# 1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION

## 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 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.*

Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:

## 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 categories below. Note that the PI may change the Primary Contact anytime without an amendment.

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### GUIDANCE NOTES

A Principal Investigator (PI) either has 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.

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

Instructors who are applying for research ethics approval for class-based projects in courses they are teaching can be listed as a PI on their application. Please contact the REB manager if you are submitting a class project and require the capacity to list yourself as a PI on the application.

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.
Study Team Members

Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.

To add Co-Investigators and additional study team members in questions 1.3 and 1.4:

1. Click "Add".
2. Enter the name, or enter the first few letters of the person’s name and click "Go".
3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.
4. Select the boxes beside ALL applicable names and click "OK".

To delete a person from the list, select the box next to his or her name and click "Remove".

1.3. Co-Investigators

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 Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student’s name in this section.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Institution/Department</th>
<th>Rank</th>
</tr>
</thead>
</table>

1.4. Additional Study Team Members - Online Access

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.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Institution/Department</th>
<th>Rank</th>
</tr>
</thead>
</table>

1.5. Additional Study Team Members - No Online Access

Click "Add" to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.

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. Tri Council Policy Statement (TCPS) Tutorial

* Tri Council Policy Statement2 (TCPS2) Tutorial

All undergraduate and graduate students and medical residents are required to complete the TCPS2 Tutorial (CORE) before submission. This tutorial provides an essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below:

1.6.A. All Undergraduate/Graduate Students:

* 1.6.B. All Medical Residents:

All non-Faculty personnel who are associated with a research project and who will have contact with the research participants are required to complete the TCPS2 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, etc. The REB requires that all Principal Investigators be familiar with the TCPS2 and recommends that Principal Investigators also complete the TCPS2 tutorial, especially when the Principal Investigator supervises or teaches classes for graduate students or medical residents.

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
**1.7. Project Title**

Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.

The title given in the application form must correspond to the title on all study documents, including the consent form. If the study is supported by research grant or contract funding that is being administered by the University or one of the teaching hospitals, the title should correspond to the title on the grant or contract.

For studies that have multiple titles that correspond with multiple funding sources, please enter these titles and the respective funding sources in question 2.4.

For class-based projects please ensure to include “Class Project” in the first part of the title and the project nickname (question 1.8).

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**1.8. Project Nickname**

Enter a nickname for this study. What would you like this study to be known as to the Principal Investigator and study team?

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.

For class-based projects, include “Class Project” in the first part of the nickname.

For Family Practice Residency projects, include "Family Practice Project" in the first part of the nickname.

For Harmonized Review projects include "Harmonized Review Project" in the first part of the nickname.
### 2. STUDY DATES & FUNDING INFORMATION

**- HUMAN ETHICS APPLICATION**

#### Project Period

*2.1.A.*

*Please choose ONE of the following:*

- You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),

  -  

  OR

- You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd.

  Estimated start date:

*2.1. B.*

**Estimated end date:**

#### Source of Funds

*2.2.A. Types of Funds*

Please select the applicable box(es) below to indicate the type(s) of funding you are receiving to conduct this research. **You must then complete section 2.3 and/or section 2.4 for the name of the source of the funds to be listed on the certificate of approval.**

<table>
<thead>
<tr>
<th>Type(s) of Funding</th>
</tr>
</thead>
</table>

*2.2.B. For Industry Sponsored studies, please provide a sponsor contact.*

*2.2.C. Please enter any applicable information about your funding which is not already shown in Box 2.3 or 2.4 (including funding applied for but not yet received).*

"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.
**Source of Funds**

Please clearly identify the application for research funding associated with this ethics application. This will ensure that awarded research funds can be made available to you once this ethics application receives approval.

### 2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services

Please click "Add" to identify the research funding application/award associated with this study. 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.

<table>
<thead>
<tr>
<th>UBC Number</th>
<th>Title</th>
<th>Funding PI</th>
<th>Sponsor</th>
</tr>
</thead>
</table>

**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 #F08-00001 was submitted in 2008).

### 2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3.

Please click "Add" to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press "Add" you can do a search for your funding award by doing a search in the "Sponsor" box - over 7000 options are listed.

