Contents For RISe Clinical Ethics Application

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

1.4A. Additional Study Team Members - Online Access

Last Name	First Name	Institution/Department	Rank

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

1.5A. Additional Study Team Members - No Online Access

Add

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

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

1.6. Tri Council Policy Statement (TCPS) Tutorial

* Have all research personnel completed the required TCPS2 tutorial:

○Yes ○No ○N/A

* **1.7. Project Title**

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

* **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?

Grey Highlighted questions appear depending on previous answer(s).

Guidance notes, click on icon to jump to guidance note

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 2.3A or 2.4A or 2.4B as appropriate)

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

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).

U.S. Funding

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

○Yes ○No

2.5.B. Please select the appropriate DHHS funding agency from the selection box.

DHHS Sponsor List

* **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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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).

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:

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

Comments:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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).

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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.

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:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Page 4.C. Clinical Study Review Type (Questions 4.7-4.11)
Please note that some of below questions for Page 4.C 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 Research Registry (Data) or Biobank**

Does this study involve the creation of a research registry (data) or biobank for future use in other research?
○Yes ○No

4.7.B. Is the purpose of this application exclusively to obtain approval for the creation of a research registry or biobank? [Note if the creation of the database/ registry or biobank 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)

4.8.C. Is this study exclusively a **retrospective** chart/records 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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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? See "biospecimens" definition, click blue.
○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

Survey Research

4.10. Survey Research- Is this a minimal risk study exclusively using a survey for data collection?

Artificial Intelligence/ Machine Learning

4.11. Does this study involve the development and/or application of Artificial Intelligence/Machine Learning algorithms?

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

5. SUMMARY OF STUDY AND RECRUITMENT - HUMAN ETHICS APPLICATION

*** 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. If applicable, include age criteria for participants.

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) how will prospective participants be identified;
b) by what means will recruitment be done (e.g., public posting, in-person, letter of initial contact, 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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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:

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:

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:

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

If yes, please provide details:

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:

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.

[Add Document]

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.

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.

*** 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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION

*** 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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

*** 6.9. Capacity to Consent**
Will participants have the capacity to give fully informed consent on their own behalf?

○Yes ○No ○Not Applicable

6.9.A. Provide details of the nature of the incapacity (e.g., young age, mental health or physical condition).

6.9.B. If a participant does not have the capacity to give fully informed consent, who will consent on their behalf?

6.9.C. If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate?
○Yes ○No

6.9.D. Please explain how assent will be sought. Please be sure to attach copies of the assent form to page 9.

6.9.1. If your research involves participants who may lack the capacity to consent, please specify:
a) Whether and how the capacity to consent will be assessed and documented.
b) The qualifications and role of the individual(s) responsible for making this assessment.
Ensure appropriate documentation (scripts, checklists) are attached to Page 9 (textbox)

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

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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:
-For Canadian sites, list institution names below.
-For international sites, list only country names 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

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

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.

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

7.3. Drug approvals

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

7.4. Marketed Drugs

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

7.5. Natural and Non-Prescription Health Products

7.6. Experimental Devices

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

7.7. PERs

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

7.8. Health Canada Regulatory Approvals

***7.8.A.** Is this study a clinical trial of a drug, device, or natural health product or uses positron-emitting radiopharmaceuticals requiring Health Canada regulatory approval
○Yes ○No

7.8.B. Please 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.

7.9. Details of Health Canada Regulatory Approvals

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

7.9 Health Canada Approval
Add

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

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

7.12. US Regulatory Requirements

***7.12.A.** Is there a requirement for this research to comply with United States regulations for research ethics? OR if this study is being funded by an NIH or DHHS grant, please mark "Yes"

○Yes ○No

7.12.B. 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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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.

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, biospecimen labels, photos, videos, scans etc.

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

8.4.B.2 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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **8.5. Data Access and Storage**

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

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

8.5.B.1. Confirm that the masterlist will be stored in a separate file from de-identified study data by checking "Yes". NOTE: This is best practice and is recommended by the REB. If you enter "No", please provide rationale
○Yes ○No

*8.5.B.1.1. Please clarify why the masterlist will not be stored separately from the de-identified data.

