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## 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:* Medicine, Department of (UBC)

*Rank:*

*Email:*

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

### 1.2. Primary Contact

### 1.3. Co-Investigators - Online Access

Last Name	First Name	Institution/Department	Rank
-----------	------------	------------------------	------

There are no items to display

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 [Clear](#)

### \* 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. 

### \* 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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To:

## 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 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
<input type="checkbox"/> Grant-in-aid
<input type="checkbox"/> Grant
<input type="checkbox"/> For-Profit Sponsor (Industry or Pharmaceutical)
<input type="checkbox"/> Internal Funds
<input checked="" type="checkbox"/> No Funding
<input type="checkbox"/> 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](#)

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To: [2. Study Dates and Funding Information - Human Ethics Application](#) ▾

### 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
<input type="radio"/> Not applicable (provide details in the box below)
<input type="radio"/> No (provide details in the box below)
<input type="radio"/> 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	
<input type="radio"/>	Behavioural
<input checked="" type="radio"/>	Clinical
<a href="#">Clear</a>	

### \* 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	
<input type="text"/>	
Site	
Vancouver Coastal Health (VCHRI/VCHA)	Vancouver General Hospital

**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	
<input type="text"/>	
Site	
Interior Health Authority	Lillooet Home & Community Care

**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. CLINICAL STUDY REVIEW TYPE - 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.

### 4.2.D. Roles of Study Sites and Institutions


Study Site	Accessing Records / Charts	Analysing Data	Recruiting Participants	Team Member Affiliations
Vancouver Coastal Health (VCHRI/VCHA) - Vancouver General Hospital	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Interior Health Authority - Lillooet Home & Community Care	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>


### 4.3. Relationship with other proposals

**4.3.A.** If this proposal is closely linked to any other proposal previously/simultaneously submitted to a UBC REB or REBC institution, 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.** 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 9.8. 

Yes  No [Clear](#)

Please provide known details:

**4.3.D.** Will biological materials be collected or analyzed by researchers or a research lab?<sup>?</sup>

Yes  No [Clear](#)

If YES, please provide the institutionally applicable Biosafety Permit Number(s):

**4.3.E.** Will radioisotopes be used in this project?

Yes  No [Clear](#)

If YES, provide the institutionally applicable Radiation Permit Number(s). (Note that if this is a BC harmonized study, information about institutionally specific requirements for Radiation permits will be on page 11):

**\* 4.4. Level of Risk**

After reviewing the minimal risk guidance notes and the criteria for minimal risk, does this study qualify for minimal risk review? Note that all studies which do not fall into the minimal risk category will undergo full board review.<sup>?</sup>

Yes  No [Clear](#)

**4.5. 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. All above minimal risk studies require a peer review.

**\* 4.5.A.** Peer review details:<sup>?</sup>



## 4.C. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

### \* 4.7.A. Creation of a Registry (Data or Tissue Bank)

Does this study involve the creation of a registry (data or tissue bank) with a local custodian for future use in other research? [if no, skip to 4.8] 

Yes  No [Clear](#)


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


Yes  No [Clear](#)

### Clinical Chart Review

**4.8.A.** Is this an application for research requiring access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet? 

Yes  No [Clear](#)


**4.8.B.** Insert the date range of the charts/data to be included in this research. (e.g. 7 September 2005 – 6 September 2011) 

**4.8.C.** Is this study exclusively a retrospective chart review where the only source of data will be medical charts/records that are currently in existence? (i.e., will pre-date the date of your initial ethics approval?) 

Yes  No [Clear](#)

**4.8.D.** Will you have access to personally identifiable information? 


Yes  No [Clear](#)

**4.8.E.** Is this a retrospective chart review study for which participant consent will be obtained? 

Yes  No [Clear](#)

---

## C. CREATION OF A RESEARCH REGISTRY OR BIOREPOSITORY - HUMAN ETHICS APPLICATION

\* **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? 

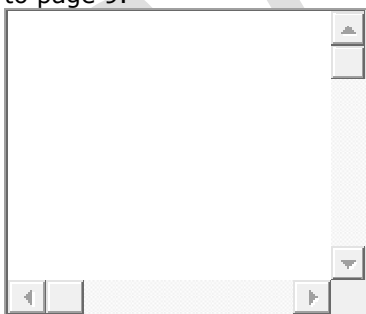
**C.4.B.** Provide specific details about the source(s), i.e., including name of the registry or type of health records, location etc.

