Contents For RISe Clinical Ethics Application

Page 1. Principal Investigator & Study Team

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**

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

1.2. Primary Contact

1.3A. Co-Investigators - Online Access

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

1.3B. Describe each Co-I's role in study, e.g. statistician, supervisor, adviser, student etc. Ensure individual is entered in Box 1.3A

Text box

1.4A. Additional Study Team Members - Online Access

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

1.4B. Describe each Additional Study Team Members' role in study, e.g. staff, research assistant etc.

Text box

1.5A. Additional Study Team Members - No Online Access

Add

Last Name	First Name	Institution/Department	Rank/Job Title	Email Address

There are no items to display

1.5B. Describe each Additional Study Team Members' (no online access) role in study, e.g. external supervisor, consultant etc.

Text box

1.6. Tri Council Policy Statement (TCPS) Tutorial

* Have all research personnel completed the required TCPS2 tutorial:

☐ Yes

☐ No

☐N/A

* 1.7. Project Title

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

Text box

* 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?

Page 2. Study Dates & Funding Information

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

☐

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.

  Estimated start date:

*** 2.1.B.**
Estimated end date:

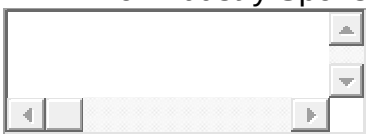
Source of Funds

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

Type(s) of Funding

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

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



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

Add

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

2.3.B. Which institution is administering the funds, if not UBC or UBC affiliated institution?

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

Add

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 2.3A or 2.4A (including funding applied for but not yet received).

Text box

U.S. Funding

* **2.5.A.** Is this a DHHS grant?

☐Yes ☐No

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

DHHS Sponsor List
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

Page 3. Conflict of Interest

Page 3 will only appear if a Conflict of Interest was declared in Box 2.6

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? If yes, please describe the nature of the conflict and to whom it relates.

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).

Text box

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

If yes, please provide details in the space below:

Text box

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

Text box

* **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

Comments:

Text box

Page 4A. Study Type (Questions 4.1-4.2C)

4.A. STUDY TYPE - HUMAN ETHICS APPLICATION

*** 4.1. Application Type**

Indicate whether your application is Clinical or Behavioural.

Type of Study

☐Behavioural
☐Clinical

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

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

Hospital/Institution	Site

4.2.B. Non-UBC Institutions and Sites for Study (including study team members' institutional affiliations under which this research is being conducted)
-If study site not found, enter "Other" then specify site in box 4.2C

Hospital/Institution	Site

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).

Text box

Page 4.B. Clinical Study Review Type (Questions 4.2D-4.6)

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

4.2.D. Roles of Study Sites and Institutions

Study Site	Accessing Records or Charts	Analyzing Data or Using Lab Space or Conducting Research Procedures	Recruiting Participants	Team Member Affiliations
UBC - Vancouver (excludes UBC Hospital)	☐	☐	☐	☐

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 application and other ethics applications listed above.

Text box

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

Please provide known details:

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

☐Yes ☐No

If you are collecting and analyzing biological materials in your lab, please provide the UBC Biosafety Permit Number, or confirm that the lab has the appropriate biosafety permits in place.

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

☐Yes ☐No

If YES, provide the institutionally applicable Radiation Permit Number(s).

* **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

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:

Text box

Please note Question 4.6 does not always appear

* **4.6.** Does this study require review and approval by University of Alberta (UofA) or University of Saskatchewan?

☐Yes ☐No

Page 4.C. Clinical Study Review Type (Questions 4.7-4.9)

Please note that some of the below questions will only show depending on how you respond to the previous questions

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 for future use in other research? [if no, skip to 4.8]
☐Yes ☐No

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

Clinical Chart Review/Secondary Analysis of Data (data only)

4.8.A. Is this an application for research which exclusively requires access to clinical charts OR data from registries or databases such as PopData BC or Pharmanet?
☐Yes ☐No

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)

Text box

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

4.8.D. Will you have access to personally identifiable information?
☐Yes ☐No

4.8.E. Is this a retrospective chart review study for which participant consent will be obtained?
☐Yes ☐No

Biospecimen Analysis (Biospecimen and data)

Please click here for video explaining the next two questions

4.9.A. Is this study exclusively analyzing previously collected biospecimen and data related to the biospecimens?
☐Yes ☐No

4.9.B. Are BC researchers, in this application, only conducting biospecimen analysis, with all participant recruitment occurring outside of BC?
☐Yes ☐No

Page 5. Summary of Study and Recruitment

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.

