Table of Contents for Clinical Application Pages

1. PRINCIPAL INVESTIGATOR & STUDY TEAM- HUMAN ETHICS APPLICATION

Pleasenote that all required fields are marked with a red asterisk and need to be filled out before beingable 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

PrimaryAppointment: Medicine, Department of (UBC)
Rank:
Email:

EnterPrincipal 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. AdditionalStudy 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?

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 startdata collection at a later date i.e., 2 months or more after approvals are obtained. Clickthe calendar icon below to select the dates or enter the dates manually using the formatyyyy-mm-dd.

Estimated startdate:

*2.1.B.

Estimated enddate:
Thursday, Septer

Sourceof Funds

* 2.2.A.Types of Funds

Pleaseselect the applicable box(es) below to indicate the type(s) of funding you are receiving to conductthis research. You must then complete section 2.3 and/or section 2.4 for the name of thesource 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
☑	NoFunding
☐	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 grantbelow.

DHHS SponsorList
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 ifBox 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 thisresearch is being conducted)

Hospital/Institution	Site
Vancouver Coastal Health (VCHRI/VCHA)	Vancouver General Hospital

4.2.B. Non-UBCInstitutions and Sites for Study (including study team members' institutional affiliations underwhich this research is being conducted)

Hospital/Institution	Site
Interior HealthAuthority	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, articipant's home, in the field - provide details).

4.B. CLINICAL STUDY REVIEW TYPE- HUMAN ETHICS APPLI CAT ION

Please note that allrequired fields are marked with a red asterisk and need to be filled out before you will be able toproceed to the next page. Please save your work before continuing onto the next page to preventlosing 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	☑	☐		
Interior Health Authority - Lillooet Home & Community Care			☑	

4.3. Relationship with other proposals

4.3.A.Ifthis proposal is closely linked to any other proposal previously/simultaneously submitted toaUBCREB or REBC institution, enter the Institution or Health Authority name and associated ResearchEthics Board study number of that proposal.

InstitutionName:

REBstudynumber:

4.3.B. Please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.

4.3.C. Have youreceived any information or are you aware of any rejection of this study by any Research EthicsBoard?If yes, please provide known details and attach any available relevant documentationinBox9.8.

○ Yes ○ No Clear

Please provideknown details:

4.3.D. Will biological materials be collected or analyzed by researchers or a research lab?

Yes No Clear

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

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

Yes No Clear

IfYES, providethe institutionally applicable Radiation Permit Number(s). (Note that if this is a BC harmonized study, information about institutionally specific requirements for Radiation permits will beon 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.

Yes No Clear

4.5. Peer Review
Ifthis 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:

4.C. CLINICAL STUDY REVIEW TYPE-APPLI CAT ION HUMAN ETHICS

*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.]

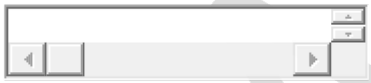
○ Yes ○ No Clear

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

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

C. CREATION OF A RESEARCHREGISTRY ORBIOREPOSITORY - HUMAN ETHICS APPLICATION

*C.1. What is the scope andpurpose of the research registry or biorepository?

*C.2. What are the anticipated public and scientific benefitsofthe 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 detailsabout 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 remainidentifiable / 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 thedata 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

Doyou 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.)

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 CLINICALCHARTREVIEWS –HUMAN ETHICS APPLI CAT ION

Please note that allrequired 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 pagein an effort to make sure your work is not lost. You can do so by clicking on the "Save" link atthe 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 recordsand 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 datacollection/ 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 tosafeguard the identifiable information.

Yes No Clear

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

*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.

*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.

*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 stageof collection, processing and analysis, and indicate whether a current list of the namesofstudy personnel (including co-investigators) and their delegated tasks will be maintainedinthe 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

Willdata be transferred outside of UBC or its affiliated hospitals?

Yes No Clear

Ifyes, 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 APPLI CAT ION

Please note thatallrequired 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 pagein an effort to make sure your work is not lost. You can do so by clicking on the "Save" linkatthe 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

Ifexisting 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 theresearch 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.

6. PARTICIPANT INFORMATION AND CONSENT PROCESS
- HUMAN ETHICS APPLICATION

Please note that all required fields aremarkedwith a red asterisk and need to be filled out before you will be able to proceed to the nextpage.Please save your work before continuing onto the next page to prevent losing your work.Youwillfind 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

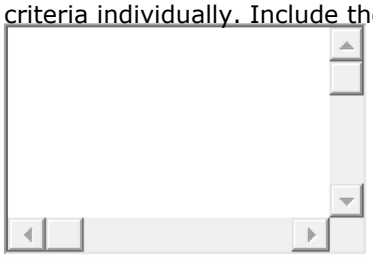
Please specify:
a) who will explain the consent form,
b) who will consent participants,
c) details of where the consent will be obtained and under what circumstances, and
d) the relationship between the person obtaining consent and the participant.