8.5.B.2. Confirm that the signed consent forms will be stored separately from the de-identified data by checking "Yes". NOTE: This is best practice and is recommended by the REB. If you enter "No", please provide rationale
○Yes ○No

*8.5.B.2.1. Please clarify why signed consent forms will not be stored separately from the de-identified data.

* **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?

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **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.

8.6.B.

If applicable, for each study component (eg, Main study, and Sub-studies):
a) Specify biospecimen(s) collected
b) describe what will happen to the study biospecimens at the end of the study;
c) how long the study biospecimens will be retained;
d) where, when and how the biospecimens will be destroyed
e) 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.
f) IF samples are transferred to another site, please respond to the above sub-question regarding transferred samples.

* **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 at any point during the study or in the future?

○Yes ○No

8.7.B.

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 & Country); and
d) how the data and/or biospecimens will be sent.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **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 at any point during the study or in the future?

○Yes ○No

8.8.B.

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 biobank) at any point during the study or in the future?

○Yes ○No

8.9.B.

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

9. DOCUMENTATION – HUMAN ETHICS APPLICATION

The Research Ethics Office cannot change document names or dates, and cannot remove or add documents.

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 entered in RISe match version dates listed in attached documents.**

Response to Proviso, Deferral, Changes
Revisions should be **tracked WITHIN** the document. 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. You may add a new document but you must indicate in your response letter 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)

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

Document Name	Version	Date	Document	Password (if applicable)

9.2. Consent Forms
Add

Document Name	Version	Date	Document	Password (if applicable)

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

9.3. Assent Forms

Add

Document Name	Version	Date	Document	Password (if applicable)

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)

9.5. Advertisement to Recruit Participants

Add

Document Name	Version	Date	Document	Password (if applicable)

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

Please attach each separately.

Add

Document Name	Version	Date	Document	Password (if applicable)

9.7. Letter of Initial Contact

Add

Document Name	Version	Date	Document	Password (if applicable)

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)

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.

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)

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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**.

***10.1** 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

10.3 Please add the name of the Sponsor, this text will appear on the Invoice:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Page C. Creation of a Research Registry or Biobank
Please note that Page C will only appear if Box 4.7A is marked as "Yes"

C. Creation of a Research Registry or Biobank

***C.0** Please select Application type:
○ Biobank (Biospecimen +Data) ○ Data registry

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

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

C.3. Over what period of time will data and/or biospecimens be collected?

C.3B Does this registry/ biobank focus on the analysis of biological material or data originating from Indigenous peoples, communities, or organizations?

○Yes ○No

C.3.B.1 Please note that additional provisos will be issued regarding research conducted on biological material and or data originating from Indigenous peoples or distinct communities.

C.4.A. Sources
Please name/list information source(s) are you accessing?

C.4.B. Provide specific details about the source(s), i.e., type of health records, location etc.
b) Please describe how permission to access this information, and to collect and use this information, will be obtained.
Note: A data collection form must be attached to Box 9.8.A.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

☐	Direct from live individuals (procedure conducted for research purposes) Select biospecimen source: If "Other" or multiple sources will be used, specify them here:
☐	Indirect from live individuals (procedure conducted for clinical purposes and leftover biospecimens collected for research) Select biospecimen source: If "Other" or multiple sources will be used, specify them here:
☐	Post mortem biospecimen 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, in-person, letter of initial contact 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.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.
b) Include a justification for its inclusion in the registry / biobank and/or retention of the link.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

C.5.C. Elaborate further how long data will remain identifiable / biospecimens will be linked (i.e., When, if ever, will it be de-identified?).
b) Justify why data / biospecimens need to remain identifiable, if this is the case.

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

Add

Name	Degree	Affiliation	Role on project	Email

C.6.A. Consent
Will participants consent to be included in the registry or biobank?
○Yes ○No

C.6.B. Specify who will explain the consent form and invite participants to be included in the registry / biobank. Include details of where consent will be obtained and under what circumstances (e.g., in-person, online consent, phone, etc). If participants will not have capacity to consent, please click blue ? icon for additional questions.

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

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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

* **C.10.** Where will the data/biospecimens be kept?

