Table of Contents for **Behavioural Application** Pages

1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. To save information on each page as you are working, click "Save" at the top or bottom of the page in the blue bar. Your work on each page will automatically be saved once you click "Continue".

* 1.1. Principal Investigator

Primary Appointment:
Rank:
Email:

Enter Principal Investigator's secondary appointments or affiliations (including Health Authorities), if applicable:

1.2. Primary Contact

Primary Appointment:
Rank:
Email:

1.3. Co-Investigators - Online Access

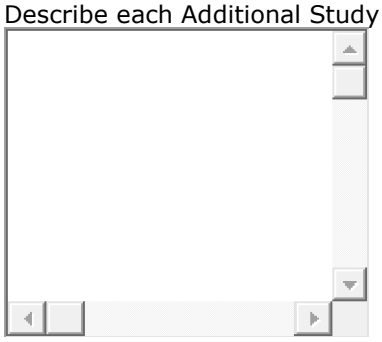
Last Name	First Name	Institution/Department	Rank
			M&P Staff

Describe each Co-I's role in study, e.g. statistician, supervisor, adviser, student etc.

1.4. Additional Study Team Members - Online Access

Last Name	First Name	Institution/Department	Rank
There are no items to display			

Describe each Additional Study Team Members' role in study, e.g. staff, research assistant etc.



1.5. Additional Study Team Members - No Online Access

Last Name	First Name	Institution/Department	Rank/Job Title	Email Address
There are no items to display				

Describe each Additional Study Team Members' (no online access) role in study, e.g. external supervisor, consultant etc.

1.6. Tri Council Policy Statement (TCPS) Tutorial

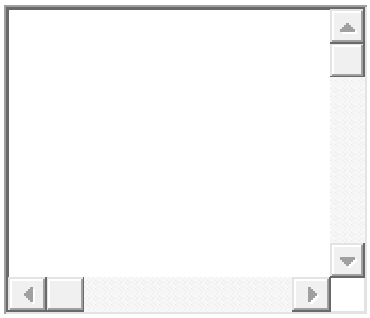
* Have all research personnel completed the required TCPS2 tutorial:

- (•) Yes
- ( ) No
- ( ) N/A

*** 1.7. Project Title**

Enter the title of this research study as it will appear on the certificate. Title given **must match** the title on all study documents.

Last updated Feb-19



*** 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?

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2. STUDY DATES & FUNDING INFORMATION - HUMAN ETHICS APPLICATION

To save information on each page as you are working, click "Save" at the top or bottom of the page in the blue bar. Your work on each page will automatically be saved once you click "Continue".

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 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.**

	Type(s) of Funding
☐	Grant-in-aid
☐	Grant
☐	For-Profit Sponsor (Industry or Pharmaceutical)
☐	Internal Funds
☐	No Funding
☐	Other (Enter details in 2.3 or 2.4 as appropriate)

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

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

UBC Number	Title	Funding PI	Sponsor
There are no items to display			

2.3.B. If a research funding application was submitted to another institution besides a UBC affiliated institution, which institution is administering the funds?

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

Title	Sponsor
There are no items to display	

2.4.B. 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).

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 Clear

2.5.B. If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant below.

DHHS Sponsor List
There are no items to display

Attach DHHS Grant Application for each sponsor listed above.

Title
There are no items to display

*** 2.6. Study Related Conflict of Interest**

Conflicts of Interest (COIs) in research are situations where someone's personal interests (financial, career, or other) could compromise or could be perceived to compromise the objective conduct of research or integrity of the data. Conflicts of interest can arise naturally from an Investigator's engagement inside and outside the University, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COI must be recognized, disclosed, and assessed. This question asks Investigators to disclose COIs that may relate to the research study that is the subject of the REB application.

Do the Principal Investigator, Co-Investigators and/or their related parties have any personal interest(s) that could compromise or reasonably be perceived to compromise the objective conduct of the research or the integrity of the data generated by the study? Personal interests may include business, commercial or financial interests, dual roles (e.g. PI and Doctor), as well as personal matters and career interests.

○ Yes ○ No Clear

Page 3 will only appear if Box 2.6 is marked "Yes"

3. CONFLICT OF INTEREST - HUMAN ETHICS APPLICATION

To save information on each page as you are working, click "Save" at the top or bottom of the page in the blue bar. Your work on each page will automatically be saved once you click "Continue".

3.1. Are the researcher(s), members of the research team, and/or their partners or immediate family members in a situation in which they have or could be perceived to have a personal interest in connection with this study that conflicts with or could conflict with their obligations to the participants, their institution or where applicable to the sponsor?

While not exhaustive, the below are examples that may give rise to a COI. The PI, Co-I, and/or their partners/immediate family members*:

- has a financial interest in or expects to receive a financial interest (e.g. ownership of stock, stock options, salary, consulting fees, retainers, honoraria, bonuses, gifts, speaker's fees, advisory board remuneration) in or from any entity (a company, partnership, or non-profit corporation) whose interests could be affected by the outcome of this research.
- provides services (e.g., non or fee-paying consulting, advisory, board membership, etc) to any entity (a company partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research.
- has intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments, etc).

*Note: "immediate family members" includes partners and children (whether living in the household or not).

3.2. Do any of the researchers conducting this study occupy more than one role with respect to potential participants (e.g. acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, manager, student, or employer, etc.) that may create a real, potential, or perceived conflict of interest that could affect the integrity of the research?

Yes No Clear

If yes, please provide details in the space below:

3.3. Please advise how you propose to manage any actual, perceived, or potential COI outlined above in 3.1. or 3.2.:

* **3.4.** Are all COI declarations for the Principal Investigator and Co-Investigators up to date?

	Status
○	Not applicable (provide details in the box below)
○	No (provide details in the box below)
○	Yes, all COI declarations are current

Clear

Comments:

4.A. STUDY TYPE - HUMAN ETHICS APPLICATION

*** 4.1. Application Type**

Indicate whether your application is Clinical or Behavioural.

	Type of Study
◉	Behavioural
○	Clinical

Clear

*** 4.2. Institutions and Sites for Study**

4.2.A. UBC Institutions and Sites for Study (including study team members' institutional affiliations under which this research is being conducted)

Hospital/Institution	Site
There are no items to display	

4.2.B. Non-UBC Institutions and Sites for Study (including study team members' institutional affiliations under which this research is being conducted)

Hospital/Institution	Site
There are no items to display	

4.2.C. Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., name of privately owned clinic, community centre, school, classroom, participant's home, in the field - provide details).