6.7.A. Waiver/Alteration of Consent

Ifyou 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 toConsent

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

Yes

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.

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.

7. NUMBER OF PARTICIPANTS AND REGULATORY APPROVALS/REGISTRATION FORCLINICALSTUDY - HUMAN ETHICS APPLICATION

Please note that all requiredfields are marked with a red asterisk and need to be filled out before you will be able to proceedtothe next page. Please save your work before continuing onto the next page to prevent losingyour 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

Ifknown, please list the other sites below:

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

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

7.2. Number ofParticipants

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

7.2.B. How manyparticipants (including controls) will be enrolled at institutions covered by this Research EthicsApproval?

Ifpossible, breakdown the estimated number per institution.

7.2.C. Of these,how many are controls?

Ifpossible, 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

Ifapplicable, 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

Acopy 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 - HUMANETHICS APPLICATION

Please note that all required fields are marked witharedasterisk and need to be filled out before you will be able to proceed to the next page. Pleasesaveyour work before continuing onto the next page to prevent losing your work. You will findthe"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

Ifyes, please describe what personal identifying information will be collected, and justify the need forit 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)ifa 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.

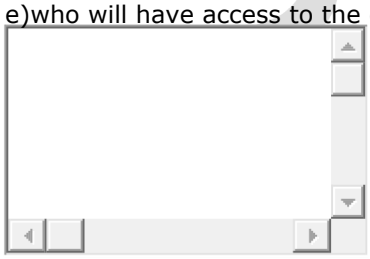
*8.5.C. Describe the safeguards in place to protect the confidentiality and security of the data.

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

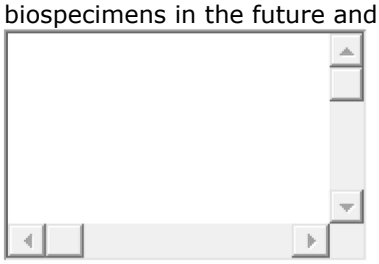
8.6.A.

Please describe:
a)what will happen to the data at the end of the study;
b)how long the study data will be retained;
c)when and how the data will be destroyed;
d)what plans there are for future use of the data; and
e)who will have access to the data in the future and for what purpose.



8.6.B.

Ifapplicable:
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.

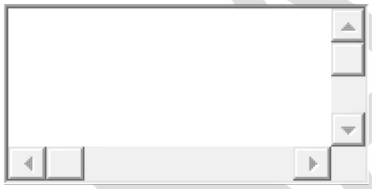


*8.7. Data and/or Biospecimen Transfer to Other Institutions

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

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.

9. DOCUMENTATION- HUMAN ETHICS APPLICATION

Please attach the documentation for the study. The Research Ethics Officecannot 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 anew 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 regulatoryapproval (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.FEEFORSERVICE FORCLINICALSTUDY - HUMAN ETHICS APPLI CAT ION

Industry For-ProfitSponsors

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

* Please indicatewhichof 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.

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.

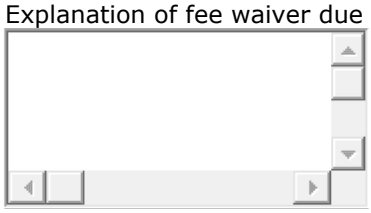
Please select one of the following:

	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]

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

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.

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:

Ifyou 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

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.

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.

10. FEE FOR SERVICE FOR CLINICAL STUDY - APPLI CAT ION

HUMAN ETHICS

Industry For-ProfitSponsors

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

* Please indicate whichof 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.

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

11. INFORMATION FOR VANCOUVER COASTAL HEALTH AUTHORITY (VCHA)/VANCOUVER COASTALHEALTH RESEARCHINSTITUTE(VCHRI) - Applicationfor Approval to ConductResearch at VCHA

All research studiesandclinicaltrialsinvolving human participants ("Research Projects") that are conducted at VCHAmustbeapprovedbythe appropriate VCHA Health Service Delivery Area ("HSDA"). There arefourHSDAs:Vancouver Acute, Vancouver Community, Richmond Health Services, and Coastal.IfaResearchProject will be conducted at more than one VCHA HSDA site, the researcher mustobtainapprovaltoconduct research at each HSDA where the Research Project will be conducted. Onceapprovaltoconduct research has been granted by the applicable VCHA HSDA, the ResearchProjectmaybeginatthat site. The approval process ensures that all research involving humans conductedatVCHAisreviewed from an ethical, safety and resource use framework. AccordingtoVCHApolicy,Research Projects cannot begin until final approval from VCHRI has been granted.