Text box

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

Text box

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. If applicable, include age criteria for participants.

Text box

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.

Text box

5.4.A. Recruitment

Provide a detailed description of the method of recruitment. Include, where applicable:
a) how will prospective participants be identified;
b) by what means will recruitment be done (e.g., public posting, direct contact, third party recruitment, etc.);
c) who will contact prospective participants;
d) If you have more than 1 BC site, indicate if there are site-specific recruitment methods.
e) attach all letters of initial contact or other recruitment materials (i.e., posters, phone/email scripts, Social media posting, Twitter tweets) to page 9

Text box

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.

Text box

5.5. Does this research focus on Indigenous peoples, communities, or organizations?
☐Yes ☐No

5.5.1.A. Will the research be conducted on Indigenous reserves, Métis settlement(s), or lands governed under a self-government agreement or an Inuit or First Nations land claims agreement?
☐Yes ☐No

If yes, please provide details:

Text box

5.5.1.B. Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?
☐Yes ☐No

If yes, please provide details:

Text box

5.5.1.C. Does the research seek input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics?
☐Yes ☐No

If yes, please provide details:

Text box

5.5.1.D. Will Indigenous identity or membership in an Indigenous community be used as
☐Yes ☐No

If yes, please provide details:

Text box

5.5.1.E. Will the results of the research refer to Indigenous communities, peoples, language, history or culture?
☐Yes ☐No

If yes, please provide details:

Text box

5.5.2. Community Engagement

5.5.2.A. If you answered yes to questions a), b), c), d), or e), have you initiated or do you intend to initiate an engagement process with the Indigenous collective, community or communities for this study?
☐Yes ☐No

5.5.2.B. If you answered "Yes" to question 5.5.2.A., describe the process that you have followed or will follow with respect to community engagement. Include the role or position of those consulted, including their names if appropriate. Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) below.

Text box

Attachment:
Add

Title
There are no items to display

5.5.3. No community consultation or engagement

If you answered "no" to question 5.5.2.A., briefly describe why community engagement will not be sought and how you can conduct a study that respects Indigenous communities and participants in the absence of community engagement.

Text box

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. If records from multiple institutions will be used (as listed in 4.2.A/B), these should be addressed separately in your response.

Text box

* 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.

Text box

Page 6. Participant Information and Consent Process

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

*** 6.1. Time to Participate**

Text box

6.2. Time to Participate – Normal/Control Participants

Text box

6.3. Known Study Risks/Harms

Text box

6.4. Potential Benefits

Text box

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.

Text box

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.

Text box

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.

Text box

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.

Text box

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.

Text box

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.

Text box

*** 6.9. Capacity to Consent**

Will participants have the capacity to give fully informed consent on their own behalf?

6.10. Describe how participants' ongoing consent will be maintained throughout the research

Text box

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

Text box

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.

Text box

6.13. Communication of Study Results

Indicate plans for communicating study results to participants.

Text box

Page 7. Number of Participants and Regulatory Approvals/Registration for Clinical Study

7. NUMBER OF PARTICIPANTS AND REGULATORY APPROVALS/REGISTRATION FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

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

If known, please list the other sites below:

Text box

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

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

Text box

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 the current BC Research Ethics Approval?

7.2.B.2. If possible, breakdown the estimated number per BC institution.

Text box

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

7.2.C.2. If possible, breakdown the estimated number per BC institution.

Text box

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:

Text box

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.

Text box

7.4. Marketed Drugs

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

Text box

7.5. Natural and Non-Prescription Health Products

Text box

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.

Text box

7.7. PERs

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

Text box

7.8. Health Canada Regulatory Approvals

7.8.A. Is this study a clinical trial of a drug, device, or natural health product requiring Health Canada regulatory approval (If this study does not require Health Canada approval, skip to 7.10)

☐Yes ☐No

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 submitting to Health Canada for approval.