4.B. BEHAVIOURAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

4.2.D. Roles of Study Sites and Institutions

Study Site	Accessing Records or Charts	Analysing Data or Utilizing Lab Space	Recruiting Participants	Team Member Affiliations
UBC - Vancouver (excludes UBC Hospital)	☐	☐	☐	☐
Simon Fraser University - Burnaby	☐	☐	☐	☐

Relationship to Previous Ethics Applications

4.3.A. If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Institution or Health Authority name and associated Research Ethics Board study number of that proposal.

Institution Name:

REB study number:

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 Box 9.7.

○ Yes ○ No Clear

Please provide known details:

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 (Institution 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.

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.

Participant Vulnerability	**Research Risk**		
	Low	Medium	High
Low	1 ☐	1 ☐	2 ☐
Medium	1 ☐	2 ☐	3 ☐
High	2 ☐	3 ☐	3 ☐

Please check **one** box only

* **4.5.B.** Provide an explanation for the assessment of research risk and group vulnerability reported above.

* **4.5.C.** Does your application fall under minimal risk (i.e., was it assigned an overall risk level of 1 or a blue box on the minimal risk matrix above)?

◉ Yes ○ No Clear

* **4.6.** Does this study require review and approval by another **Canadian** REB outside of Research Ethics British Columbia (REBC)?

○ Yes ○ No Clear

Page E only appears if Box 4.6 is marked "Yes"

E. MULTI-JURISDICTIONAL STUDIES - HUMAN ETHICS APPLICATION

*** E.1.** Are any of the following REBs are also required to review and approve this study?

Please check all that apply:

	Title
☑	University of Alberta
	University of Saskatchewan
☐	None of the above

*** E.2.** Has USask or U of Alberta REB approved this study?

◉ Yes ○ No Clear

Please check all that apply.

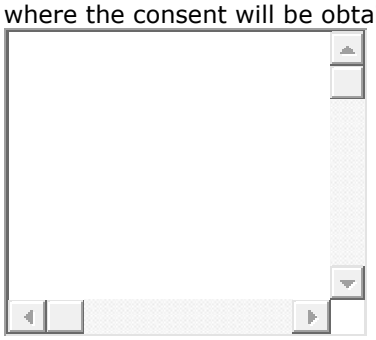
	Title
☐	University of Alberta
☐	University of Saskatchewan

*** E.3. Local Recruitment**

Provide a detailed description of the method of recruitment for the local (UBC) sites. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact and other recruitment materials are amended to meet local requirements and attached to this submission on Page 9.

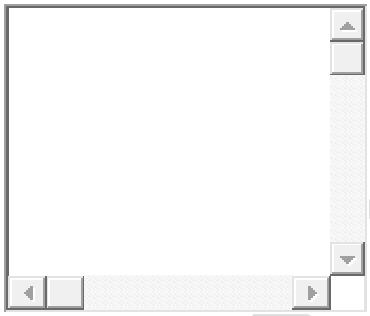
*** E.4. Local Consent Process**

Specify who will explain the consent form and consent participants for the local (UBC) sites. Include details of where the consent will be obtained and under what circumstances.



*** E.5. Disposition of Local (UBC) Study Data**

E.5.A. Describe what will happen to the data at the end of the study (including how long the study data will be retained, when and how the data will be destroyed), and what plans there are for future use of the data, including who will have access to the data in the future and for what purpose.



E.5.B. If applicable describe what will happen to the study samples at the end of the study, including how long the study samples will be retained and where, when and how the samples will be destroyed,
and what plans there are for future use of the samples, including who will have access to the samples in the future and for what purposes.

4.C. BEHAVIOURAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION (continue)

* **4.7.A Creation of a Research Database or Registry**

Does this study involve the creation of a research database or registry with a local custodian for future unspecified research?

Yes No Clear

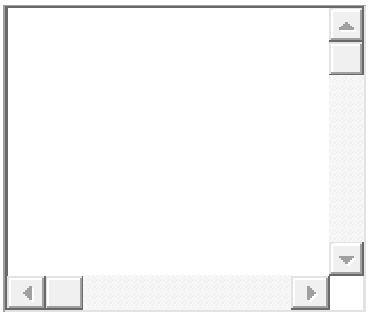
4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research database or registry? [Note: if the creation of the database or registry is part of a bigger project also included in this application, you must answer "no" below].

Yes No Clear

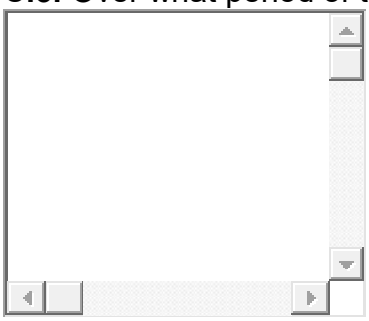
Page C only appears if Box 4.7A is marked "Yes"

C.1. What is the scope and purpose of the research registry or biorepository?

* **C.2.** What are the anticipated public and scientific benefits of the research registry or biorepository?

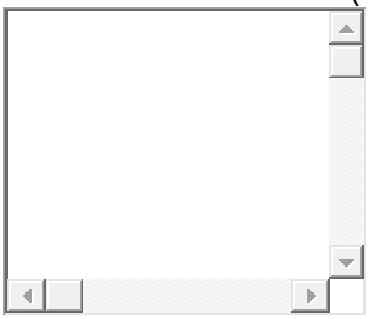


C.3. Over what period of time will data be collected?

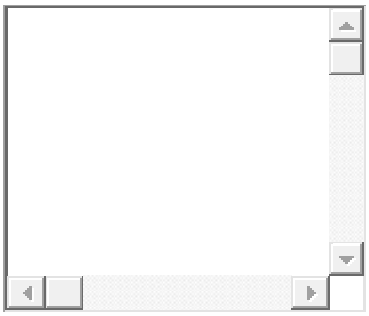


C.4.A. Sources

What information source(s) are you accessing?



C.4.B. Provide specific details about the source(s), i.e., including name of the registry or type of health records, location etc.



C.4.C. 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.4.D. Provide a detailed description of the method of recruitment. Include, where applicable:
a) who will contact prospective participants;
b) by what means will recruitment be done (e.g., public posting, direct contact, third party recruitment, etc.);
c) how will prospective participants be identified;
d) all applicable site-specific information;
e) attach letters of initial contact or other recruitment materials (i.e., posters, phone/email scripts) to page 9.

C.4.E. Please provide the Biobank Registration number, if applicable.

C.5.A. Confidentiality

Are you collecting personally identifying information/will the biospecimens or data be linked to personally identifiable information?

Yes No Clear

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

C.5.C. Elaborate & justify further how long will data remain identifiable / biospecimens be linked (i.e., when, if ever, will it be anonymized). Justify why data / biospecimens 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/biospecimens.

Add

Name	Degree	Affiliation	Role on project	Email
There are no items to display				

C.6.A. Consent

Will participants consent to be included in the registry or biorepository?