<table>
<thead>
<tr>
<th>Title</th>
<th>Sponsor</th>
</tr>
</thead>
</table>

### U.S. Funding

- **2.5.A. Is this a DHHS grant? (To view a list of DHHS funding agencies click on "add" in 2.5.B below)**
  - [ ] Yes
  - [ ] No

- **2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.**

Attach DHHS Grant Application for each sponsor listed above

<table>
<thead>
<tr>
<th>Title</th>
</tr>
</thead>
</table>

### 2.6. Conflict of Interest

Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members?

- Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a "finders fee" for each participant enrolled is not allowed).
- Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest).
- Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board.
- Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).

- [ ] Yes
  - [ ] No

The REB needs to be satisfied that participants are informed of conflict of interest matters in the consent process. Note that "immediate family members" includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements. If you answer yes to this question you will be asked to provide more detail on view 3 of the application.
4. STUDY TYPE - HUMAN ETHICS APPLICATION

4.1. UBC Research Ethics Board

Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:

BC Cancer Agency Research Ethics Board - Behavioural

UBC’s REBs have signed a one board of record agreement. Studies taking place at multiple UBC sites require review and approval by only one UBC-Affiliated REB. Choice of Board should be determined by the PI’s primary appointment and/or the main location of the research.

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.

4.2. Institutions and Sites for Study

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 your research will not be carried out at an institutional site, please check the "N/A" box. Otherwise 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 Agency, C for Children’s and Women’s Health Centre of BC, P for Providence Health Care, U for UBC Campus, V for Vancouver Coastal Health (VCHRI/VCHA).

N/A: ☐

4.2.A. Institutions and Sites for Study

<table>
<thead>
<tr>
<th>Hospital/Institution</th>
<th>Site</th>
</tr>
</thead>
</table>

4.2.B. Other locations that are outside of a Hospital/Institution but still under the jurisdiction of a UBC REB as noted above.

Institutional Approval: Research at UBC's affiliated hospitals 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. The Hospital Administrator for facilities/services at the hospital or centre selected will be granted viewing access to this application; however, it is the PI’s responsibility to pursue and obtain the necessary approvals from the various hospitals.
**4*. BEHAVIOURAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION**

### Relationship to Previous Ethics Applications

**4.3.A.**

If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.

**4.3.B.**

If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.

**4.3.C.**

Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.

- Yes
- No

### Peer Review

If this research proposal has received any independent scientific/methodological peer review, please include the names of committees or individuals involved in the review. State whether the peer review process is ongoing or completed.

**4.4.A.**

External peer review details:

**4.4.B.**

Internal (UBC or hospital) peer review details:

**4.4.C.**

If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.

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According to Article 2.7 of the TCPS2, "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 to the BREB, 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.
Minimal Risk

* 4.5.A

After considering the level of risk your research involves and the vulnerability of your study population, please tick one box below that best represents the overall level of risk your study entails.

<table>
<thead>
<tr>
<th>Participant Vulnerability</th>
<th>Research Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low Medium High</td>
</tr>
<tr>
<td>Low</td>
<td>1 1 2</td>
</tr>
<tr>
<td>Medium</td>
<td>1 2 3</td>
</tr>
<tr>
<td>High</td>
<td>2 3 3</td>
</tr>
</tbody>
</table>

Please check one box only

* 4.5.B

Explain/justify the level of risk and group vulnerability reported above.

* 4.5.C

Does your application fall under "minimal risk" (i.e., it was assigned an overall risk level of 1 on the minimal risk matrix) and therefore is eligible to be considered for Delegated Review?

The TCPS2 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” (TCPS2, p. 197).

Considerations of 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).

If your study involves low vulnerability participants and low/medium research risk, or low research risk and low/medium vulnerability participants, it is assigned an overall risk level of 1 and falls under the "minimal risk" category.

Click [here](#) for further information on the risk matrix and minimal risk criteria.

* 4.6. Harmonized Review of Multi-Jurisdictional Studies

Is this study a multi-jurisdictional study that requires review by one or more institutions? (Note: If submitting an amendment for an already approved study, you must respond "No" to this question)

[ ] Yes [ ] No

A multi-jurisdictional study is a research study that requires review and approval by more than one Canadian research ethics board (i.e., by more than one Canadian REB as well as a UBC affiliated REB) as a result of the requirements of the TCPS2 and/or UBC’s and/or another institution’s human ethics policies.