**C.4.C.** What are the sources of your biospecimens? Check all that apply.

<input type="checkbox"/>	Direct from live subject (procedure conducted for research purposes)  Select biospecimen source: <input type="text"/> If "Other" or multiple sources will be used, specify them here: <input type="text"/>
<input type="checkbox"/>	Indirect from live subject (procedure conducted for clinical purposes and excess tissue leftover after clinical diagnosis obtained for research)  Select biospecimen source: <input type="text"/> If "Other" or multiple sources will be used, specify them here: <input type="text"/>
<input type="checkbox"/>	Post mortem tissue collection  Select biospecimen source: <input type="text"/> If "Other" or multiple sources will be used, specify them here: <input type="text"/>

**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.


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](http://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.)

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

**Page A only appears if Box 4.8A is marked "Yes" and Box 4.8C is marked "Yes" and box 4.8E is marked "No"**

## **A. RETROSPECTIVE CLINICAL CHART REVIEWS - 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.

\* **A.1.** Summarize the research proposal using the following headings 1) Purpose 2) Hypothesis 3) Justification 4) Objectives 5) Analysis of Data

\* **A.2.** Describe how permission to access the medical records and to collect and use these records will be obtained. 

**A.3.** Briefly describe the type of data that you intend to collect (e.g., disease, diagnosis, outcome, demographic, aggregate, personal-level). **Please attach** a data collection/ data extraction form to Question 9.8A of the application for review. 

**A.4.** Number of Records/Patient Charts 

**\* A.5. Personal Information**

**A.5.1.**

A) Indicate what personally identifying information you will have access to when conducting your study.

B) Will personal identifiers be retained as a part of the dataset? If yes, list which personal identifiers?

C) Include a justification of why personal identifiers will be retained

**\* A.6. Waiver of Consent**

**A.6.1.** Is the identifiable information essential to the research?



Yes



No

[Clear](#)

**\* A.6.1. Explanation:** Please provide further explanation and/or justification, in the text box below.

⏪ ⏩

**\* A.6.2.** The use of the identifiable information without the participants consent is unlikely to adversely affect the welfare of the participants to whom the information relates.



Yes



No

[Clear](#)

**\* A.6.2. Explanation:** Please provide further explanation and/or justification in the text box below.

⏪ ⏩

**\* A.6.3.** The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.



Yes



No

[Clear](#)

\* **A.6.3. Explanation:** Please provide further explanation and/or justification in the text box below.

An empty text box with a light gray background and a thin border. It has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.


\* **A.6.4.** The researchers will comply with any known preferences previously expressed by individuals about any use of their information.

Yes  No [Clear](#)

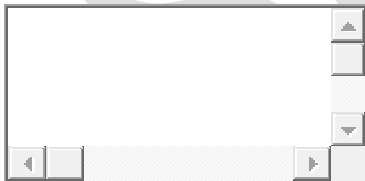
\* **A.6.4. Explanation:** Please provide further explanation and/or justification in the text box below.

An empty text box with a light gray background and a thin border. It has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.

\* **A.6.5.** It is impossible or impracticable to seek consent from individuals to whom the information relates.

  Yes  No [Clear](#)

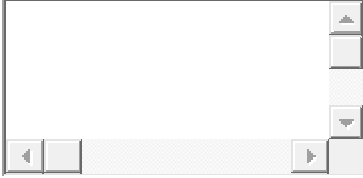
\* **A.6.5. Explanation:** Please provide further explanation and/or justification in the text box below.

An empty text box with a light gray background and a thin border. It has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.

\* **A.6.6.** The researchers have obtained any other necessary permissions for the use of the information for research purposes.


Yes  No [Clear](#)

\* **A.6.6. Explanation:** Please provide further explanation and/or justification in the text box below.



\* **A.7.** 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.



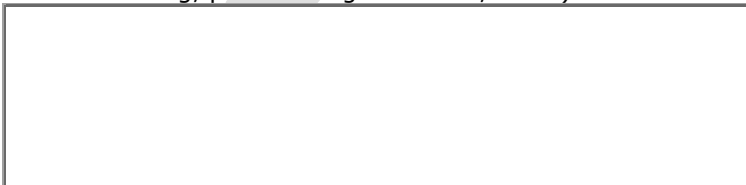
\* **A.8.** Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms. 