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

C.11.1. Confirm that the masterlist will be stored separately from de-identified study data by checking "Yes". NOTE: This is best practice and is recommended by the REB. If you enter "No", please provide rationale

○Yes ○No

*__C.11.1.1.__ Please clarify why the masterlist will not be stored separately from the de-identified data.

C.11.2. Confirm that the signed consent forms will be stored separately from the de-identified data by checking "Yes". NOTE: This is best practice and is recommended by the REB. If you enter "No", please provide rationale.

○Yes ○No

*__C.11.2.1.__ Please clarify why signed consent forms will not be stored separately from the de-identified data.

* **C.12.** Please 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 be sent outside of the institution?

○Yes ○No

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

C.13.A.1.

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

C.13.B. Will biospecimens be sent outside of the institution?
○Yes ○No

C.13.B.1.
Please
a) Explain why it is necessary to send the biospecimens outside of the institution;
b) indicate what biospecimens will be sent;
c) where the biospecimens will be sent (list institution & country);
d) who the biospecimens will be sent to;
e) how the biospecimens will be transferred; and
f) where the biospecimens will be stored.

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?
○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.

C.14.C. Please clarify if consent will be obtained for the linkage:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

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

C.16.C.1. Is your biobank / registered in the CTRNet Biobank Certification Program?

☐ Yes. If yes, please provide your registration record: _____

☐ No. If no, please go to https://biobanking.org/canreg to get information about the program.

C.16.C.2. This biobank 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.** How do you plan on updating registry/biobank participants with important information/updates such as types of research, governance, and operations?

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

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

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

A.1B. Does this research focus on data originating from Indigenous peoples, communities, or organizations?

○ Yes ○ No

A.1B.2 Please note that additional provisos will be issued regarding research conducted on data originating from Indigenous peoples or distinct communities.

* **A.2.**

a) Please list information source(s) and sites (if applicable)
b) Please name the data custodian (Health authority records should list the Health Authority)
c) Describe how permission to access the medical records/data and to collect and use these records/data will be obtained.

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

A.4. Number of Records/Patient Charts

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **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. 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 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

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

* **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 below.

Grey Highlighted questions appear depending on previous answer(s).

Guidance notes, click on icon to jump to guidance note

* **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 below.

* **A.6.5.** It is impossible or impracticable (due to a degree of hardship or onerousness that jeopardizes the conduct of the research) to seek consent from individuals to whom the information relates. Please fully justify.
○Yes ○No

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

* **A.6.6.** The researchers have obtained / will obtain 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 below.

* **A.7.** Describe the risks associated with the possible disclosure of the data. Include any foreseeable circumstances where disclosure of identifying data may be required by law.

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

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **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.

A.10.1. Confirm that the masterlist will be stored separately from de-identified study data by checking "Yes". NOTE: This is strongly recommended by the REB. If you enter "No", rationale will be required

○Yes ○No

*A.10.1.1. Please clarify why the masterlist will not be stored separately from the de-identified data.

* **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.** 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

* **A.13. Data Transfer**
Will data be transferred outside of the institution OR transferred to the institution?
○Yes ○No

A.13.B 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.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

* **Data Linking**

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

○Yes ○No

A.14.B. Please 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.

A.15 Data collection/extraction form attached in box 9.8A?

○Yes ○No

If no, please clarify:

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

For a tutorial on how to complete this form please see this video here

*__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)

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

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

*__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 amount 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:

*__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?

d) Describe what permissions have been obtained / are required to access the data.

Grey Highlighted questions appear depending on previous answer(s).

Guidance notes, click on icon to jump to guidance note

*M.5.B. Do researchers plan to link the biospecimen data to any other data (including personal health or research data of the individual)?

○Yes ○No

M.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.

M.6. Consent

*6.A. Was consent obtained from participants for the use of biospecimens and related data?

○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.

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 biospecimen is essential to the research

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

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

*M.6.5 **Justify** how it is impossible or impracticable (due to a degree of hardship or onerousness that jeopardizes the conduct of the research) to seek consent from individuals to whom the biospecimen relates

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

*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.

*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.

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:

*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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

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

*M.7.5. **Justify** why it is impossible or impracticable (due to a degree of hardship or onerousness that jeopardizes the conduct of the research) to seek consent from individuals to whom the information relates

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

*M.8. Does this study focus on analysis of biological material originating from Indigenous peoples or other distinct communities?