When you click "Yes" to question 4.6 you will be directed to a branch off which asks specific questions about multi-jurisdictional studies.

If submitting an amendment for an already approved study, you must respond "No" to this question.

4.7.A Creation of a Research Database or Registry

Does this study involve the creation of a research database or registry for future unspecified research? [if no, skip to 4.8]

[ ] Yes [ ] No

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
<table>
<thead>
<tr>
<th>4.7.B</th>
<th></th>
</tr>
</thead>
</table>
| **Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry?**  
[Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer "no" below]. |  |
| Yes | No |  |
| 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. |  |
### C. Creation of a Research Database, Registry or Biorepository - HUMAN ETHICS APPLICATION

#### C.1. What is the scope and purpose of the database, registry or biorepository?

Some institutions may request that a Privacy Impact Assessment (PIA) be completed when creating a research database or registry. Consult your hospital or institutional privacy office for more information.

In addition to other attributes, biorepositories may be considered as: a) mono-user biobanks (i.e., a collection aimed at supporting a specific, single research project; b) an oligo-user biobank (i.e., a collection aimed at supporting several research projects, a research group or a research consortium); or c) a poly-user biobank (i.e., a collection aimed at supporting undetermined, multiple users with REB-approved research projects, through a defined access/application mechanism).

#### C.2. What are the anticipated public and scientific benefits of the database, registry or biorepository?

Include a clear date range of the information that will be included in the registry or biorepository. If data will be collected indefinitely, clearly indicate that data will be collected indefinitely or until the participant withdraws, if applicable.

#### C.3. Over what period of time will data be collected?

Answer C.4.A. and B if your project involves creation of a database or registry.

Answer C.4.C. if your project involves creation of a biorepository.

Tissue biospecimens are any human biospecimens or biological material comprised of whole solid tissues, cells isolated from solid tissues and fluids other than blood.

### C.4. Sources

#### C.4.A. What information source(s) are you accessing?

**Provide specific details about the source(s), i.e., including name of the database or type of health records, location etc.**

#### C.4.B.

**What are the sources of your biospecimens, check all that apply.**

- [ ] Direct from live subject (procedure conducted for research purposes)
  
  Select biospecimen source:
  
  If "Other" or multiple sources will be used, specify them here:

- [ ] Indirect from live subject (procedure conducted for clinical purposes and excess tissue leftover after clinical diagnosis obtained for research)
  
  Select biospecimen source:
  
  If "Other" or multiple sources will be used, specify them here:

- [ ] Post mortem tissue collection
  
  Select biospecimen source:
  
  If "Other" or multiple sources will be used, specify them here:
C.5.A. Confidentiality
Are you collecting personally identifying information/will the biospecimens be linked to personally identifiable information? [If not, skip to C.9]
- Yes  - No

C.5.B.
Indicate the type of personally identifying information you will be collecting that will be linked to the specimens. Include a justification for its inclusion in the registry or database and/or retention of the link.

C.5.C.
How long will data remain identifiable/specimens be linked (i.e., when, if ever, will it be irreversibly anonymized). Justify why data/specimens need to remain identifiable, if this is the case.

C.5.D.
List the individuals (who are not already listed on page 1 of the application) who will have access to personally identifying information at any stage in the data collection or review/abstraction of the data/analysis of the specimens including those who will have access to master lists of keys linking identifiable participants to research data/specimens.

<table>
<thead>
<tr>
<th>Name</th>
<th>Degree</th>
<th>Affiliation</th>
<th>Role on project</th>
<th>Email</th>
</tr>
</thead>
</table>

C.6.A. Consent
Will participants consent to be included in the database or registry? Have their specimens been included in the biorepository? [If no, skip to C.7.]
- Yes  - No

C.6.B.
Specify who will explain the consent form and invite participants to contribute. Include details of where consent will be obtained and under what circumstances. For biorepositories, please explain whether the consent process is pre-procedure or post-procedure.

C.7.
If you are collecting personally identifying information or if you are collecting biospecimens that will be linked to personally identifiable data and do not plan to obtain individual participant informed consent, please provide justification for not doing so following the criteria outlined on the right. Please address each criterion individually.