\* **A.9.** Explain who will have access to the data at each stage of collection, processing and analysis, and indicate whether a current list of the names of study personnel (including co-investigators) and their delegated tasks will be maintained in the study file. If a list will not be



\* **A.10.** Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio-recording, personal digital device, other) 



\* **A.11.** Describe the safeguards in place to protect the confidentiality and security of the data (including where the data will be stored) 

\* **A.12.** Describe what will happen to the data at the end of the study, including how long the data will be retained and where, 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. 

\* **A.13. Data Transfer**

Will data be transferred outside of UBC or its affiliated hospitals?



Yes

No

[Clear](#)

If yes, please describe a) the type of data to be transferred, b) who the data will be transferred to, c) where the data will be transferred and d) how the data will be sent.

\* **Data Linking**

**A.14.A.** Do you plan to link the data to any other data?



Yes

No

[Clear](#)

**A.14.B.** If yes, a) Identify the data set, b) how the linkage will occur, c) provide a list of data items in the other database. d) identify what personal information will be used to link the databases and e) how confidentiality regarding this shared information will be preserved.

---



## 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.

### \* 5.1. 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 protocol.

\* **5.1.B.** Summarize the research proposal: Purpose, Hypothesis, Justification, Objectives, Research Design and Statistical Analysis. 

### 5.2. Inclusion Criteria

Describe the participants being selected for this study. List the criteria for their inclusion, and justify the grounds for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research. 

### 5.3. Exclusion Criteria

Describe which potential participants will be excluded from participation. List the criteria for their exclusion, and justify the grounds for their exclusion. 

#### 5.4.A. Recruitment

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.

#### 5.4.B. Recruitment of Normal/Control Participants

Describe how prospective normal/control participants will be identified, contacted, and recruited, if the method differs from the above.

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

Yes  No [Clear](#)

#### 5.6. Use of Records

If existing records (e.g. health records, clinical lists or other records/databases) will be used to IDENTIFY potential participants for the purpose of recruitment, please describe how permission to access this information, and to collect and use this information, will be obtained.

#### \* 5.7. Details of Study Procedures

Describe in a step-by-step manner the research procedures. When applicable, outline or describe standard of care or standard procedure. This is particularly important for addressing what is incremental to standard of care.



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To: [6. Participant Information and Consent Process - Human Ethics Application for Clinical Study](#) ▾

## 6. PARTICIPANT INFORMATION AND CONSENT PROCESS - 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.

### \* 6.1. Time to Participate

### 6.2. Time to Participate – Normal/Control Participants

### 6.3. Known Study Risks/Harms

### 6.4. Potential Benefits

## 6.5. Reimbursement / Remuneration

**6.5.A.** Are there any costs participants can reasonably be expected to incur in order to participate – e.g. transportation, parking, child care, etc.? Specify what they are and whether or not these will be fully reimbursed.

**6.5.B.** Describe any remuneration (payments/incentives/gifts-in-kind) to be offered to the participants. Provide full details of the amounts, form of payment, payment schedules, and value of gifts-in-kind. [?](#)

## 6.6. Obtaining Consent


Please specify:

- who will explain the consent form,
- who will consent participants,
- details of where the consent will be obtained and under what circumstances, and
- the relationship between the person obtaining consent and the participant. [?](#)

## 6.7.A. Waiver/Alteration 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 explain how the study meets all the criteria. CLICK on blue question mark. Ensure that you address each criteria **individually**. Include the corresponding letter (a, b, c, d, e) before each answer. [?](#)

### 6.7.B. Waiver of Consent in Individual Medical Emergencies

If you are asking for a waiver or an alteration of the requirement for participant informed consent in individual medical emergencies, please justify the waiver or alteration and explain how the study meets all the criteria. CLICK on blue question mark. Ensure that you address each criteria **individually**. Include the corresponding letter (a, b, c, d, e, f) before each answer. 




### 6.8. Time to Consent

How long after being provided with detailed information/consent form about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given. 



### \* 6.9. 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. 


### 6.10. Ongoing Consent




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



### 6.12. Restrictions on Disclosure

Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the sponsor has placed on investigators, including those related to the publication of results. 



### 6.13. Communication of Study Results

Indicate plans for communicating study results to participants.