Yes No Clear

C.6.B. Specify who will explain the consent form and invite participants to be included in the registry / biorepository. 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 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.

C.8.A. Participant access to data and withdrawal

Will individual participants have the right to access their data, or right to amend or withdraw their information?

Yes No Clear

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

* **C.9.** What is the entity or who is the person that will have custodianship of the research registry/biorepository?

* **C.10.** What will be the address of the research registry (i.e. where will the data be kept) or the location of the biorepository?

* **C.11.** What steps will be taken to ensure the security of the data and/or biospecimens?

* **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.

* **C.13.A. Data and/or Biospecimen Transfer to Other Institutions**

Will data and/or biospecimens be sent outside of the institution? [If "No", skip to Box C.14]

Yes No Clear

C.13.B.

If "Yes":
a) Explain why it is necessary to send the data and/or biospecimens outside of the institution;
b) indicate what data and/or biospecimens will be sent;
c) where the data and/or biospecimens will be sent (list institution & location);
d) who the data and/or biospecimens will be sent to;
e) how the data and/or biospecimens will be transferred (faxed, emailed, couriered, encrypted electronic transfer etc.); and
f) where the data and/or biospecimens will be stored.

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

Yes No Clear

* **C.14.A. Data Linking**

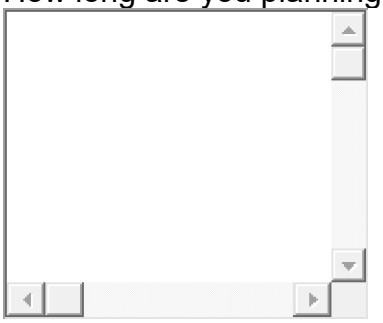
Do you plan to link all or some of the data and/or the biospecimens to another data source (e.g., database, biorepository)?

Yes No Clear

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.15.A. Data Retention**

How long are you planning to keep the data/biospecimens?



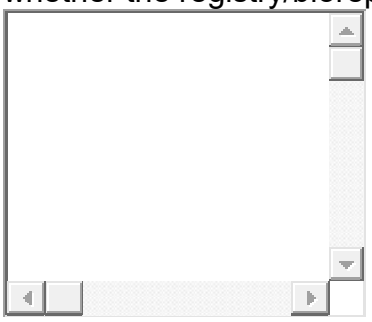
C.15.B. If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens.

*** C.16. Access to Registry/Biorepository**

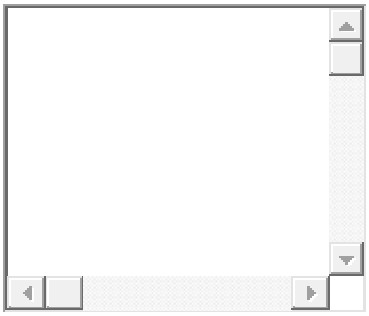
Will the information in the database/biorepository be retained as an ongoing database/biorepository (or as part of an ongoing database/biorepository) for future research? [If "No", skip to C.17]

Yes No Clear

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



C.16.B. Please clarify who will have access to use the registry/biorepository for future research and how access will be granted.



C.16.C.1. Is your biobank /collection of human research biospecimens registered in the BC Biobank Certification Program?

Yes. If yes, please provide your registration record number. ☐

No. If no, please go to www.bcbiobank.ca to get information about the program. ☐

C.16.C.2. This project does not need to register because it is not currently a requirement of my institution. ☐

* **C.17.** Describe any potential commercial uses for the data/biospecimens, 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 Clear

C.18.B. If "Yes", click "Add" to enter the following information. (If administration requires the prior ethical approval of the study before registration. Registration information should be added when it becomes available.)

Add

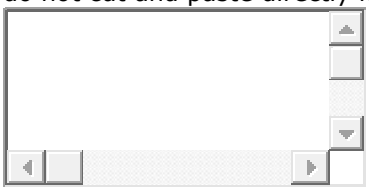
Has it been registered?	Authorized Registry used	Clinical Trial unique identifier
There are no items to display		

5. SUMMARY OF STUDY AND RECRUITMENT - HUMAN ETHICS APPLICATION

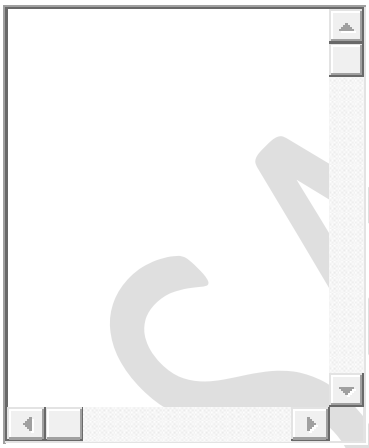
Please note that all required fields are marked with a red asterisk and need to be filled out before being able to proceed onto the next page. Please make sure to save your work before continuing onto the next page in an effort to make sure your work is not lost. You can do so by clicking on the **"Save"** link at the top or the bottom of this page.

Study Summary

5.1.A. Provide a brief statement about the project written in lay language. Do not exceed 100 words and do not cut and paste directly from the study proposal.



* **5.1.B.** Summarize the research proposal, including study purpose, hypothesis, study population, and research method.



5.2. Inclusion Criteria

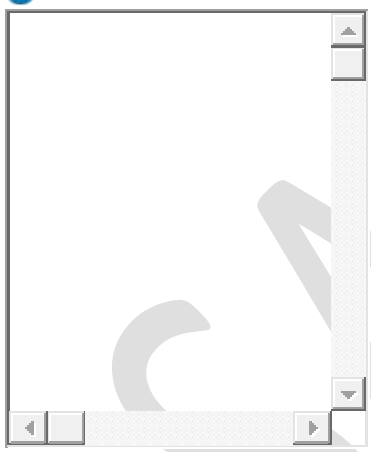
Describe the participants being selected for this study, and list the criteria for their inclusion.

5.3. Exclusion Criteria

Include details if otherwise eligible participants will be excluded due to other characteristics. If no exclusion criteria are applicable, enter n/a.

5.4. Recruitment

Provide a detailed description of the steps you will use to recruit participants. Include:
a) Who will contact prospective participants?
b) By what means will recruitment be done (e.g., public posting, third party recruitment, etc.)?
c) How will prospective participants be identified?
d) Include all site specific information.
e) Attach all materials, including letters of initial contact, posters, scripts and advertisements, to Box 9.4.