Refer to TCPS2 5.5 D. Consent and Secondary Use of Identifiable Information for Research Purposes:

Article 5.5 Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:

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;
<table>
<thead>
<tr>
<th>C.8.A. Participant access to data and withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will individual participants have the right to access their data, or right to amend or withdraw their information?</td>
</tr>
<tr>
<td>[ ] Yes  [ ] No</td>
</tr>
</tbody>
</table>

| C.8.B. Provide details of the process for accessing and/or withdrawing data, including what data can be withdrawn. |

<table>
<thead>
<tr>
<th>C.9. What is the entity or who is the person that will have custodianship of the database or registry/biorepository?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A data/biorepository custodian is an entity or person who is responsible for overseeing the management and use of the data/biorepository, including the main rules governing use of the database/biorepository, 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/biospecimens.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C.10. What will be the address of the database, registry or the location of the biorepository?</th>
</tr>
</thead>
<tbody>
<tr>
<td>This should be a mailing address; however, if there is a URL, please also provide it.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>C.11. What steps will be taken to ensure the security of the data/biospecimens?</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

| C.12. For databases and registries, describe the risks associated with the possible disclosure of the data. Include any foreseeable circumstances where disclosure of identifying data may be required by law. |

- the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;
- the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- it is impossible or impracticable to seek consent from individuals to whom the information relates; and
- the researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.
### C.13.A. Data/Biospecimen Transfer
Will data/biospecimens be sent outside of the institution? [If no, skip to C.14]

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### C.13.B.
Explain why it is necessary to send the data/biospecimens outside of the institution, and indicate what data/biospecimens will be sent, where it/they will be sent, who it/they will be sent to, how it/they will be transferred (faxed, emailed, couriered, encrypted electronic transfer etc.) and where it/they will be stored.

#### C.13.C.
Will there be a data transfer/material transfer agreement?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Note that if this changes in the future an amendment must be submitted before data is transferred.

#### C.13.C. Attach a copy of the data transfer agreement to box 9.8. of the application.

### C.14.A. Data Linking
Do you plan to link all or some of the data or the biospecimens to another data source (e.g., database, biorepository)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### C.14.B.
Identify the data set, how the linkage will occur, and provide a list of data items in the other database. Also, identify what personal information will be used to link the databases and how confidentiality regarding this shared information will be preserved.

#### C.14.A. Data Linking
Note that if this changes in the future an amendment must be submitted before data is linked.

### C.15.A. Data Retention
How long are you planning to keep the data/biospecimens?

#### C.15.B.
If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens.

### C.16.A. Future Use
Will the information in the database/biorepository be retained as an ongoing database/biorepository (or as part of an ongoing database/biorepository) for future research? [If no, skip to C.17]

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

#### C.16.B.
Provide a full description of the data/biospecimen stewardship process, including whether the database/biorepository will have formalized standard operating procedures.

#### C.16.B. Reference who will have access to the database in the future and under what circumstances, what will happen if an individual data custodian leaves the institution, where the ongoing database will be stored or maintained, and what security measures will be in place.

UBC’s REBs encourage researchers who are creating biorepositories to consider certification of their biorepository with the Canadian Tumour Repository Network (CTRNet) Biobank Certification Program or accreditation with the College of American Pathologists (CAP) Biorepository Accreditation Program.
**C.17.**
Describe any commercial uses for which the data/biospecimens may be used, including any disclaimers concerning participant remuneration for such use.

**C.18. Registration for Publication of Clinical Trials**

**C.18.A.**
Does this clinical study fall within the definition stated on the right (in the guidelines)?

- [ ] Yes
- [ ] No

**C.18.B.**
If "Yes", click "Add" to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available.)

<table>
<thead>
<tr>
<th>Has it been registered?</th>
<th>Authorized Registry used</th>
<th>Clinical Trial unique identifier</th>
</tr>
</thead>
</table>

If there is any possibility of the intent to publish results of the study it must be registered BEFORE the study is started, (but not necessarily before ethical approval is granted.) The International Committee of Medical Journal Editors (ICMJE) now require registration for all clinical trials as defined by "Any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". Health related interventions include any intervention used to modify a biomedical or health-related outcome; for example, drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration. For more information concerning registration requirements, click [here](link).
### E. Harmonized Review of Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

<table>
<thead>
<tr>
<th><strong>E.1.</strong> Is this the first/initial application for review of the multi-jurisdictional study at any of the sites where the research is going to be conducted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
</tbody>
</table>

The first/initial application for review is the first application for ethical review of the research submitted to any of the Institutions with which UBC has a signed reciprocity agreement.