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To: [6. Participant Information and Consent Process - Human Ethics Application for Clinical Study](#) ▾

## 7. NUMBER OF PARTICIPANTS AND REGULATORY APPROVALS/REGISTRATION FOR CLINICAL 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" link at the top and bottom of each page.

### 7.1. Other Study Sites

**7.1.A.** Is this research being conducted at any sites other than those selected on page 4 of this RISE submission, including world-wide? 

Yes  No [Clear](#)

If known, please list the other sites below:

A text input field with a vertical scrollbar on the right and horizontal scrollbars at the bottom, intended for listing other study sites.

**7.1.B.** Is this study being submitted for ethical approval to any other Research Ethics Board not covered by this RISE submission, including world-wide?


[Yes](#)

[No](#)

[Unknown](#)

[Clear](#)

If yes, please provide the name of the REB(s) and if available, contact information:

A text input field with a vertical scrollbar on the right and horizontal scrollbars at the bottom, intended for providing REB details.

### 7.2. Number of Participants

**7.2.A.** How many participants (including controls) will be enrolled in the entire study (world-wide)?

**7.2.B.** How many participants (including controls) will be enrolled at institutions covered by this Research Ethics Approval?

If possible, breakdown the estimated number per institution.

**7.2.C.** Of these, how many are controls?[?](#)

If possible, breakdown the estimated number per institution.

**7.2.D.** Please enter any additional comments. If your study does not involve enrollment of human participants, please enter the number of records or samples to be obtained:

### 7.3. Drug approvals

Enter the generic name of any investigational drug(s) not yet approved or any marketed drug(s) used **outside** of its approved indication.[?](#)


### 7.4. Marketed Drugs

Enter the name of any marketed drug(s) used **within** its approved indication.


### 7.5. Natural and Non-Prescription Health Products[?](#)




## 7.6. Experimental Devices

Enter the name of any new investigational devices, or marketed devices used in experimental mode, that will be used outside of their approved indication. 

## 7.7. PERs

If applicable, enter the name of any positron-emitting radiopharmaceuticals (PERs). 

## 7.8. Health Canada Regulatory Approvals

**7.8.A.** Is this study a clinical trial or investigational test requiring Health Canada regulatory approval (If this study does not require Health Canada approval, skip to 7.10) 


Yes  No [Clear](#)

**7.8.B.** If yes, check all that apply from the list below.

- This study is a clinical trial pursuant to the provisions of Part C, Division 5, of the Food and Drugs Act.
- This study is a clinical trial of a Natural Health Product pursuant to the Natural Health Product Regulations.
- This study involves the investigational testing of a class II, III or IV medical device pursuant to the Medical Device Regulations.
- This study requires the submission of a clinical trial application pursuant to the Guidance Policy on the use of positron-emitting radiopharmaceuticals in basic research.

**7.8.C.** Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.

## 7.9. Details of Health Canada Regulatory Approvals

A copy of the approval (NOL, ITA, NOA) must also be attached in Box 9.1. 


Name of Regulatory Agency	Date of Approval	Date of Pending Application
There are no items to display		

Health Canada NOL Control Number

Date of Approval


There are no items to display

### 7.10. Stem Cell Research

Does this research fall within the categories of pluripotent stem cell research that need to be submitted to the CIHR Stem Cell Oversight Committee (SCOC)? 

Yes  No [Clear](#)

### 7.11. Registration for Publication of Clinical Trials

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

Yes  No [Clear](#)

**7.11.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.)


Has it been registered?

Authorized Registry used


Clinical Trial unique identifier

There are no items to display

### 7.12. US Regulatory Requirements

**7.12.A.** Is there a requirement for this research to comply with United States regulations for research ethics? 

Yes  No [Clear](#)


**7.12.B.** If yes, please indicate whether or not an FDA Investigational New Drug (IND) number (drug studies) or an FDA Investigational Device Exception (IDE) is required for the research. Enter the applicable number below and provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in Box 9.1.C. 

---

## 8. SECURITY OF DATA, CONFIDENTIALITY OF PERSONAL INFORMATION, AND DATA MONITORING FOR CLINICAL 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"** link at the top and bottom of each page.

### 8.1. Unblinding in an Emergency

Describe the provisions made to break the code of a double-blind study in an emergency situation, and indicate who has the code. 