○Yes ○No

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

*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.

*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.

*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 biospecimens will be destroyed?

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

*__M.12.__ Future use of biospecimen
a) What plans are there for future use of the biospecimens?
b) Who will have access to the biospecimens in the future and for what purpose?
c) How and by whom will access be determined?

*__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.

*__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 will the study data be retained?
c) How will data be destroyed?

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

*__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?

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

*M.16.B Will biospecimens or the related data be **transferred out** of the BC study site?
○Yes ○No

M.16.B.1 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.

M.16. Will biospecimens or the related data be **received** by the BC study site(s)?
○Yes ○No

M.16.1 Data and/or biospecimens are **Received** by BC Site(s) : :
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.

*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/data were originally collected)
☐	Certificate of Ethics approval(s) (obtained for initial biospecimen/ data collection)
☐	Data collection forms: provided with the samples OR extracted from records (Attach to box 9.8A)
☐	Material/ Data transfer agreement.
☐	Purchase agreement

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

Vancouver CoastalHealth Research Institute

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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)

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

☐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.

* **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)

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

☐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.

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

BC CHILDREN'S AND WOMEN'S RESEARCH ETHICS BOARD – HUMAN RESEARCH ETHICS APPLICATION	BC Children's Hospital Provincial Health Services Authority	BC WOMEN'S HOSPITAL+ HEALTH CENTRE Provincial Health Services Authority

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.

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

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

11. Research SITE INFORMATION FOR FRASER HEALTH

Institutional Approval at Fraser Health

Research conducted within Fraser Health jurisdiction requires Fraser Health Institutional Approval, via a Letter of Authorization to Conduct Research (LOA). **No research procedures or activities may commence at Fraser Health until the LOA is issued.**

Institutional approval requires both ethical approval **and** operational approval. The operational approval process at Fraser Health requires a separate application on the ROMEO Research Portal, and may include privacy review, department agreements for providing research related services, research contracts, and investigator affiliation. The Principal Investigator and Primary Contact listed on RISe will receive an automated email with more information following the initial submission of the project on RISe.

When the LOA is issued, research procedures can begin at Fraser Health.
More information can be found on the Fraser Health website.

If you have questions or require assistance, contact the Fraser Health Department of Evaluation and Research Services Research (DERS) Operational Approvals Coordinator at research.approvals@fraserhealth.ca.

11.1 Principal Investigator & Study Team Criteria for Research Conducted Under Fraser Health Jurisdiction

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

11.1.A. Is the Principal Investigator in Section 1.1 a Fraser Health employee or a Fraser Health Privileged Physician?

○Yes ○No

If **Yes**, please skip the remaining questions.

If **No**, please continue:

11.1.B. Does the PI have an existing affiliation agreement with FH to grant them PI privileges at FH sites?

Research with an external PI (regardless of affiliation) must include a Fraser Health co-

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

investigator.

11.1.C. Name of Fraser Health co-investigator(s):

11.1.D. Will the Fraser Health co-investigator be the Principal Investigator for the Fraser Health sites? (Note: A site Principal Investigator is required for regulated clinical trials)
○Yes ○No

If **Yes**, the Fraser Health co-investigator is responsible for applying for the LOA on the ROMEO Research Portal

If **No**, the Principal Investigator listed in Section 1.1 is responsible for applying for the LOA on ROMEO Research Portal

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Research SITE INFORMATION FOR INTERIOR HEALTH – HUMAN ETHICS APPLICATION

Interior Health

Institutional Approval at Interior Health

Research conducted within Interior Health requires Institutional Approval. **No research procedures or activities may commence at Interior Health until an Institutional Certificate of Approval is issued.**

An Institutional Certificate of Approval is issued once both ethical approval **and** operational approval have been obtained.

The Principal Investigator and Primary Contact listed on RISe will receive an automated email with more information regarding Operational Approval within Interior Health following the initial submission of the project on RISe.