UBC has entered into partial reciprocity and collaborative review arrangements with certain other institutions and entities in situations where a study requires review and approval by more than one Canadian Research Ethics Board. For detailed guidance on harmonization processes and requirements click [here](#). For a list of institutions with which UBC has a reciprocity or collaborative review agreement click [here](#).

<table>
<thead>
<tr>
<th><strong>E.2.</strong> Are you the Lead Investigator for this multi-jurisdictional study? (See definition on right)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐</td>
</tr>
</tbody>
</table>

The Lead Investigator is the only Investigator conducting the multi-jurisdictional study at various sites or the Investigator chosen from amongst numerous Investigators from various sites to lead the multi-jurisdictional study.

The Lead Investigator is the Investigator who submits the first/initial application for ethical review of the multi-jurisdictional study at any of the sites where the research is going to be conducted. The Lead Investigator is required to submit the initial application for review of the research to his or her home institution's REB regardless of where the research is taking place.

If this is an initial application for review of the study and you are NOT the lead investigator, you cannot continue with this submission.

If you are a UBC faculty member, you cannot answer 'no' to question E.1 and 'yes' to question E.2 because UBC must perform the review of initial/first application since UBC is your home institution.

<table>
<thead>
<tr>
<th><strong>E.3.</strong> Please indicate which institution with which UBC has an Ethics Review Agreement is your home institution. Check the institution below</th>
</tr>
</thead>
</table>

If your institution appears on this list the application will truncate to view 9, where you will need to append all UBC site specific documents as applicable. Please append to view 9 all available documentation and information from the Lead PI and his/her REB, including the Lead PI's REB Application, Certificate of Approval, Informed Consent and recruitment documents and all available correspondence between the Lead PI's REB and the Lead PI, including, if available, the minutes from the Lead PI REB's review of the study.

If your institution does not appear on this list, you will be directed to 4.8 and will need to fill out the full REB application.
### 5. SUMMARY OF STUDY AND RECRUITMENT - HUMAN ETHICS APPLICATION

#### Study Summary

**5.1.A**

Provide a short summary of the project written in lay language suitable for non-scientific REB members. **DO NOT exceed 100 words and do not cut and paste directly from the study proposal.**

*5.1.B*

Summarize the research proposal:

- The summary should include the following: the research question and/or hypothesis (where and if a hypothesis is appropriate to the study), the study population, and the study methods.

The REB will review the study proposal attached to question 9.1 for the expanded description of how the study aims will be achieved and how the analysis will be undertaken. The board's main interest here is what the researcher will actually be doing with participants as he/she undertakes the study so that they can assess potential risks to the participants and how the researcher is handling them, etc.

Describe the purpose in lay language or include definitions of jargon or technical terms. Also, all acronyms must be written out in full the first time that they appear in the application form, recruiting and consent materials.

#### 5.2. Inclusion Criteria

Describe the participants being selected for this study, and list the criteria for their inclusion.

Please enter the inclusion criteria as an itemized list.

The selection of participants must take TCPS2 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". However, the TCPS2 cautions against recruiting participants into research studies solely because they are easy to access or manipulate.

#### 5.3. Exclusion Criteria

Describe which participants will be excluded from participation, if any, and list the criteria for their exclusion.

If applicable, provide all exclusion criteria. If not applicable, write "N/A".

**Article 4.1** of the TCPS2 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

Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on view 9 (section 9.7).

Privacy legislation in BC states that organizations cannot provide contact information for clients without their consent unless the researchers have obtained permission from the Provincial Privacy Commissioner.

Click [here](#) for information on recruitment.

UBC policy does not allow initial contact by telephone. However, surveys which use random digit dialing may be allowed. If your study involves initial contact by random digit dialing, please click [here](#) to complete the Telephone Contact Form, then save and attach the form to question 9.6.
### 5.5. Use of Records

If existing records (e.g., health records, course grade sheets or other records/databases) will be used to IDENTIFY potential participants, please describe how permission to access this information, and to collect and use this information, will be obtained.

Where the investigator is in a dual relationship— that is, the researcher maintains the records (e.g., as a clinician, educator, etc.) and is proposing to undertake research on them, steps need to be taken to ensure participants' rights are not violated.