Guidelines and formsmaybedownloadedfrom 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

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

Yes No Clear

If"Yes"youmust select here to print and complete a declaration form with signatures then attach thecompleted form below by clicking the "Browse" button. If "No" proceed to Box 11.3. Selectthe"Browse" button to attach the declaration form.

11.2. C.

DoesthePrincipal Investigator in Box 1.1 have a UBC appointment?

Yes No Clear

If"Yes" you mustdesignate a VCHA employee or medical staff below as the "Site Investigator at VCHA" if differentfrom the Principal Investigator listed in Box 1.1. Alternatively, the Principal Investigator inBox1.1 may obtain VCHRI Affiliated Investigator Status.

Select the SiteInvestigator 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 andneed to be filled out before you will be able to proceed to the next page. Please save your workbefore continuing onto the next page to prevent losing your work. You will find the "Save" linkatthe 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, Child~~ren'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.
Inorder 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 aUBC 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

Ifyou 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 inpossession 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.

Whichof the following hospital services are required for the conduct of your research? (Please checkall 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 thatapply).

	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 clickingthe "Browse" button.

Ifyouhave any questions please contact:
AlexTrethewey
Pre&PostReview Manager,
OfficeofResearch Ethics,
Providence Health Care Research Institute
alex.trethewey@ubc.ca
(604) 682-2344 x68366

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.

11. BC CANCER AGENCY CENTRE PI - HUMAN ETHICS APPLI CAT ION

Please note that allrequired fields are marked with a red asterisk and need to be filled out before you will be able toproceed to the next page. Please save your work before continuing onto the next page to preventlosing 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 FraserValley Centre:

D.

Lead PI for theCentre for Southern Interior:

E.

Lead PI for the Centre for Abbotsford Centre:

F.

Lead PI for theCentre for the North:

*11.2.

Ifthis 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

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1. 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

IfNO, 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

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.

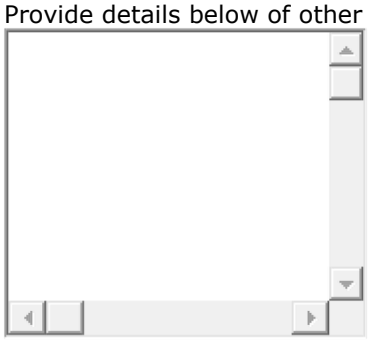
11.1.A. At which of the Fraser Health sites will the research be conducted?

	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 checkall 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

IfNO, is the Principal Investigator in Box 1.1 a Fraser Health privileged physician?

○ Yes ○ No Clear

IfNO, the academic PI is required to become affiliated with FH by signing onto the FH affiliation agreement with their home institution.

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

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

PIAffiliation status with Fraser Health:

	Affiliation Status
○	Affiliation Granted
○	Affiliation Request Submitted
○	No

Clear

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

IfNO, 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 FraserHealth site PI:

11.4.

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

11.4.B. Pleaseindicated 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

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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:

ResearchOperations@islandhealth.ca

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

Yes No Clear

Ifyes, 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)

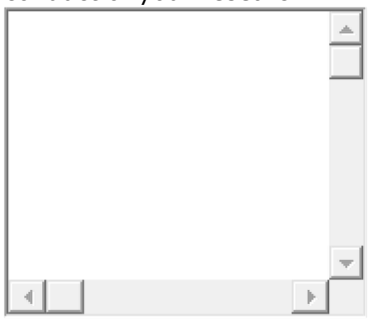
☐	Laboratory (anatomical pathology)
	Medical Records – Access to Electronic Health Record
	Medical Records – Access to Paper Charts
	Pharmacy
	Physiotherapy
	Respiratory
	Other (please specify below)

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:



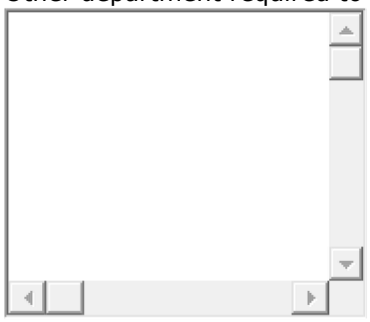
For other Island Health locations, please describe here:

Whichof the following hospital services are required for the conduct of your research? (Please checkall 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:



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