For further information about conducting research within Interior Health, please visit: Research | Interior Health

If you have questions or require assistance, please contact the Interior Health Research Department at research@interiorhealth.ca

11.1 Principal Investigator & Study Team Affiliation

11.1A. Is the Principal Investigator in Section 1.1 an Interior Health employee or an Interior Health Privileged Physician?
○Yes ○No

11.1.B Does this study include **co-investigators** who are Interior Health employees or Interior Health Privileged Physicians?
○Yes ○No

11.1.C Will the Interior Health co-investigator be the Principal Investigator for the Interior Health sites? (Note: A site Principal Investigator is required for regulated clinical trials)
○Yes ○No

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

. Research SITE INFORMATION FOR ISLAND HEALTH – HUMAN ETHICS APPLICATION

Institutional Approval at Island Health

Research conducted within Island Health requires Institutional Approval. **No research procedures or activities may commence at Island Health until an Institutional Certificate of Approval is issued.**

An Institutional Certificate of Approval is issued once both ethical approval **and** operational approval have been obtained.

The Principal Investigator and Primary Contact listed on RISe will receive an automated email with more information regarding Operational Approval within Island Health following the initial submission of the project on RISe.

For further information about conducting research within Island Health, please visit: Island Health Research Ethics and Approvals

If you have questions or require assistance, please contact the Island Health Research Department at researchoperations@islandhealth.ca or researchethics@islandhealth.ca

To complete Island Health's Operational Application please click this link: https://viha.researchservicesoffice.com/Romeo.Researcher/

11.1 Operational Application and Principal Investigator & Study Team Affiliation

11.1.A. I confirm that I have completed the Island Health Operational Application:
○Yes ○No

11.1.B. Does this study include **co-investigators** who are Island Health employees or Island Health Affiliated/Privileged Physician?
○Yes ○No

11.1.C. Will the Island Health co-investigator be the Principal Investigator for the Island Health sites? (Note: A site Principal Investigator is required for regulated clinical trials)
○Yes ○No

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Institutional Approval at Northern Health

Research conducted within Northern Health requires Institutional Approval. **No research procedures or activities may commence at Northern Health until an Institutional Certificate of Approval is issued.**

An Institutional Certificate of Approval is issued once both ethical approval **and** operational approval have been obtained.

The Principal Investigator and Primary Contact listed on RISe will receive an automated email with more information regarding Operational Approval within Northern Health following the initial submission of the project on RISe.

For further information about conducting research within Northern Health, please visit: Research | Northern Health.

If you have questions or require assistance, please contact Northern Health Research Engagement Team at research@northernhealth.ca.

11.1 Principal Investigator & Study Team Affiliation

11.1.A Is the Principal Investigator (PI) in Section 1.1 a Northern Health employee?
○Yes ○No

11.1.B Does the Principal Investigator in Section 1.1 have an affiliation agreement with Northern Health to grant them PI privileges at Northern Health sites?
○Yes ○No

11.1.C Does this study include co-investigators who are Northern Health employees?
○Yes ○No

It is strongly recommended that research studies with an external PI include a Northern Health co-investigator on Page 1.

11.1.D Will the Northern Health co-investigator be the Principal Investigator for the Northern Health sites? (Note: A site Principal Investigator is required for regulated clinical trials)
○Yes ○No

11.1.E For all studies: Has the Northern Health co-investigator completed TCPS training?
○Yes ○No

Completing TCPS training prior to submitting an application for review is mandatory.
If you have questions about how to access this training, please email research@northernhealth.ca

11.1.F For clinical trials: Has the Northern Health co-investigator completed the Good Clinical Practices (GCP) training?
○Yes ○No
If yes, please email the certificate to research@northernhealth.ca

11.1.G Is the study being conducted by a private clinic located in northern BC?
○Yes ○No

11.1.H Is the study being conducted in a northern BC community?
○Yes ○No

Contents for Guidance Notes for Clinical Application

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Guidance Notes in Application