Text box

7.9. Details of Health Canada Regulatory Approvals

A copy of the Health Canada approval must also be attached in Box 9.1.

7.9.A. Name of Regulatory Agency

Add

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

7.9.B. Health Canada Approval

Add

Health Canada NOL Control Number /Other Health Canada approval #	Date of Approval

There are no items to display

7.11. Registration for Publication of Clinical Trials

7.11.A. Does this clinical study fall within the definition stated in the guidance (Click blue question mark)?

☐Yes ☐No

7.11.B. If yes, click "Add" to enter the following information.

Add

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

7.12.B. If yes, A) please indicate whether or not an FDA Investigational New Drug (IND) number (drug studies) or an FDA Investigational Device Exemption(IDE) is required for the research.

B) Enter the applicable number below and

C) provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in Box 9.1.C.

Text box

Page 8 Security of Data, Confidentiality of Personal Information and Data Monitoring for Clinical study

8. SECURITY OF DATA, CONFIDENTIALITY OF PERSONAL INFORMATION, and DATA MONITORING FOR CLINICAL STUDY - HUMAN ETHICS APPLICATION

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.

Text box

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.

Text box

*** 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.

Text box

*** 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, biospecimen labels, photos, videos, scans etc.

Text box

* **8.4.B.** Will any personal health information or personal identifiers be retained as part of the dataset?
☐Yes ☐No

If yes, please describe what personal identifying information will be collected, and **justify** the need for it to be retained as a part of the dataset.

Text box

* **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.

Text box

* **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.

Text box

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

Text box

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?

Text box

*** 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 are there for future use of the data; and
e) who will have access to the data in the future and for what purpose.

Text box

8.6.B.

If applicable, for each study component (eg, Main study, and Sub-studies):
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
d) what plans are there for future use of the biospecimens, including who will have access to the biospecimens in the future and for what purpose.
e) IF samples are transferred to another site, please respond to the above sub-question regarding transferred samples.

Text box

*** 8.7. Data and/or Biospecimen Transfer Out of BC Site(s)**

8.7.A. Will data and/or biospecimens be sent outside of the BC site(s) where it is being collected?

☐Yes ☐No

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.

Text box

*** 8.8. Data and/or Biospecimen Transfer Received by BC Site(s)**

8.8.A. Will the BC researchers be receiving data and/or biospecimens from other sites?
☐Yes ☐No

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.

Text box

*** 8.9. Data Linkage**
8.9.A. Will the data be linked to any other data source (including a biorepository)?
☐Yes ☐No

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.

Text box

Page 9. Documentation

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 including on the file name uploaded, 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**

Add

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.

Add

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)

Add

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

9.2. Consent Forms

Add

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

9.3. Assent Forms

Add

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

9.4. For studies administering study drugs or Natural health products, attach Investigator Brochures/Product Monographs

Add

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

9.5. Advertisement to Recruit Participants

Add

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.

Add

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

9.7. Letter of Initial Contact

Add

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.

Add

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

9.8.B. If an online survey, e-consent or 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.

Text box

9.9. Reference Documents - These documents **will NOT be listed in the Certificate of approval"**

Please attach reference documents here. For e.g., Consent forms or Ethics certificates from non-BC sites (click blue question mark for info).

Add

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

Page 10. Fee for Service for Clinical Study

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

Industry For-Profit Sponsors

The review fee is $3500 for the initial review and $750 for the annual renewal. **Please wait for the invoice from the UBC Clinical Research Ethics Board (CREB) to submit payment. The invoice will have 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
☐ Internal Service Delivery Transaction
☐ Wire Transfer

Enter information stating when the fee will be sent:

Text box

Page 11. Information for Vancouver Coastal Health

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

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

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

*** 11.1.A.**
Have you already received approval from VCHA to conduct this study?
☐Yes ☐No

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

*** 11.2.A.**
Does the Principal Investigator in question 1.1 have a UBC appointment?
☐Yes ☐No

If "No" you must select here to print and complete a declaration form with signatures then attach the completed form below by clicking the "Choose File" button.