### 5.6. Summary of Procedures

Describe in a step-by-step manner the research procedures. 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.

### 5.7. Checklist for Research Methods

Are any of the following procedures or methods involved in this study? Check all that apply.

This does NOT represent a comprehensive list of research methods. These methods are included here because they represent possible departures from established processes for obtaining free and informed consent. Therefore, please do not tick the "expert interviews" box unless you are actually doing expert interviews.

Please ensure you have included a detailed description of any of the procedures or methods selected here in the procedures question 5.6.

Click here for further information on these methods of data collection.
### 6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

#### 6.1. Time to Participate

*How much time will a participant be asked to dedicate to the project?*

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 you also include this information in the consent process and that the amount of time stated is consistent in the application, recruitment letters or posters, and consent information.

#### 6.2. Risks

*Describe what is known about the risks of the proposed research for participants.*

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. Benefits

*Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.*

Specify the benefits to the participants. If there are no benefits, state this explicitly. If any specific therapeutic benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study.

#### 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.

The REB cautions against analyses that may contribute to stereotyping of groups on the basis of ethnic or cultural background, sexual orientation, etc. Therefore, when the study includes specific groups or a range of groups and asks participants to categorize themselves according to 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 TCPS2.

#### 6.5. Reimbursement

*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 the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.*

In accordance with TCPS2, the REB takes 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 TCPS2 Article 3.1).

Click [here](#) for further information on reimbursement and payments.

#### 6.6. Obtaining Consent

*Specify how potential participants will be invited to take part in the study. Include details of where the consent will be obtained and documented, and under what circumstances.*

Article 3.12 of TCPS2 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.

The REB recognizes that written consent is not necessarily 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 question 9.2 of the application.

### 6.6.A. Waiver of Consent

If you are asking for a waiver or an alteration of the requirement for participant informed consent please justify the waiver or alteration and confirm that the study meets the criteria on the right. Please address each criterion individually.

<table>
<thead>
<tr>
<th>Conditions for waiver/alteration of consent:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) The research involves no more than minimal risk to participants;</td>
</tr>
<tr>
<td>2) The lack of consent is unlikely to adversely affect the welfare of the participant;</td>
</tr>
<tr>
<td>3) It is impossible or impracticable to carry out the research and to answer the research question properly without the waiver or alteration;</td>
</tr>
<tr>
<td>4) Whenever possible and appropriate, the participants will be debriefed and provided with additional pertinent information after participation;</td>
</tr>
<tr>
<td>5) The waivered or altered consent does not involve a therapeutic intervention.</td>
</tr>
</tbody>
</table>

### 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.

TCPS2, 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

Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click "Select" to complete the question and view further details.

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. Renewal of Consent

Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.

TCPS2, Article 3.3 states, "In general, participation should be based on consent that is voluntary, informed, and ongoing throughout the duration of the research”.

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 contact letters or consent documents that have been translated into other languages to question 9.2 of the application.
### 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.

Click [here](#) for information on UBC's Conflict of Interest policy.
### 7. NUMBER OF PARTICIPANTS AND LOCATIONS FOR BEHAVIOURAL STUDY - HUMAN ETHICS APPLICATION

#### 7.1 External Approvals

External approvals for research involving other institutions and other jurisdictions: Provide written proof of agency approval for projects carried out at other institutions and, when applicable, other jurisdictions.

Indicate external approvals below:

<table>
<thead>
<tr>
<th>A. Other Institutions:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Please select "Add" to enter the name of the institution and if you have already received approval attach the approval letter.

<table>
<thead>
<tr>
<th>Name of Institution</th>
<th>Document(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>B. Other Jurisdiction or Country (if answer is &quot;No&quot; go to 7.1.G):</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Please select "Add" to enter the name of the jurisdiction or country and if you have already received approval attach the approval letter.

<table>
<thead>
<tr>
<th>Name of Jurisdiction or Country</th>
<th>Document(s)</th>
</tr>
</thead>
</table>

#### 7.1 A. External Approvals

Written evidence of approval (to use the premises or to access students, clients, patrons or patients) is required for projects carried out at other institutions. If agency approval cannot be obtained without prior approval of the UBC 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 UBC REB must accompany a request to the institution for approval.