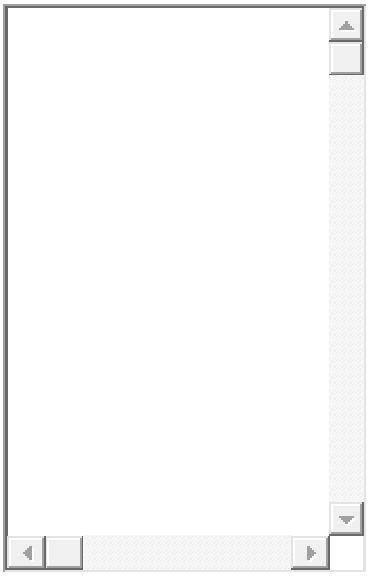


5.5. Use of Records

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

*** 5.6. Summary of Procedures**

Describe briefly in a step-by-step manner what the researcher will be doing with participants, after they have been recruited and consented.



5.7. Research Types

Select all that apply to your study. Please review the research methods descriptions before responding. If none apply, please select "None of these Methods"

- ☐ Action Research (researchers investigating their own practice)
- ☐ Autobiography/Auto-Ethnography
- ☐ Community Based Research (collaboration with community on design and methods)
- ☐ Data Linkage
- ☐ Deception
- ☐ Ethnographic Fieldwork
- ☐ Expert Interviews
- ☐ Focus Groups
- ☐ Masters Research

- [ ] Naturalistic Observation
- [ ] Participant Pools
- [ ] PhD Dissertation Research
- [ ] Random Digit Dialing
- [ ] Secondary Use of Data
- [ ] Undergraduate Research
- [ ] Use of Medical Records
- [ ] Videotaping
- [ ] None of these Methods

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

*** 6.1. Time to Participate**

6.2. Risks and Mitigation

6.3. Potential Benefits

6.4. Impacts on Community

6.5. Reimbursement and Incentives

6.6. Obtaining Consent

Include details of where and when consent will be obtained and how it will be documented.

6.6.A. Waiver of Consent

6.7. Time to Decide

*** 6.8. Capacity to Consent**

Will every participant have the capacity to give fully informed consent on his/her own behalf?

Not Applicable

6.8.A. Provide details of the nature of the incapacity (for instance, young age, mental or physical condition).

6.8.B. If a participant does not have the capacity to give fully informed consent, who will consent on his/her behalf? Ensure the relevant consent form (parent/caregiver, substitute decision maker, legally authorized representative) is attached to page 9.

6.8.C. If a participant does not have the capacity to give fully informed consent, will he/she be able to give assent to participate?

Yes No Clear

6.8.D. If yes, explain how assent will be sought. Please be sure to attach copies of the assent form to page 9.

6.9. Ongoing Consent

6.10. Provisions for Consent (e.g., special assistance, Braille, translations/translator)

6.11. Restrictions on Disclosure

7. NUMBER OF PARTICIPANTS AND LOCATIONS FOR BEHAVIOURAL STUDY -HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** button at the top and bottom of each page.

*** 7.1. External Approvals**

A. Other Institutions:

Yes No Clear

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

Name of Institution	Document(s)
There are no items to display	

*** C.** Other Jurisdiction or Country (if "NO," go to 7.1.G):

Yes No Clear

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

Name of Jurisdiction or Country	Document(s)
There are no items to display	

E. Has a Request for Ethics Approval been submitted to the institution or responsible authority in the other jurisdiction or country? (**Append a copy of any such document to this application once it is received**).

Yes No Clear

F. If a Request for Approval has **not been** submitted, provide the reasons below:

G. Does this research focus on Indigenous peoples, communities or organizations?

(•) Yes ( ) No Clear

G.1.A. Will the research be conducted on Indigenous reserves, Métis settlement(s), or lands governed under a self-government agreement or an Inuit or First Nations land claims agreement?

( ) Yes ( ) No Clear

If yes, please provide details:

G.1.B. Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?

( ) Yes ( ) No Clear

If yes, please provide details:

G.1.C. Does the research seek input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics?

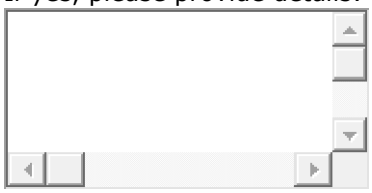
( ) Yes ( ) No Clear

If yes, please provide details:

G.1.D. Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?

( ) Yes ( ) No Clear

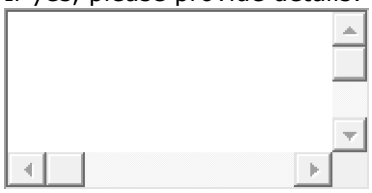
If yes, please provide details:



G.1.E. Will the results of the research refer to Indigenous communities, peoples, language, history or culture?

Yes No Clear

If yes, please provide details:



G.2. Community Engagement

G.2.A. If you answered yes to questions a), b), c), d), or e), have you initiated or do you intend to initiate an engagement process with the Indigenous collective, community or communities for this study?

Yes No Clear

G.2.B. If you answered "Yes" to question G.2.A., describe the process that you have followed or will follow with respect to community engagement. Include the role or position of those consulted, including their names if appropriate. Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) below.

Attachment:

Title
There are no items to display

G.3. No community consultation or engagement

If you answered "no" to question G.2.A., briefly describe why community engagement will not be sought and how you can conduct a study that respects Indigenous communities and participants in the absence of community engagement.

H. Registration for Publication of Clinical Trials.

Yes No Clear

If 'Yes', click 'Add' to enter the following information.

Has it been registered?	Authorized Registry used	Clinical Trial unique identifier

There are no items to display

7.2. Number of Participants

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

B. How many participants will take part at institutions covered by this Research Ethics Approval?

*** 7.3. Principal Investigator and Research Team Experience**

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

8.2. Access to Data

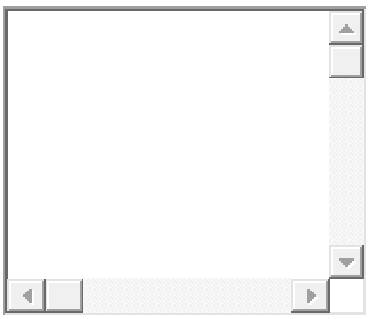
8.3. Protection of Personal Information

8.4. Transfer of Data

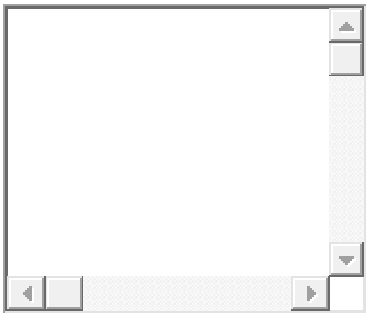
Will any data that identify individuals be transferred (made available) to persons or agencies outside the University?