### 8.2. Data Monitoring Procedures

Describe data monitoring procedures while research is ongoing. Include details of planned interim analyses, Data and Safety Monitoring Board, or other monitoring systems. 




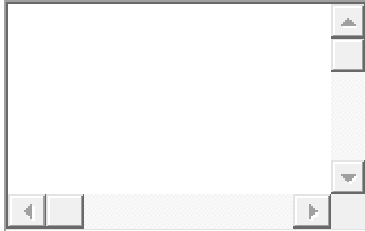
### \* 8.3. Study Stoppage

Describe the circumstances under which the ENTIRE study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.



**\* 8.4. Personal Identifiers**

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



**\* 8.4.B.** Will any personal health information or personal identifiers be retained as part of the dataset?


Yes  No [Clear](#)

If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.



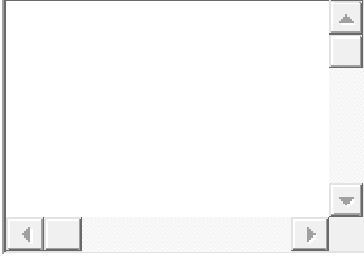
**\* 8.5. Data Access and Storage**

**8.5.A.**

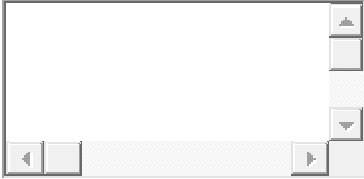
- a) Explain who will have access to the data at each stage of processing and analysis;
- b) indicate whether a current list of the names of study personnel (including co-investigators and research staff) and their delegated tasks will be maintained in the study file;
- c) if a list will not be maintained, please explain. 



\* **8.5.B.** Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio recording, personal electronic device, other). Please confirm that any digital data will be stored on an encrypted, password protected computer, storage device, or hospital network server.



\* **8.5.C.** Describe the safeguards in place to protect the confidentiality and security of the data.




**8.5.D.** If any data or images are to be kept on the Web, what precautions have you taken to prevent it from being copied?



\* **8.6. Disposition of Study Data and Biospecimens**

**8.6.A.**


Please describe:

- what will happen to the data at the end of the study;
- how long the study data will be retained;
- when and how the data will be destroyed;
- what plans there are for future use of the data; and
- who will have access to the data in the future and for what purpose. 



**8.6.B.**

If applicable:

- a) describe what will happen to the study biospecimens at the end of the study;
- b) how long the study biospecimens will be retained;
- c) where, when and how the biospecimens will be destroyed; and
- d) what plans there are for future use of the biospecimens, including who will have access to the biospecimens in the future and for what purpose. 



**\* 8.7. Data and/or Biospecimen Transfer to Other Institutions**

**8.7.A.** Will data and/or biospecimens be sent outside of the Institution where it is being collected?



Yes

No

[Clear](#)

**8.7.B.**

If yes, please describe:

- a) the type of data and/or biospecimens to be transferred;
- b) who the data and/or biospecimens will be transferred to;
- c) where the data and/or biospecimens will be transferred (list institution & location); and
- d) how the data and/or biospecimens will be sent.



**\* 8.8. Data and/or Biospecimen Transfer to Institution**

**8.8.A.** Will the researchers be receiving data and/or biospecimens from other sites?

Yes

No

[Clear](#)

**8.8.B.**

If yes, please describe:

- a) the type of data and/or biospecimens to be received;
- b) who the data and/or biospecimens will be received from;
- c) where the data and/or biospecimens will be received from (list institution and location); and
- d) how the data and/or biospecimens will be received.

**\* 8.9. Data Linkage**

**8.9.A.** Will the data be linked to any other data source (including a biorepository)?

Yes  No [Clear](#)

**8.9.B.**

If yes:

- a) Identify the data set;
- b) how the linkage will occur; and
- c) explain how confidentiality regarding the shared information will be preserved.

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To: [8. Data Monitoring- Human Ethics Application For Clinical Study](#)

## 9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach the documentation for 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, document names etc. are accurate and match those on the attached documents. Submit final versions only (i.e. not "drafts").

**New Applications:** Attach the documents to the applicable section.

#### **Response to Proviso, Deferral, Changes Required by REBA, or Amendments:**

Revisions required by the Board should be highlighted. 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 or PAA coversheet that you have added a new document for review.