#### 7.1 E Other Jurisdictions

TCPS2 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 Research with aboriginal communities

Click here for TCPS2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada

Click here for CIHR Guidelines for Health Research Involving Aboriginal People

#### 7.1 H Registration of Clinical Trials

If there is any possibility of the intent to publish the results of the study in an ICMJE (International Committee of Medical Journal Editors) member journal, and it falls under their definition of a clinical trial (which includes behavioural treatments, dietary interventions and process-of-care changes), the study must be registered BEFORE it is started (but not necessarily before ethical approval is granted). Please click here for further details and/or check out the Clinical Research Ethics Board’s RISe Application Guidance Notes.
### H. Registration for Publication of Clinical Trials. Does this study fall within the clinical/intervention trial definition stated on the right (in the guidelines)?

- Yes
- No

*If 'Yes', click 'Add' to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available).*

<table>
<thead>
<tr>
<th>Has it been registered?</th>
<th>Authorized Registry used</th>
<th>Clinical Trial unique identifier</th>
</tr>
</thead>
</table>

#### 7.2. Number of Participants

**A.**

*How many participants will take part in the entire study (i.e., the entire study, world-wide)?*

**B.**

*How many participants will take part at institutions covered by this Research Ethics Approval (i.e., only at the institutions covered by this approval)?*

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. Researcher Qualifications

*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).*
**8. Security of Data and Confidentiality of Personal Information for Behavioural Study - Human Ethics Application**

### 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? (For example, study documents must be kept in a secure locked location and computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer, back up files should be stored appropriately.)*

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

### 8.2. Access to Data

*Who will have access to the data (e.g., co-investigators, students or translators)? How will all of those who have access to the data be made aware of their responsibilities concerning privacy and confidentiality issues?*

*Give the names (if known) of those who will have access to the raw data, which may include information that would identify the participants. The research participants must also be told in the consent process who will have access to his/her data and what use will be made of it, either now or in the future. Temporary student assistants, 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.*

### 8.4. Transfer of Data

*Will any data that identify individuals be transferred (available) to persons or agencies outside of the University?*

- [ ] Yes  - [ ] No

*If YES, describe in detail what identifiable information is released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement if applicable.*

---

Click [here](#) for further information on Confidentiality.

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.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5. Retention and Destruction of Data</td>
<td>UBC policy requires that data be kept for at least 5 years within a UBC facility. If you intend to destroy the data at the end of the storage period, describe how this will be done to ensure confidentiality (e.g., tapes should be demagnetized, paper copies shredded). <strong>UBC has no explicit requirement for shredding of data at the end of this period and it may be kept indefinitely.</strong> Please note that the responsibility for the security of the data rests with the Principal Investigator.</td>
</tr>
<tr>
<td>8.6. Future Use of Data</td>
<td>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 BREB for review and approval before the research begins. The BREB 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.</td>
</tr>
<tr>
<td>8.7. Feedback to Participants</td>
<td>TCPS2, 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.</td>
</tr>
</tbody>
</table>
9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach the documentation for the study. The Research Ethics Office will NOT check the content of each attachment and cannot change document names or dates.

INSTRUCTIONS

View the guidelines to the right of each section to see where the document should be attached. Documents will appear on the certificate of approval with the information that you enter when you attach the document. Please check that version dates, document names etc. are accurate and match those on the attached documents. Submit final versions only (i.e. not "drafts") except that blanks can be included for names and addresses in documents to be sent to specific individuals or organizations. Revisions required by the Board should be highlighted.

New Applications: Attach the documents to the applicable section (refer to guidelines on right)

Response to Proviso or Deferral or Changes Required by REBA:
If you are submitting a revised version of a document that is already attached; delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other documents). You may add a new document but you must indicate in your response that you have added a new document for review.

Amendments:
If you are submitting a revised version of a document that is already attached; delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other previously approved documents, those should remain in the application).

If you are submitting a new document that is being added to the study; simply attach it to the applicable section (leave all other previously approved documents in the application).