Yes No Clear

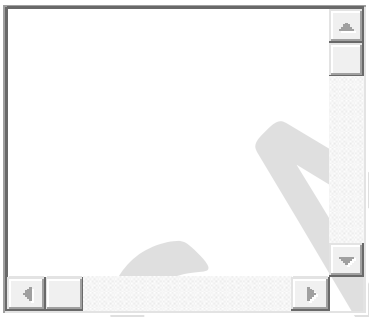
If yes, describe in detail what identifiable information will be released, to whom, how the data will be transferred, how and where it will be stored and what safeguards will be used to protect the identity of participants and the privacy of their data. Attach the data transfer agreement if applicable.



8.5. Retention and Destruction of Data



8.6. Future Use of Data



8.7. Feedback to Participants

9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach all supporting documents required for conducting the study. The Research Ethics Office cannot change document names or dates.

INSTRUCTIONS

Documents will appear on the certificate of approval with the information that you enter when you attach the document. Please check that version dates and document names are accurate and match those on the attached documents. Submit final versions only.

Submitting revised documents

If you are submitting a revised version of a document, delete the old document and attach the revised version with tracked changes or highlight. Do not remove documents that you have used in the study but are no longer using, e.g. phase 1 consent forms once you have moved onto phase 2.

If you are adding a new document, you must indicate in your proviso response or amendment coversheet that you have added a new document and explain its purpose.

9.1. Research Proposal

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.2. Documentation of Consent

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.3. Documentation of Assent

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.4. Advertisement to Recruit Participants

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.5. Questionnaire, Questionnaire Consent Cover Letter, Tests, Interview Scripts, etc.

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.6. Letter of Initial Contact

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.7. Other Documents

Document Name	Version	Date	Document	Password (if applicable)
There are no items to display				

9.8. Websites and Social Media

10. FEE FOR SERVICE FOR BEHAVIOURAL STUDY - HUMAN ETHICS APPLICATION

Payment of the $3000 fee-for-service must be sent to the UBC C&W Research Ethics Board for all research sponsored by a **for-profit agency**. It is the responsibility of the Investigator to communicate this with his/her industry sponsor, collect the payment and forward it onto the UBC C&W Research Ethics Board office.

This fee is a one-time-only fee for each specific application and covers initial review, annual renewals, and amendments. If the research project is withdrawn prior to initial review by the Research Ethics Board submission of the fee payment is not necessary. Once initial review has taken place, refunds will not be issued, regardless of whether the project gets approved or not.

A Certificate of Approval shall not be issued until fee payment has been received.

Exemptions:
The following will be exempted from paying the fee:

All applications that are:

(1) Studies that do not have funding
(2) Studies funded by a grant from a non-profit organization
(3) Studies that receive internal grants from UBC, PHSA or their affiliated agencies or research institutes
(4) Studies funded by cooperative groups (i.e. COG)
(5) Studies funded by CIHR, SSHRC, NSERC and NIH (including NIH Institutes)

Mechanism for Submitting the Fee:

- ○ Internal Transfer from a C&W or PHSA account. Please return a copy of the invoice, providing C&W or PHSA cost centre information as indicated, signed by the appropriate authorizing signatory and return to the REB office.
- ○ Cheque Payable to: Provincial Health Services Authority | Amount: $3,000.00 CAD | Reference: REB number (HXX-XXXXX) | Mail to: UBC C&W Research Ethics Board, Attention: Talysa Dhahan, Room A2-141A, 950 West 28th Avenue, Vancouver, BC V5Z 4H4, Canada

Clear

Attach copy of the invoice and include the REB number (HXX-XXXXX) as a reference.

There are Multiple Page 11s. Only select Heatlh Authority sites from Box 4.2A & 4.2B will appear here.

11. INFORMATION FOR VANCOUVER COASTAL HEALTH AUTHORITY (VCHA)/VANCOUVER COASTAL HEALTH RESEARCH INSTITUTE (VCHRI) -Application for Approval to Conduct Research at VCHA

All research studies and clinical trials involving human participants ("Research Projects") that are conducted at VCHA must be approved by the appropriate VCHA Health Service Delivery Area ("HSDA"). There are four HSDAs: Vancouver Acute, Vancouver Community, Richmond Health Services, and Coastal. If a Research Project will be conducted at more than one VCHA HSDA site, the researcher must obtain approval to conduct research at each HSDA where the Research Project will be conducted. Once approval to conduct research has been granted by the applicable VCHA HSDA, the Research Project may begin at that site. The approval process ensures that all research involving humans conducted at VCHA is reviewed from an ethical, safety and resource use framework. According to VCHA policy, Research Projects cannot begin until final approval from VCHRI has been granted.

Guidelines and forms may be downloaded from the VCHRI web site at vchri.ca/operational-approval

*** 11.1**

Have you already received approval from VCHA to conduct this study?

○ Yes ◉ No Clear

If Yes, please provide the VCHA/VCHRI approval number (e.g. V06-0000)

*** 11.2. A.**

Does the Principal Investigator in Box 1.1 have a medical appointment with VCHRI/VCHA **and** a UBC faculty appointment?

◉ Yes ○ No Clear

If "Yes" proceed to Box 11.3.

11.2.B.

Does the Principal Investigator in Box 1.1 have a medical appointment with VCHRI/VCHA (but not a faculty appointment at UBC), or is the Principal Investigator an employee of VCHA?

○ Yes ○ No Clear

If "Yes" you must select here to print and complete a declaration form with signatures then attach the

completed form below by clicking the "Browse" button. If "No" proceed to Box 11.3.

Select the "Browse" button to attach the declaration form.

11.2. C.

Does the Principal Investigator in Box 1.1 have a UBC appointment?

Yes No Clear

If "Yes" you must designate a VCHA employee or medical staff below as the "Site Investigator at VCHA" if different from the Principal Investigator listed in Box 1.1. Alternatively, the Principal Investigator in Box 1.1 may obtain VCHRI Affiliated Investigator Status.

Select the Site Investigator at VCHA **if different** from the Principal Investigator in Box 1.1.

If "No" please contact VCHA/VCHRI Clinical Trials Administration at (604) 875-5649.

11.3.

Select the VCHA Health Service Delivery Area(s) that will be involved in this study.

	Location
☐	Coastal (Coastal encompasses hospitals, community health centres and residential care facilities in the following sites: Lions Gate Hospital, North Shore Community, Powell River/Sunshine Coast, Sea to Sky Corridor including Bella Bella and Bella Coola).
☐	Richmond Health Services (Richmond Health Services encompasses the following networks: acute care, community care, primary health care, mental health and addictions.)
☐	Vancouver Acute (Vancouver Acute encompasses the following sites: Vancouver General Hospital, UBC Hospital, GF Strong Rehabilitation Centre, Arthritis Research Centre of Canada, Mary Pack Arthritis Centre, Djavad Mowafaghian Centre for Brain Health)
☐	Vancouver Community (Vancouver Community encompasses community health centres, mental health centres, addiction sites and residential care facilities in Vancouver)

11. UBC CHILDREN'S AND WOMEN'S RESEARCH ETHICS BOARD - HUMAN RESEARCH ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** link at the top and bottom of each page.