#### \* 9.1.A. Protocol

Document Name	Version	Date	Document	Password (if applicable)
---------------	---------	------	----------	--------------------------

**9.1.B.** Health Canada regulatory approval (receipt will be acknowledged). Please include details of this approval in Box 7.9 of the RISE application form.

Document Name	Version	Date	Document	Password (if applicable)
---------------	---------	------	----------	--------------------------

There are no items to display

**9.1.C.** FDA IND or IDE letters (receipt will be acknowledged)

Document Name	Version	Date	Document	Password (if applicable)
---------------	---------	------	----------	--------------------------

There are no items to display

#### 9.2. Consent Forms

Document Name	Version	Date	Document	Password (if applicable)
---------------	---------	------	----------	--------------------------

There are no items to display

#### 9.3. Assent Forms



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


#### 9.4. Investigator Brochures/Product Monographs

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

#### 9.5. Advertisement to Recruit Participants

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

#### 9.6. Questionnaire, Questionnaire Cover Letter, Tests, Interview Scripts, etc.


Please attach each separately. 

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

#### 9.7. Letter of Initial Contact

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

#### 9.8. Data collection forms and Other Documents

**9.8.A.** Please attach data collection forms, chart extraction forms, case report forms, or other documents. 

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

**9.8.B.** If a website is part of this study, enter the URL below. Since URLs may change over time or become non-existent, you must also attach a copy of the documentation contained on the web site to this section or provide an explanation.

Please note that fees vary by REB. Board of record will determine the fee.

## 10. FEE FOR SERVICE FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

### Industry For-Profit Sponsors

The review fee is \$3000 for the initial review and \$500 for the annual renewal. **Please wait for the invoice from the Clinical Research Ethics Board (CREB) to submit payment. The invoice will detail payment instructions and wire transfer information.**

\* Please indicate which of the following methods of payment will be used for this application.

N/A (Not funded by an Industry For-Profit Sponsors)

A Cheque

A Journal Voucher

[Clear](#)

**OR**

Enter information stating when the fee will be sent:



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To:

## 10. FEE FOR SERVICE FOR BC CANCER AGENCY - HUMAN ETHICS APPLICATION

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 \$4,000. 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.**

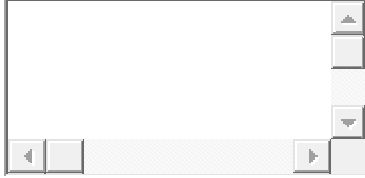
Please select one of the following:

- Mechanism for submitting the fee
- Fee N/A as per above criteria
  - Payment will be made by the Sponsor (the REB will send an invoice to the Principal Investigator and Primary Contact)
  - Internal transfer of funds. Please complete question C with the account information
  - Request for Fee Waiver due to circumstances other than those listed above. A request will only be considered if an explanation is provided below in question B

[Clear](#)

**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.

[None]

If you have any questions please contact:  
Kristie Westerlaken, Manager BCCA Research Ethics Board  
(604) 877-6284 or [reb@bccancer.bc.ca](mailto:reb@bccancer.bc.ca)

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To: [10. Fee for Service - Human Ethics Application for Providence Health Care](#) ▾

## 10. FEE FOR SERVICE FOR PROVIDENCE HEALTH CARE RESEARCH INSTITUTE - HUMAN ETHICS APPLICATION

### Fee-For-Service Payment Details

The fee for ethical review applies 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 and adverse event reports).

Final Approval to start the research will not be issued until the ethics review fee is received. In addition, the Research Ethics Board reserves the right to withhold issuing the Certificate of Ethical approval until the fee is received.

### Fee Waiver Criteria

The following types of funding are excluded from the fee requirement:

1. Grant-in-aid - funding from government, non-profit organizations or industry. However, if the sponsor expects deliverables, a fee will be applicable.
2. Internal (includes self-funded and funding from Providence Health Care Foundation).

If you have a request for fee waiver due to circumstances other than those listed above, the request should be made by completing box 10.1. B for consideration. The request must clearly outline the reason why an exemption should be considered.