Box	Guidance note
	Page 1 Principal Investigator & Team
1.1	Please select the Principal Investigator (PI) for the study. Once you hit "Select", you can enter the PI's name, or enter the first few letters of his or her name and hit "Go". You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading. The PI bears the overall responsibility for the conduct of the study and is required to act within the guidelines of the TCPS2. UBC affiliated Pis must have a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Assistant Professor, Associate Professor, Professor or BCCA Investigator) OR is deemed a PI by an affiliated institution or by a Dean. Non-UBC affiliated Pis will be present here, if allowed by your institution, e.g. harmonized applications being processed through Research Ethics BC (REBC). If you cannot find the PI's name in the list, have it added into the RISe system by emailing the following information to RISe Support: Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher number via email.
1.2	Provide the name of ONE primary contact person in addition to the PI who will receive ALL correspondence, certificates of approval and notifications from the REB for this study. This primary contact will have online access to read, amend, and track the application. Selecting a primary contact is optional. If a primary contact is not selected, the PI will be the only person to receive all correspondence from the Research Ethics Board Administration (REBA). Graduate students preparing ethics applications for their dissertation projects should list themselves as the primary contact. The Primary Contact may also be listed in one of the application boxes below. Note that the PI may change the Primary Contact anytime without an amendment.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance note
1.3	List all the Co-Investigators of the study. These members WILL have online access which will allow them to read, amend and track the application. These members will be listed on the certificate of approval (except BC Cancer Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section. Please make sure you have added yourself as either the Principal Investigator, primary contact, co-investigator, or a study team member with online access in order to continue with the application. **If you cannot find your name or any of your study team members' names** in the list, have them added or inform them to add themselves by emailing the following information to RISe Support(risesupport@ors.ubc.ca): Full Name (Including Middle Initial), Department (or affiliation with the University), UBC Rank, Email Address, Phone Number and UBC employee number (if applicable). Once an account is created, new users will receive their researcher numbers via email. If you are applying to the BC Cancer, co-investigators will not be listed on the certificates of approval; however, all participating BC Cancer centre PIs will be listed. You will be asked to enter the BC Cancer centre PI's names in View 11. For further information click here for the **BC Cancer Research Ethics Board policy**.
1.4	List the additional study team members who WILL have online access to read, amend, and track the application but WILL NOT be listed on the certificate of approval. Examples of additional study team members who you may wish to have online access to the application include Clinical Trial Coordinators and Research Assistants.
1.5	The study team members listed in this section do not have online access to RISe. Please print off the application and ensure that each member listed in this section has read and understood the objectives and procedures of this study.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance note
1.6	All research personnel who are associated with a research project are required to complete the TCPS2 online tutorial (CORE) and enter their date of completion in their RISe profile before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, medical residents, research assistants, research coordinators and faculty, whether they are the Principal Investigator or not. The TCPS CORE Tutorial is free and can be completed in about four hours. CORE Certificates do not need to be attached. Copies should be retained and available on request. Click here for the **TCPS 2 Document**. Click here for the **TCPS 2 'CORE' Tutorial**. This tutorial provides an essential orientation to Canadian human research ethics guidelines. CORE-2022 is now available, please contact the REB for your institution to inquire about CORE-2022, as completion requirements may differ.
1.7	The title given in the application form must correspond to the title on all study documents, including the consent form.
1.8	The nickname will not be printed on the certificate. It will be used throughout the online application and review process to serve as a quick reference to identify the project.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

	Page 2 Study Dates & Funding Information
2.1A	In multi-phase projects, include the period that involves research with human participants.
2.1B	Note that the study closure date does not activate an ethics application closure. All ethics applications need to be closed by the PI at the appropriate time by submitting a Post Approval Activity (PAA) for a Completion. At the time of closure, the data retention and destruction plans may need to be updated if available data storage methods or locations have become outdated. In multi-phase projects, include the period that involves research with human participants. You will need to close your application in RISe once all research activity has concluded by submitting a PAA Request for Completion of Research. Note that the closure steps require you to include details about storage of data as laid out in Box 8.5.
2.2A	"Source of Funds" refers to the funder, sponsor, grantor, or agency (government, industry, and non-profit) that is providing the funds needed to undertake the project. Note that you should not indicate that your study is "For Profit" if a sponsor is only collaborating and not funding the study, e.g., they are providing the study drug or laboratory space only.
2.3A	Question 2.3 lists the research funding applications/awards that have been submitted to the UBC Office of Research Services and entered into our database. Identifying the associated research funding application/award will ensure that awarded research funds will be made available to you once this ethics application receives approval. Please ensure you select the correct application. Note that the first two digits of the application number indicate the year the application was submitted (e.g., Application #F08-00001 was submitted in 2008). Selecting "Add" will list the sources of all research funding applications that have been submitted by the PI (and the person completing this application if different from the PI). If the research funding application/award associated with this study is not listed below, please enter those details in question 2.4.
2.5A	Please see here for list of HHS agencies and offices
2.6	If you answer YES to this question (2.6), you will be asked to provide more detail on page 3 of the application.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