Prior to commencing any human subject research at the Children's and Women's Health Centre of BC, researchers must be in possession of **two certificates of approval**. These are:

1) A certificate of ethical approval issued by one of the UBC Research Ethics Boards (UBC C&W REB; UBC PHC REB; UBC CREB; UBC BREB; UBC BCCA REB) and
2) A C&W Institutional Certificate of final approval issued by the Children's and Women's Health Centre of BC

Criteria for obtaining C&W Approval

Prior to initiation of the research, Children's and Women's Health Centre of BC must provide written approval of all human subject research that includes any of the following:

- All clinical and behavioural research projects conducted at the Oak Street campus and its affiliated sites including:
  - Site-associated Provincial Health Services Authority agencies
  - BC Children's Hospital
  - BC Mental Health and Addiction Services
  - BC Women's Hospital and Health Centre
  - BC Children's Hospital Research Institute
  - BC Mental Health and Addictions Research Institute
  - Women's Health Research Institute
- Studies for which the Principal Investigator holds appointments with the Children's and Women's Health Centre of British Columbia, which directly involve patients, records or resources at the Children's and Women's Health Centre of British Columbia. Note that this also includes research projects which involve the use of human remains, cadavers, tissue, biological fluids, embryos and/or foetuses.

The C&W Institutional Certificate of Approval will list ONLY those C&W services/hospital areas that have issued approval for the research to be conducted in their areas. Please ensure that you accurately complete section 11.3 of the application form accordingly.

* **11.1.**
In order for a research project to be undertaken at C&W, either an employee or a member of the medical staff (as legally defined) needs to be designated as the Principal Investigator. This individual must have actual responsibility with respect to the project.

Select the Principal Investigator for the Children's and Women's Health Centre.

*** 11.2.**
Does the Children's and Women's Principal Investigator in Box 1.1 (and Box 11.1, if different) have a UBC academic or clinical appointment?

Yes No Clear

If "No", you must select here to print and complete a declaration form with signatures for the Investigator that does not have a UBC appointment. Once completed attach the form below by clicking the "Browse" button.

Select "Browse" to attach the declaration form.

*** 11.3.**

Select which hospital form(s) are required for this application.

Form(s) to be submitted
Utilization form for Hospital Program (if C&W Program resources such as space or staff are required)
If Industry Sponsored, signed contract agreement between Sponsor, Hospital and University
Utilization form for Health Records (if C&W Health Records are required)
Utilization form for Laboratory services (if C&W Lab/Pathology services are required)
Utilization form for Pharmacy (if C&W Pharmacy services are required)
Other Resource/Service Utilization (provide explanation below)
Not Applicable

If you selected "Other Resource/Service Utilization", please specify below.

To retrieve the forms listed above select here. Once the forms have been completed, send them to the UBC Children's and Women's Research Ethics Board Office, Room A2-136, 950 West 28th Ave., Vancouver BC V5Z 4H4.

11. HOSPITAL INFORMATION FOR PROVIDENCE HEALTH CARE - HUMAN ETHICS APPLICATION

Prior to commencing any human subject research at Providence Health Care, researchers must be in possession of **two certificates of approval**. These are:

1) A certificate of ethical approval issued by one of the UBC Research Ethics Boards (UBC PHC REB; UBC CREB; UBC BC Cancer REB; BREB) and
2) A PHC Institutional Certificate of final approval issued by the PHC VP of Research

Criteria for obtaining PHC Final Approval

Prior to initiation of the research, Providence Health Care must provide written approval of all human subject research that includes any of the following:

1) Use of Providence Health Care facilities and services
2) Involvement of human tissue, data or records held at Providence Health Care
3) Involvement of Providence Health Care patients (patients with a PHC Chart number)
4) Involvement of Providence Health Care staff

* **11.1.**

11.1.A.

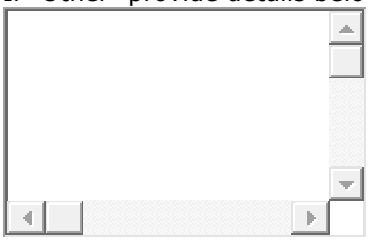
Which of the following hospital services are required for the conduct of your research? (Please check all that apply).

	Hospital Facility/Service
☐	N/A
☐	Cardiac Cath Lab
☐	Centre for Excellence in HIV/AIDS
☐	Contract/Agreement (For Profit Sponsor/Government Funding or Grant-in-Aid)
☐	ECG
☐	Imaging (e.g. X-ray, CT scan, MRI)
☐	Laboratory (blood collection)
☐	Laboratory (anatomical pathology)
☐	Medical Records - Discharged Patients
☐	Medical Records - Use of Sunrise Clinical Manager
☐	Medical Records - Outpatient Clinics
☐	Nuclear Medicine
☐	Nursing - Please complete question 11.3

☐	Pharmacy
☐	Physiotherapy
☐	Respiratory
☐	Other (please specify in 11.2 B.)

11.1.B.

If "Other" provide details below.



* **11.2.**

11.2.A.

Which of the following hospital areas will be required to provide services for the conduct of the research? If the PI for the research is employed by the hospital area in question and has obtained approval for use of his or her own area, please do not select the relevant option. (Please check all that apply).

	Hospital Area
☐	N/A
☐	Communications (for display of Posters, Brochures, Advertisements)
☐	Centre for Excellence in HIV/AIDS
☐	Outpatient Clinics (please specify in 11.3 B.)
☐	Emergency Department
☐	Nursing Units (please specify in 11.3 B.)
☐	Operating Room
☐	Pre-Admission Clinic(s) (please specify in 11.3 B.)
☐	Renal Program/Units (please specify in 11.3 B.)
☐	Other (please specify in 11.3 B.)
☐	Pacific Lung Centre

11.2.B.

Provide details below of other hospital areas affected by the study.

11.3.

Does the Principal Investigator in Box 1.1 have a UBC appointment?

Yes No Clear

If "No", you must select here to print and complete a declaration form with signatures. Once completed, scan the declaration form to your computer then attach the completed form below by clicking the "Browse" button.

If you have any questions please contact:

Alex Trethewey
Pre&Post Review Manager,
Office of Research Ethics,
Providence Health Care Research Institute
alex.trethewey@ubc.ca
(604) 682-2344 x68366

11. BC CANCER AGENCY CENTRE PI - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** link at the top and bottom of each page.

11.1.

Select the Principal Investigator for each participating BC Cancer 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?