### Mechanism for Submitting Fee

#### \* 10.1. A.

Select one of the following:

Mechanism for Submitting the Fee

Payment will be made by the Sponsor

Fee N/A as per above criteria

[Clear](#)

#### 10.1. B.

Additional Information:



If you have any questions regarding fee waivers, please contact:

Julie Hadden

Manager Ethical Reviews

Office of Research Services

Providence Health Care Research Institute

[jhadden@providencehealth.bc.ca](mailto:jhadden@providencehealth.bc.ca)

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To: [10. Fee for Service - Human Ethics Application for C&W](#) ▾

## 10. FEE FOR SERVICE FOR BEHAVIOURAL/CLINICAL 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.



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To: [10. Fee for Service - Human Ethics Application for Clinical Study](#) ▾

## 10. FEE FOR SERVICE FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

### Industry For-Profit Sponsors

The review fee is \$3000 for the initial review and \$500 for the annual renewal. **Please wait for the invoice from the Clinical Research Ethics Board (CREB) to submit payment. The invoice will detail payment instructions and wire transfer information.**

\* Please indicate which of the following methods of payment will be used for this application.

N/A (Not funded by an Industry For-Profit Sponsors)

A Cheque

A Journal Voucher

[Clear](#)

**OR**

Enter information stating when the fee will be sent:

To save information on each view as you are working, especially if you are working on the view for a long period of time, select the "Save" button located at the top or bottom of the view in the blue bar. Your work on each view will automatically be saved once you hit the "Continue" button.

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**There are Multiple Page 11s. Only select Health 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](http://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.

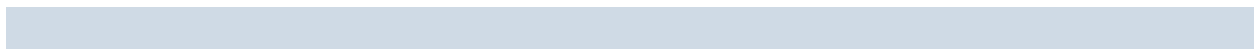
Select the Site Investigator at VCHA **if different** from the Principal Investigator in Box 1.1.

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                 |   |
|--------------------------|---|
| <input type="checkbox"/> | 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). |
| <input type="checkbox"/> | Richmond Health Services (Richmond Health Services encompasses the following networks: acute care, community care, primary health care, mental health and addictions.)  |
| <input type="checkbox"/> | 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)     |
| <input type="checkbox"/> | 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 fetuses.

**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
<input type="checkbox"/> Utilization form for Hospital Program (if C&W Program resources such as space or staff are required)
<input type="checkbox"/> If Industry Sponsored, signed contract agreement between Sponsor, Hospital and University
<input type="checkbox"/> Utilization form for Health Records (if C&W Health Records are required)
<input type="checkbox"/> Utilization form for Laboratory services (if C&W Lab/Pathology services are required)
<input type="checkbox"/> Utilization form for Pharmacy (if C&W Pharmacy services are required)
<input type="checkbox"/> Other Resource/Service Utilization (provide explanation below)
<input type="checkbox"/> 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
<input type="checkbox"/> N/A
<input type="checkbox"/> Cardiac Cath Lab
<input type="checkbox"/> Centre for Excellence in HIV/AIDS
<input type="checkbox"/> Contract/Agreement (For Profit Sponsor/Government Funding or Grant-in-Aid)
<input type="checkbox"/> ECG
<input type="checkbox"/> Imaging (e.g. X-ray, CT scan, MRI)
<input type="checkbox"/> Laboratory (blood collection)
<input type="checkbox"/> Laboratory (anatomical pathology)
<input type="checkbox"/> Medical Records - Discharged Patients
<input type="checkbox"/> 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.**

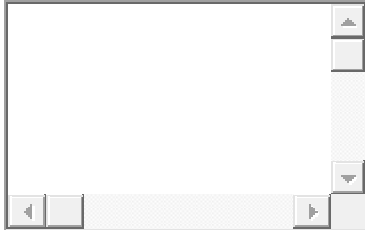
Which of the following hospital areas will be required to provide services for the conduct of the research? If the PI for the research is employed by the hospital area in question and has obtained approval for use of his or her own area, please do not select the relevant option. (Please check all that 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](mailto:alex.trethewey@ubc.ca)  
(604) 682-2344 x68366

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## 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
<input type="radio"/> Submitted (attach agreement in question 9.8)
<input type="radio"/> N/A
<input type="radio"/> Pending

[Clear](#)

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## 1. RESEARCH APPROVAL INFORMATION FOR INTERIOR HEALTH - HUMAN ETHICS APPLICATION

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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](mailto: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.

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

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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.