11.2.B.
If No, please attach the declaration form.
Choose File

11.3.
If your research study involves Vancouver Community sites, have you consulted with the VCHRI Research Facilitator?
☐Yes ☐No

Page 11. Hospital Information for Providence Health Care

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

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

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

Criteria for obtaining PHC Final Approval

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

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

* **11.1.**

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

Hospital Facility/Service
☐N/A
☐Cardiac Cath Lab
☐Centre for Excellence in HIV/AIDS
☐Contract/Agreement (For Profit Sponsor/Government Funding or Grant-in-Aid)
☐ECG
☐Imaging (e.g. X-ray, CT scan, MRI)

☐Laboratory (blood collection)

☐Laboratory (anatomical pathology)

☐Medical Records - Discharged Patients

☐Medical Records - Use of Sunrise Clinical Manager

☐Medical Records - Outpatient Clinics

☐Medical Records - Use of Cerner/ CST

☐Nuclear Medicine

☐Nursing - Please complete question 11.1B

☐Pharmacy

☐Physiotherapy

☐Respiratory

☐Other (please specify in 11.2 B.)

11.1.B.
If "Other" provide details below.

Text box

* **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 11.2 B.)

☐Emergency Department

☐Nursing Units (please specify in 11.2 B.)

☐Operating Room

☐Pre-Admission Clinic(s) (please specify in 11.2 B.)

☐Renal Program/Units (please specify in 11.2 B.)

☐Other (please specify in 11.2 B.)

☐Pacific Lung Centre

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

Text box

11.3.
Does the Principal Investigator in Box 1.1 have a UBC appointment?
☐Yes ☐No

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.

Choose File

If you have any questions please contact:

Paula Piper
Research Ethics Coordinator,
Office of Research Ethics
Providence Health Care Research Institute
paula.piper@hli.ubc.ca

Page 11. UBC Children's and Women's Research Ethics Board

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

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

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

Criteria for obtaining C&W Approval

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

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

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

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

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

*** 11.2.**
Does the Children's and Women's Principal Investigator in Box 1.1 (and Box 11.1, if different) have a UBC academic or clinical appointment?
☐Yes ☐No

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.
Choose File

*** 11.3.**
Select which hospital form(s) are required for this application.

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

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

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

Page 11. BC Cancer Agency Centre PI

11. BC CANCER AGENCY CENTRE PI - HUMAN ETHICS APPLICATION

11.1.
Select the Principal Investigator for each participating BC Cancer Centre. Once you click "Select", you can enter the PI's name, or enter the first few letters of his or her name and click "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking on the appropriate heading.

A.
Lead PI for Vancouver Centre:

B.
Lead PI for Vancouver Island Centre:

C.
Lead PI for Fraser Valley Centre:

D.
Lead PI for the Centre for Southern Interior:

E.
Lead PI for the Centre for Abbotsford Centre:

F.
Lead PI for the Centre for the North:

* **11.2.**
If this application requires a Clinical Trial Agreement, what is the status of the Agreement?

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

Page 11. Research Approval Information for Island Health

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

Prior to commencing any human participant research at Island Health, Principal Investigators must obtain:

1. A Research Ethics Board Certificate of Approval 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 approvers and provide them with the necessary information from the proposed research. If there are any discussions to be had between the researcher and the Departments that must approve the research, we will contact you.

* **11.1.A.** Will Island Health staff be invited to be participants in this study?
☐Yes ☐No

11.1.B. If yes, please summarize involvement here:

Text box

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

Text box

11.1.D. Are Island Health staff conducting the study?
☐Yes ☐No

11.1.E. Please name the Island Health Collaborator

Text box

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

Text box

11.3. Please list all types of data/information contemplated for collection at Island Health or to collected and disclosed from Island Health. Note, review of data access is recommended here

Text box

11.4. 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:

Text box

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

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

Other department required to support research:

Text box

Page 11. Research Site Information for Fraser Health

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

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 REBC process. Following review and approval, the researcher will be issued two documents:

1) A certificate of harmonized ethical approval issued via UBC RISe; and
2) A FH Letter of Authorization to Conduct Research (LOA). The LOA is FH's Institutional Approval required to conduct research at FH sites.