	Status
○	Submitted (attach agreement in question 9.8)
○	N/A
○	Pending

Clear

11. RESEARCH APPROVAL INFORMATION FOR INTERIOR HEALTH - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** link at the top and bottom of each page.

Prior to commencing any human subject research at Interior Health, researchers must be in possession of **two certificates of approval**. These are:

1) A certificate of ethical approval issued by the IH Research Ethics Board OR a Harmonized Certificate of Ethical Approval issued by any of the BCEHI partners and including the Interior Health REB.

The IH REB must review all research involving humans that includes:
- Involvement of Interior Health patients, clients, or residents
- Involvement of Interior Health staff, privileged physicians, midwives, volunteers, or students
- Involvement of human tissue, data or records held by Interior Health
- Use of Interior Health facilities and/or services

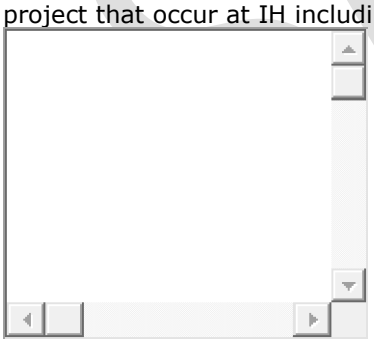
2) An IH Institutional Certificate of Approval issued by the IH Research Department once all other relevant approvals and contracts are in place. These may include:
- Operational review is required: click for an IH Application for Operational Approval
- Clinical Trial Agreement or other research contract
- Affiliation Agreement
- Information Sharing Agreement

The IH Research Department will coordinate review of all other aspects of human subject research except ethical review. To obtain the appropriate application forms and/or for assistance in determining which forms are applicable to your research project, please contact research@interiorhealth.ca.

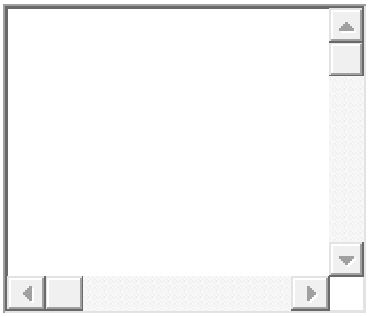
* **11.1.** Does the Principal Investigator in Box 1.1 have IH privileges?

Yes No Clear

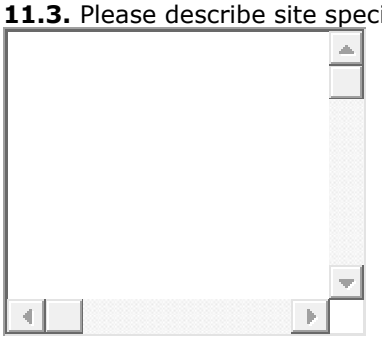
If NO, identify which co-investigator or research team member will be responsible for all aspects of the project that occur at IH including recruitment, data collection, etc.



11.2. At which Interior Health sites will the research be conducted? Click here for a facilities list. Do not list cities, towns, or geographic regions, but rather the IH sites where recruitment or other study procedures will occur.



11.3. Please describe site specific recruitment strategies for IH.



11. RESEARCH SITE INFORMATION FOR FRASER HEALTH - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** link at the top and bottom of each page.

Prior to initiation of the research, Fraser Health must provide written approval of all human subject research that includes any of the following:

1) Use of Fraser Health facilities and services;
2) Involvement of human tissue, data or records held at Fraser Health;
3) Involvement of Fraser Health patients (patients with a FH Chart number);
4) Involvement of Fraser Health employees.

In order to conduct research at Fraser Health (FH), all studies must be reviewed and approved in conjunction with the BCEHI process. Following review and approval, the researcher will be issued two documents:

1) A certificate of harmonized ethical approval issued by the Board of Record BCEHI partner institutions (UBC, SFU, UVic, UNBC, Fraser Health (FH), Interior Health (IH), Island Health (IH) and Northern Health (NH)); and
2) A FH Letter of Authorization (LOA). The LOA is FH's Institutional Approval required to conduct research at FH sites.

* **11.1.**

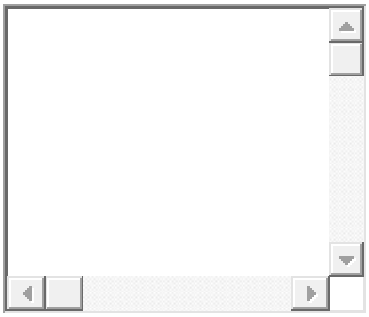
11.1.A. At which of the Fraser Health sites will the research be conducted?

	Hospital Area
☐	N/A
☐	Abbotsford Regional Hospital and Cancer Centre
☐	Burnaby Hospital
☐	Chilliwack General Hospital
☐	Community Site(s), please specify in 11.2.B.
☐	Delta Hospital
☐	Eagle Ridge Hospital
☐	Fraser Canyon Hospital
☐	Jim Pattison Outpatient Care and Surgical Centre
☐	Langley Memorial Hospital
☐	Peace Arch Hospital
☐	Physician's Private Office
☐	Royal Columbian Hospital

☐	Ridge Meadows Hospital
☐	Surrey Memorial Hospital
☐	Other (please specify in 11.2.B.)

11.1.B.

Provide details below of other Fraser Health Sites affected by the study.



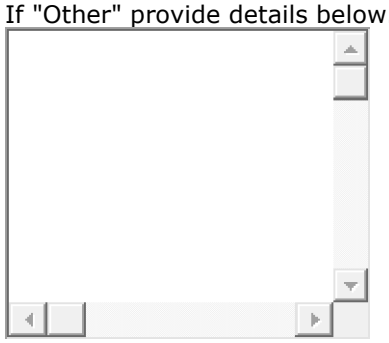
11.2.

11.2.A. Which of the following services are required for the conduct of your research? (Please check all that apply).

	Hospital Facility/Service
☐	N/A
☐	Anatomical Pathology
☐	Biomedical Engineering
☐	Communicable Diseases/Public Health
☐	Diagnostic Imaging
☐	Health & Business Analytics (Administrative Data)
☐	Health Records (Electronic)
☐	Health Records (Paper)
☐	Image Tech Lab
☐	Information Management
☐	Laboratory
☐	Patient Care Services
☐	Pharmacy
☐	Surgical Suites
☐	Other (please specify in 11.2.B)

11.2.B.

If "Other" provide details below.



11.3.

Criteria for obtaining FH Final Approval
All studies conducted at FH require the Principal Investigator (PI) to either be FH employee/privileged physician OR an Affiliated Investigator.

Is the Principal Investigator in Box 1.1 a Fraser Health employee?

Yes No Clear

If NO, is the Principal Investigator in Box 1.1 a Fraser Health privileged physician?