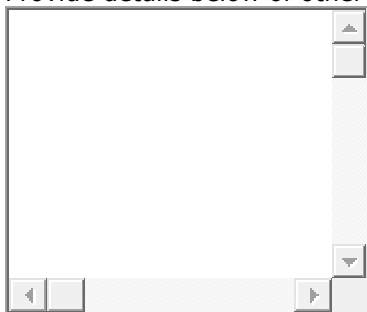
**11.1.A.** At which of the Fraser Health sites will the research be conducted?

<input type="checkbox"/> Hospital Area
<input type="checkbox"/> N/A
<input type="checkbox"/> Abbotsford Regional Hospital and Cancer Centre
<input type="checkbox"/> Burnaby Hospital
<input type="checkbox"/> Chilliwack General Hospital
<input type="checkbox"/> Community Site(s), please specify in 11.2.B.
<input type="checkbox"/> Delta Hospital
<input type="checkbox"/> Eagle Ridge Hospital
<input type="checkbox"/> Fraser Canyon Hospital
<input type="checkbox"/> Jim Pattison Outpatient Care and Surgical Centre
<input type="checkbox"/> Langley Memorial Hospital
<input type="checkbox"/> Peace Arch Hospital
<input type="checkbox"/> 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.**

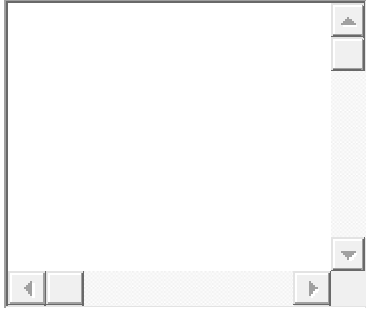
**11.2.A.** Which of the following services are required for the conduct of your research? (Please check all that apply).

- | Hospital Facility/Service  |
|--|
| <input type="checkbox"/> N/A   |
| <input type="checkbox"/> Anatomical Pathology                              |
| <input type="checkbox"/> Biomedical Engineering                            |
| <input type="checkbox"/> Communicable Diseases/Public Health               |
| <input type="checkbox"/> Diagnostic Imaging                                |
| <input type="checkbox"/> Health & Business Analytics (Administrative Data) |
| <input type="checkbox"/> Health Records (Electronic)                       |
| <input type="checkbox"/> Health Records (Paper)                            |
| <input type="checkbox"/> Image Tech Lab                                    |
| <input type="checkbox"/> Information Management                            |
| <input type="checkbox"/> Laboratory  |
| <input type="checkbox"/> Patient Care Services                             |
| <input type="checkbox"/> 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](#)

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To: [11. Research Site Information for Fraser Health](#) ▼

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

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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](mailto: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 be 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  |
|---|
| <input type="checkbox"/> N/A  |
| <input type="checkbox"/> Cardiac – Heart Health   |
| <input type="checkbox"/> Contract/Agreement (For Profit Sponsor/Government Funding or Granting) |
| <input type="checkbox"/> Medical Imaging (e.g. X-ray, CT scan, MRI)                             |
| <input type="checkbox"/> 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)

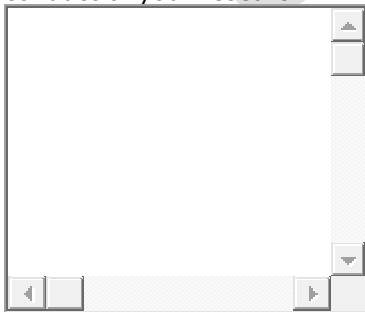
Other:

A rectangular text box with a light gray background and a thin border. It contains no text. The box has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.

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

A rectangular text box with a light gray background and a thin border. It contains no text. The box has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.

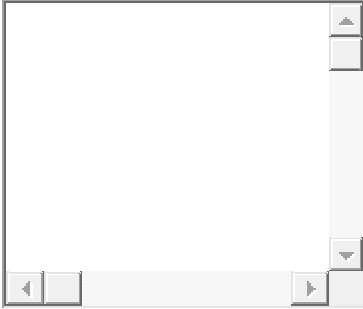
Please name any Island Health Health Centres that will be directly involved as a site for the conduct of your research:

A rectangular text box with a light gray background and a thin border. It contains no text. The box has a vertical scrollbar on the right side and a horizontal scrollbar at the bottom.

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

- Nursing
- Pharmacy
- Physiotherapy
- Respiratory
- Other (please specify below)

Other department required to support research:

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