9.1. Research Proposal

Examples of types of proposals are listed on the right. Click "Add" to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant application</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dissertation proposal</td>
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<td></td>
<td></td>
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<tr>
<td>Research proposal</td>
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</tbody>
</table>

9.2. Documentation of Consent

Examples of types of consent documents are listed on the right. Click "Add" to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant consent form</td>
<td></td>
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<td></td>
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<tr>
<td>Parent/guardian consent form</td>
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<tr>
<td>Other consent forms</td>
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<tr>
<td>Description of process for obtaining consent (e.g. oral consent script)</td>
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<tr>
<td>Click <a href="#">here</a> for more guidelines on behavioural informed consent forms</td>
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</tbody>
</table>

9.3. Documentation of Assent

Examples of types of assent documents are listed on the right. Click "Add" to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant assent form</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other assent forms (e.g. oral assent script)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Click <a href="#">here</a> for more information on assent for the Vancouver &amp; Okanagan BREBs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Click <a href="#">here</a> for UBC C&amp;W Research Ethics Board assent template</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9.4. Advertisement to Recruit Participants

Examples are listed on the right. Click "Add" to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advertisement to Recruit Participants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Click <a href="#">here</a> for BCCA Research Ethics Board policies participant handouts and advertisements</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc.

Please click “Add” to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
</table>

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

Please click “Add” to enter the required information and attach the forms.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
</table>

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”.

9.7. Other Documents

A.

Other documents: Examples of other types of documents are listed on the right. Click "Add" to enter the required information and attach the documents.

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Version</th>
<th>Date</th>
<th>Document</th>
<th>Password (if applicable)</th>
</tr>
</thead>
</table>

B.

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 Research Ethics Office.

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.
The fee for ethical review applies only to research that receives funding from a "for-profit" sponsor (for example, pharmaceutical/medical devices company or other for-profit organization).

The fee for ethical review is $3,000. This is a one-time-only fee for each new application and covers all subsequent transactions (e.g. amendments, renewals). **NOTE: Review of Serious Adverse Events (SAE’s) are not included in this fee and will be billed separately.**

The certificate of approval will not be issued until payment of the ethical review fee (and the BC Cancer Agency Clinical Trial Agreement if applicable) has been received.

**Invoice:** If payment is not received when your application is submitted to the Research Ethics Board an invoice will be sent to the applicant.

It is the responsibility of the Principal Investigator to ensure payment of this fee and for communicating this requirement to the Sponsor.

**Fee Waiver Criteria**
The following types of funding are excluded from the fee requirement:

i. Cooperative groups (e.g. NSABP);
ii. National Cancer Institute of Canada Clinical Trials Group
iii. Grant from a non-profit organization, for example, CIHR, NIH or a cancer-specific foundation
iv. BCCA internal

The fee may be waived in other circumstances if requested (complete the following to request a waiver).

**Mechanism for Submitting the Fee**

* A.

Please select one of the following:

B.

Explanation of fee waiver due to circumstances other than those listed above.

C.

Internal transfer of funds. Funds can only be transferred from another BCCA account. Please hit "Select" to complete the information.

If you have any questions please contact: Bonnie Shields, Manager BCCA Research Ethics Board
(604) 877-6284 or reb@bccancer.bc.ca
## 11. BC CANCER AGENCY CENTRE PI - HUMAN ETHICS APPLICATION

### 11.1.

Select the Principal Investigator for each participating BC Cancer Agency Centre. Once you click "Select", you can enter the PI's name, or enter the first few letters of his or her name and click "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking on the appropriate heading.

#### A.

*Lead PI for Vancouver Centre:*

#### B.

*Lead PI for Vancouver Island Centre:*

#### C.

*Lead PI for Fraser Valley Centre:*

#### D.

*Lead PI for the Centre for Southern Interior:*

#### E.

*Lead PI for the Centre for Abbotsford Centre:*

#### F.

*Lead PI for the Centre for the North:*

### 11.2.

If this application requires a Clinical Trial Agreement, what is the status of the Agreement?

The Certificate of Approval will not be released until the BC Cancer Agency has received a copy of the signed contract, which should be attached in question 9.8. All industry-related and "for-profit" sponsored studies require a Clinical Trials Agreement between the sponsor, the BC Cancer Agency and the investigator. Click [here](#) to review the submission criteria for a Clinical Trials Agreement.
You have reached the end of the Human Ethics Application.

OPTIONS

1) submit application (PI only) - click the "Continue" button and "Submit application" on the next page. NOTE: the "Submit application" button is only visible to the PI.

2) work on this application later - click the "Continue" button. Your application will be in "Pre Submission" and saved in your inbox.