Yes No Clear

If NO, the academic PI is required to become affiliated with FH by signing onto the FH affiliation agreement with their home institution.

Is the academic PI affiliated with FH? If YES, Application will proceed.

Is the application for affiliation status submitted? If YES, Application will proceed.

PI Affiliation status with Fraser Health:

	Affiliation Status
	Affiliation Granted
	Affiliation Request Submitted
	No

Clear

If YES, please include a copy of the PI's C.V. in this application in Box 9.8.A.

If NO, then a FH employee/privileged physician who is currently on the research study team may assume responsibilities as the FH site PI in order to have oversight of the study.

Name of Fraser Health site PI:

11.4.

11.4.A. Please describe site specific recruitment strategies for FH.

11.4.B. Please indicated estimated number of participants to be recruited from FH:

11.5. Collection of Personal Information.

Will any FH held or maintained data (i.e. health records, administrative data, tissue) be collected as part of this study?

Yes No Clear

11. RESEARCH APPROVAL INFORMATION FOR ISLAND HEALTH - HUMAN ETHICS APPLICATION

Please note that all required fields are marked with a red asterisk and need to be filled out before you will be able to proceed to the next page. Please save your work before continuing onto the next page to prevent losing your work. You will find the **"Save"** link at the top and bottom of each page.

Prior to commencing any human subject research at Island Health (Vancouver Island Health Authority), Principal Investigators must obtain:

1. A Research Ethics Board Certificate of Approval issued by Island Health or including Island Health in the Harmonized Ethical Approval; and

2. Island Health Operational Review & Approvals, as applicable. Based on the information provided below, Island Health will contact the relevant department heads and provide them with the proposed research for approval. If there are any discussions to be had between the researcher and the affected Departments that must approve the research, you will hear from us.

Questions regarding approvals at Island Health can be directed to:

For questions about the Operational Review process, please contact:

Kimberly Horie, Research Administrative Coordinator
250-519-6726
Kimberly.Horie@viha.ca

* **11.1.** Will Island Health staff be invited to be participants in this study?

Yes No Clear

If yes, please summarize involvement here:

Please summarize any involvement of Island Health staff in the conduct of this study:

Please summarize any equipment owned or maintained by Island Health required for the conduct of this study?

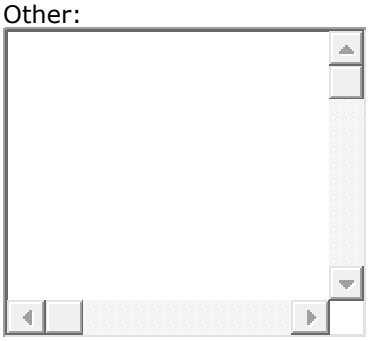
Please list all types of data/information contemplated for collection at Island Health or to collected and disclosed from Island Health:

Which of the following services are required for the conduct of your research? (Please check all that apply).

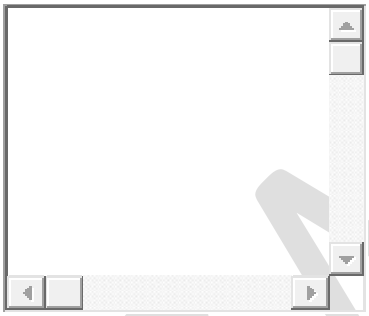
	Facility/Service
☐	N/A
☐	Cardiac – Heart Health
☐	Contract/Agreement (For Profit Sponsor/Government Funding or Granting)
☐	Medical Imaging (e.g. X-ray, CT scan, MRI)
☐	Laboratory (blood collection)
☐	Laboratory (anatomical pathology)
☐	Medical Records – Access to Electronic Health Record

- [ ] Medical Records – Access to Paper Charts
- [ ] Pharmacy
- [ ] Physiotherapy
- [ ] Respiratory
- [ ] Other (please specify below)

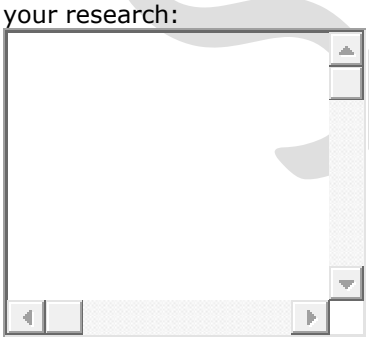
Other:



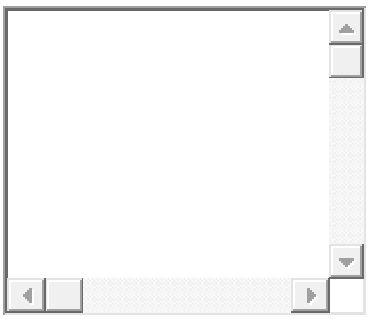
Please name any Island Health hospitals that will be directly involved as a site for the conduct of your research:



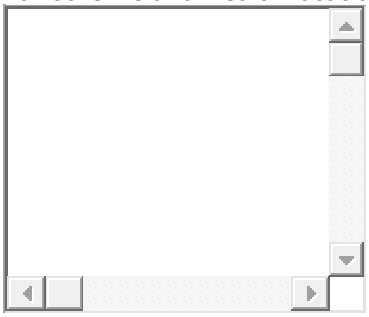
Please name any Island Health Health Centres that will be directly involved as a site for the conduct of your research:



Please name any Island Health Public Health Units that will be directly involved as a site for the conduct of your research:



For other Island Health locations, please describe here:

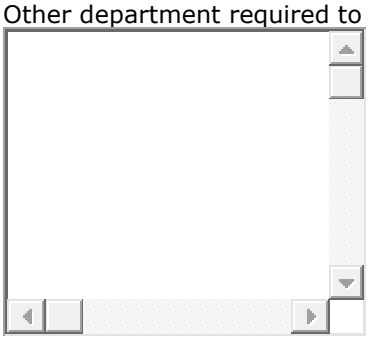


Which of the following hospital services are required for the conduct of your research? (Please check all that apply).

	Hospital Service
☐	N/A
☐	Cardiac Cath Lab
☐	Centre for Excellence in HIV/AIDS
☐	Contract/Agreement (For Profit Sponsor/Government Funding or Grant-in-Aid)
☐	ECG
☐	Imaging (e.g. X-ray, CT scan, MRI)
☐	Laboratory (blood collection)
☐	Laboratory (anatomical pathology)
☐	Medical Records - Discharged Patients
☐	Medical Records - Use of Sunrise Clinical Manager
☐	Medical Records - Outpatient Clinics
☐	Nuclear Medicine
☐	Nursing
☐	Pharmacy

- ☐ Physiotherapy
- ☐ Respiratory
- ☐ Other (please specify below)

Other department required to support research:



12. SAVE APPLICATION - HUMAN ETHICS APPLICATION

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.