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	Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place. TCPS 2 (2018), 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	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	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. Click here for information on Conflict of Interest policy.

Box	Guidance Notes
	Page 7
7.1.A	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	TCPS 2 (2018) Article 8.3(b) states, "Research conducted under the auspices of a Canadian research institution and conducted outside its jurisdiction... shall 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	Click here for TCPS 2 (2018) Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada.
7.1.H	Does this study fall within the clinical/intervention trial definition stated on the right (in the guidelines)? 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	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	Who will actually conduct the study and what are their qualifications to conduct this kind of research? (e.g., describe relevant training, experience, degrees, and/or courses). If this is a student project, ensure that your supervisor's experience is explained.

Box	Guidance Notes
	Page 8
8.1	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	Box 8.2. Provide the names of those who will have access to the raw data. For UBC research team members, please describe how they will be made aware of their responsibilities concerning privacy and confidentiality. Temporary student assistants and research staff may be referred to by their role instead of name. If you are using a transcription service, include the service name, if known, and describe the data security measures you will be using with the transcription service: e.g. how data will be transferred, location of data storage, how long it will be stored, and when/how it will be destroyed. In the consent form: - Describe who will have access to participant data and how the data will be used, both during the current study and in the future (if applicable). Include information about how files will be transcribed and how data will be protected during transcription.
8.3	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 here 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.

Box	Guidance Notes
8.5	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 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. 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. You will be asked to reconfirm your data retention plans on the PAA coversheet when you close the study.
8.6	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	Are there any plans for providing feedback on the findings or results of the research to participants? TCPS 2 (2018), Chapter 4 on equitable distribution of research benefits states that researchers should generally ensure that participating individuals, groups and communities are informed of how to access the results of the research. Results of the research should be made available to them in a culturally appropriate and meaningful format, such as reports in plain language in addition to technical reports.

Box	Guidance Notes
	Page 9
9.1A	• Grant application • Dissertation proposal • Research proposal
9.2	• 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	• 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
9.4	**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.
9.5	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	**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. **Telephone contact form** – Initial contact by telephone is discouraged by the BREB. Interviews may be conducted by telephone after making contact by mail/email and obtaining consent. For surveys where initial contact is made by random digit dialing, complete and attach appendix 4 "Telephone Contact Form".

Box	Guidance Notes
9.7	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	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.

Box	Guidance Notes
	Page 11 Vancouver Coastal Health
11.1	If you have not yet received hospital approval to conduct this study an email will be sent to the PI listed in Box 1.1 and the primary contact listed in Box 1.2 on submission to the ethical review board listing the steps required to receive approval by the appropriate VCHA Health Service Delivery Area(s).
11.2A	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 do not have an appointment at VCHA, you must either: 1. 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).
11.3	IMPORTANT: To avoid delays, researchers should simultaneously submit this application for ethical review (by selecting the "submit" button on the application homepage once the application is complete) and send the applicable forms to the Health Service Delivery Area(s) (HSDA) specified in Box 11.3 as approval from both the ethical review board and the HSDAs are required before a project may proceed.

Box	Guidance Notes
	Page 11 BC Cancer Agency
11.1	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 the BC Cancer policy on listing Principal Investigators and Co-investigators (see "BCC & non-BCC Researchers"). 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	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.

Box	Guidance Notes
	Page 11 Children's and Women's
11.1	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	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	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.

Box	Guidance Notes
	Page 11 Providence Health Care
11.1	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 Alex Trethewey (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. NOTE: Use of Anatomical Pathology If the research is being conducted by an external researcher in possession of a certificate of ethical approval issued by a UBC Research Ethics Board other than the Providence Health Care Research Ethics Board, please follow the following instructions: Requests for pathology tissue blocks/slides for new and on-going research projects should be copied to: Alex Trethewey Pre&Post Review Manager Office of Research Ethics Providence Health Care Research Institute alex.trethewey@ubc.ca (604) 682-2344 x68366 The request should include a copy of a current Certificate of Ethical Approval and a copy of the relevant approved consent form.
11.2.A	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	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.

Box	Guidance Notes
	Page 11 Fraser Health
11.2	Please note that if Fraser Health services or access to a patient care area are required a **Department Agreement for Providing Research-Related Services [DAR] Form** will be required. For details, refer to the DAR form at: https://www.fraserhealth.ca/-/media/Project/FraserHealth/FraserHealth/Health-Professionals/Research-and-Evaluation-Services/Forms-guidance-notes-and-templates/Forms_guidance_notes_templates_201902/DAR_form.docx
11.3	Please note that Affiliated Investigators must also have a Fraser Health Co-Investigator submit a letter to the FHREB detailing their roles and responsibilities in the project. This document may be added to RISe Section 9.8.A. For more information about becoming an Affiliated Investigator, please visit our website at https://www.fraserhealth.ca/employees/research-and-evaluation/get-involved-in-research/becoming-an-academic-affiliated-researcher#.XbITquhKiUk to the initiation of research at FH Sites, the FHREB must provide written approval of all human subject research that includes any of the following:
11.4	If Yes, please note that you are required to complete an Appendix 2 (Privacy, Confidentiality, and Data Security) form to obtain a Department Access Agreement (DAA). This form should be uploaded in Box 9.8.A.