NOTE: To apply for FH Institutional Approval, please download the appropriate Fraser Health Institutional Approval Application Form for Harmonized Studies from https://www.fraserhealth.ca/employees/research-and-evaluation/find-resources/research-forms-guidance-notes-templates#.XK0m7uaouUk and submit to Research.Approvals@fraserhealth.ca

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

Hospital Facility/Service
☐N/A
☐Anatomical Pathology
☐Biomedical Engineering
☐Communicable Diseases/Public Health
☐Diagnostic Imaging
☐Health & Business Analytics (Administrative Data)

☐Health Records (Electronic)

☐Health Records (Paper)

☐Image Tech Lab

☐Information Management

☐Laboratory

☐Patient Care Services

☐Pharmacy

☐Surgical Suites

☐Other (please specify in 11.2.B)

11.2.B.
If "Other" provide details below.

Text box

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

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

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

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

If NO, has an application for affiliation status submitted to FH? If YES, Application will proceed.

PI Affiliation status with Fraser Health:

Affiliation Status
☐Affiliation Granted
☐Affiliation Request Submitted
☐No

Name of Fraser Health study co-investigator:

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

Page 11. Research Approval Information for Interior Health

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

Prior to commencing any human participant 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 Research Ethics BC 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 persons in care
- Involvement of Interior Health employees, medical staff, 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 Operational Approval Certificate issued by the IH Research Department. This signifies that Operational Approval and any other necessary approval is in place. Operational Approval is mandatory for **every** research study. Other approvals may include: a Clinical Trial Agreement or other research contract, an Affiliation Agreement, or an 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.

* **11.1A.** Is the Principal Investigator in Box 1.1 formally affiliated with Interior Health (e.g. employee, medical staff, or written confirmation of affiliated researcher status?
☐Yes ☐No

11.1B. If YES, affiliated researcher, please attach a copy of the letter from Interior Health confirming the offer of affiliated researcher status.
Choose File

11.1C. 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.

Text box

11.2. At which Interior Health facilities or sites will the research be conducted? Click here for a facilities list.

Text box

11.3. Please describe site specific recruitment strategies for IH if it has not already been described in full in section 5.4.

Text box

Page E. Multi-Jurisdictional Studies

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

E. Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

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

Please check all that apply.

Title

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

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

☐Yes ☐No

Please check all that apply.

Title

☐University of Alberta
☐University of Saskatchewan

Page C. Creation of a Research Registry or Biorepository

Please note that Page C will only appear if Box 4.7A is marked as "Yes"

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?

Text box

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

Text box

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

Text box

C.4.A. Sources

What information source(s) are you accessing?

Text box

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

Text box

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.

Text box

C.5.A. Confidentiality

Are you collecting personally identifying information/will the biospecimens or data be linked to personally identifiable information?
☐Yes ☐No

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.

Text box

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.

Text box

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

Add

Name	Degree	Affiliation	Role on project	Email

There are no items to display

C.6.A. Consent

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

☐Yes ☐No

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. If participants will not have capacity to consent, please click blue ? icon for additional questions.

Text box

C.7. If you do not plan to obtain individual participant informed consent, please explain how the study meets all the criteria. CLICK on blue question mark. Please address each criterion individually. Include the corresponding letter (a, b, c, d, e, f) before each answer

Text box

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

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

☐Yes ☐No

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

Text box

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

Text box

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

Text box

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

Text box

* **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.

Text box

* **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

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.

Text box

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

☐Yes ☐No

* **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

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.

Text box

*** C.15.A. Data/ Biospecimen Retention**

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

Text box

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

Text box

*** 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

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

Text box

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

Text box

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.

Text box

C.18. Registration for Publication of Clinical Trials

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

☐Yes ☐No

C.18.B. If "Yes", click "Add" to enter the following information.

Add

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

There are no items to display

Page A. Retrospective Clinical Chart Reviews/ Secondary Analysis of Data (data only)

Please note that Page A will only appear depending on how Boxes 4.8 are answered.

A. Retrospective Clinical Chart Reviews/ Secondary Analysis of Data (data only)- 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

Text box

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

Text box

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.

Text box

A.4. Number of Records/Patient Charts

Text box

* 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

Text box

* A.6. Waiver of Consent

A.6.1. Researchers will be using identifiable information (names, MRN) to pull records and will have access to identifiable information: medical records. With this in mind, please answer:

Is the identifiable information essential to the research?
☐Yes ☐No

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

Text box

*** 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

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

Text box

* **A.6.3.** The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.
☐Yes ☐No

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

Text box

* **A.6.4.** The researchers will comply with any known preferences previously expressed by individuals about any use of their information.
☐Yes ☐No

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

Text box

* **A.6.5.** It is impossible or impracticable to seek consent from individuals to whom the information relates.
☐Yes ☐No

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

Text box

* **A.6.6.** The researchers have obtained any other necessary permissions for the use of the information for research purposes.
☐Yes ☐No

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

Text box

* **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.

Text box

* **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.

Text box

* **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 maintained, please explain.

Text box

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

b) Clarify ownership of storage device/computer/cabinet.

Text box

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

Text box

* **A.12.** Please describe:

A) What will happen to the data at the end of the study
B) How long the data will be retained
C) Where, when and how the data will be destroyed
D) what plans are there for future use of the data, including who will have access to the data in the future and for what purpose

Text box

*** A.13. Data Transfer**

Will data be transferred outside of the institution OR transferred to the institution?
☐Yes ☐No

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.

Text box

*** Data Linking**

A.14.A. Do you plan to link the data to any other data?
☐Yes ☐No

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.

Text box

A.15 Data collection/extraction form attached in box 9.8A?
☐Yes ☐No

If no, please clarify:

Text box

Page M. Analysis of Biospecimen

Please note that Page M will only appear depending on how Boxes 4.9A &4.9B are answered.

M. Analysis of Biospecimens - HUMAN ETHICS APPLICATION

*M.1. Summarize the research proposal using the following headings 1) Purpose 2) Hypothesis 3) Justification 4) Objectives 5) Specimen Analysis (tests performed-including any whole genome sequencing)

Text box

*M.2. Describe what permissions have been obtained or are required to access the biospecimens.

Text box

*M.3.A. Please describe what types of biospecimens will be used (types include: tissue site, normal or disease category, and preservation format).

Text box

*M.3.B Are biospecimens needed for clinical care, such as for standard of care diagnostic purposes? Yes/No

- Box 3.B.1 If yes, please confirm that research analysis of specimen will not interfere with any clinical or diagnostic purpose.
  Yes/No

*M.4. Please provide:
a) Number of individuals for which samples will be obtained
b) Total Volume of each specimen
(eg, 50 individuals - 20ml total blood and 10ml total CSF collected per individual)
c) If samples are from the Pathology Dept, list full date range of samples to be included (eg, Samples from Jan 1, 2000-Jan 1, 2020:

Text box

*M.5.A. Please clarify:
a) What data will be collected/ provided along with the samples?
b) How is this data obtained?
c) What analysis will be performed with the data provided?

Text box

*M.5.B. Do researchers plan to link the data obtained from the biospecimens to any other data (including personal health or research data of the individual)?
Yes / No

- 5.B.1. If yes, :
  a) Identify the data set;
  b) How the linkage will occur;
  c) Provide a list of data fields/items in the other database ;
  d) Identify what personal information will be used for the linkage and;
  e) How confidentiality regarding this shared information will be preserved.

Text box

M.**6. Consent**

*6.A. Was consent obtained from participants for the use of biospecimens? Yes/No.

M.6.B. If yes, please explain the consenting process and the relevant details of what the participants consented to. Attach template consent form in Box 9.9.

- Text box

Waiver of Consent- Biospecimens

Box M.6.A Indicates that consent was not obtained for the use of biospecimens. As institutional policy indicates that biospecimens shall not be considered anonymous (unless the BC REB determines otherwise) please complete the following waiver criteria.

*M.6.1. Explain why access to identifiable biospecimen is essential to the research

Text box

*M.6.2. Explain how the use of identifiable biospecimen without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the biospecimen relates

Text box

*M.6.3 Explain what measures will researchers will take to protect the privacy of individuals, and to safeguard the identifiable information

Text box

*M.6.4. Explain how researchers will comply with any known preferences previously expressed by individuals about any use of their biospecimens

Text box

*M.6.5 **Justify** how it is impossible or impracticable to seek consent from individuals to whom the biospecimen relates (***Please click** on blue question mark)

Text box

*M.6.6 Explain how researchers have obtained any other necessary permission for the use of biospecimen for **research purposes**.

Text box

*M.7. Will researchers who are listed in this application have access to personal identifiers? Yes/No

- *M.7.A Please indicate:
- a) What personally identifying information will researchers have access to when conducting the study?
- b) Who will have access to the identifiable data?
- c) If a masterlist (key linking names and study IDs) is kept, clarify when this will be deleted.

Text box

- *M.7.B Will personal identifiers be retained as a part of the dataset?
  a) If yes, list which personal identifiers will be included:
  b) Include a justification of why personal identifiers will be retained.

Text box

Waiver of consent -Data

Box M.6.A Indicates that consent was not obtained and researchers will have access to **identifiable information** (e.g., names or medical record) as indicated in box M.7. Please complete the following waiver:

- *M.7.1 Please explain why access and use of identifiable information is essential to the research:

Text box

- *M.7.2. Explain how the use of the identifiable information without the individuals' consent is unlikely to adversely affect the welfare of the individuals to whom the information relates

Text box

- *M.7.3. Explain how researchers will take appropriate measures to protect the privacy of individuals and safeguard the identifiable information.

  Text box

- *M.7.4. Explain how researchers will comply with any known preferences previously expressed by individuals about any use of their information.

  Text box

- *M.7.5. **Justify** why it is impossible or impracticable to seek consent from individuals to whom the information relates

  Text box

- *M.7.6 Explain how researchers have obtained any other necessary permissions for the use of the information for **research purposes**.

  Text box

*M.8. Does this study focus on analysis of biological material originating from Indigenous peoples?
es/No

M.8.1 Please note that additional provisos will be issued regarding research conducted on biological material originating from Indigenous peoples.

Text box

*M.**9.** 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 biospecimen labels **and** data collection forms.

Text box

*M.**10.** Please Explain:
a) Who will have access to the biospecimens, data/data derived from the biospecimens at each stage of processing and analysis?
b) Indicate whether a list of the names of current and past study team members and their delegated tasks will be maintained in the study file.
c) If a list will not be maintained, please explain.

Text box

*M.11. Please describe for the biospecimens:
a) What will happen to the biospecimens at the end of the study?
b) Where **and** how long the biospecimens will be stored/retained?
c) When **and** how the biospecimen will be destroyed?

Text box

*M.12. Future use of biospecimen

a) What plans are there for future use of the biospecimen?
b) Who will have access to the biospecimen in the future and for what purpose?
c) How and by whom will access be determined?

Text box

*M.13. Data Storage
a) Describe how participant data or data derived from the biospecimens will be stored (e.g., computerized files, hard copy).
b) Please provide the details on how any digital data will be stored
(e.g. an encrypted, password protected computer, storage device, or hospital network server)
c) Clarify if the storage device/computer/cabinet is a personally-owned or provided by an organization.

Text box

*M.14.A. Please describe for the participant data or data derived from the biospecimens:
a) What will happen to the data at the end of the study?
b) How long the study data will be retained?
c) How the data will be destroyed?

Text box

*M.14.B. Please clarify the researchers' plan for handling results and findings, including clinically relevant information and incidental findings:

Text box

*M.15. Future Use of data
a) What plans are there for future use of the data?
b) Who will have access to the data in the future and for what purpose?
c) How and by whom will access be determined?

Text box

*M.16. Will biospecimens or the related data be transferred out of the BC study site(s) OR received by the BC study site(s)? Yes /No

- M.16.1 If yes, please describe:
  a) The type of biospecimens/ data to be transferred
  b) Who the biospecimens/data will be transferred to
  c) Where the biospecimens/data will be transferred
  d) How the biospecimens /data will be sent and
  e) Confirm that only de-identified data or biospecimens will be transferred.

Text box

*M.17. 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

M.18. Clarify if the following documentation is needed for the research (select all that apply).
Please attach the following if applicable, to Box 9.9 as reference

☐Previous Consent form(s) used (when biospecimens were originally collected)

☐Certificate of Ethics approval(s) (obtained for initial biospecimen collection)

☐ Data collection forms: provided with the samples OR extracted from records (Attach to box 9.8A)

☐Material transfer agreement.

☐ Purchase agreement