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

Box	Guidance Notes
	Page 3 Conflict of Interest
3.1	All investigators: Click here for TCPS 2, Chapter 7 – Conflicts of Interest UBC Investigators & Faculty: Click here for information on Policy SC3 (formerly Policy 97) Conflict of Interest and Conflict of Commitment. Reminder: receiving a recruitment or finder's fee for each participant enrolled is not permitted, and for physicians, is considered unethical practice by the Canadian Medical Association. Please click here or search for CMA Policy | "Guidelines for Physicians in Interactions with Industry".
3.2	Please refer to TCPS2, Article 7.4 for more information on Researchers & Conflicts of Interest.
3.3	The REB needs to be satisfied that conflicts of interest are appropriately managed. This can include disclosing the conflict of interest in the consent process. It also requires that any conflicts of interest be minimized to the extent possible. Some conflicts of interest will need to be managed further than disclosure, e.g. having someone arms length review the data to ensure objectivity, and/ or additional measures.
3.4	It is the individual investigators' responsibility to ensure they comply with all relevant and applicable COI policies. Researchers who are also UBC Faculty must renew their Conflict of Interest (COI) declaration annually and update it if things change. Information provided in this view will not be reflected in UBC COI declarations. Click here for information on UBC's Conflict of Interest policy.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
	Page 4A Study Type (Q4.1 to Q4.2C)
4.1	**Clinical** projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of clinical medical records, and any invasive procedure. A clinical research project that also includes questionnaires or interviews should be submitted to a Clinical Research Ethics Board. **Behavioural** projects are those that are behavioural or social scientific in nature or involve humanities research. They may involve the study of patients or healthcare providers; however, they are not clinical and do not involve invasive procedures. They do include research involving interviews, observations, and the administration of questionnaires or tests.
4.2A	Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited. This Box only has UBC and UBC affliated sites (VCH, PHC, BC Cancer, CW). For REBC sites, please add in box 4.2B. Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology). Include the PI's and Co-I's home institution as a site, even if data collection/recruitment is not happening there. Please click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval: B for BC Cancer B for BC Centre for Disease Control B for BC Children's Hospital; BC Women's Hospital P for Providence Health Care V for Vancouver Coastal Health (VCHRI/VCHA) U for University of British Columbia
	Back to Page 4A

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

4.2B	Pre-populated content is generated from PI and Co-I's profiles. This content is only pre-populated once and can be edited. Only BC sites that are a part of the REBC (https://researchethicsbc.ca/) are listed in this box. For UBC/UBC affiliated sites, please add in Box 4.2A. Enter the locations for the institutions and sites where the research will be carried out under this Research Ethics Board approval (including specimens processed by pathology, special radiological procedures, specimens obtained in the operating room, or tissue requested from pathology). *If study site(s) cannot be found, please select "Other" which is available for each Health Authority (eg, Interior Health – Other) then add site name & address to box 4.2C. If you are adding more than 5 sites in a particular Health Authority, please contact that ethics board before proceeding. Ensure that the primary affiliations of all study team members are represented here. Please click "Add" and enter the appropriate letter to see the locations for the institutions and sites where the research will be carried out : F for Fraser Health I for Interior Health and Island Health N for Northern Health S for Simon Fraser University U for University of Northern British Columbia and University of Victoria **Institutional Approvals:** Research at hospitals and in Health Authorities cannot commence until you receive local site / resource approval from the hospital(s) selected. Issuing of the certificate of ethical approval may be delayed until site approval from the hospital(s) has been obtained.
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Box	Guidance Notes
	Page 4B Clinical Study Review Type(Q4.2D-Q4.6)
4.2D	Sites Listed are populated based on Boxes 4.2.A & 4.2B. In order to remove/add site(s) please update boxes 4.2A & 4.2B on the previous page.
4.3B	Indicate whether the study is an extension or a sub-study of a primary study or if the study is utilizing samples or data collected under a previous study. A sub-study is a concurrent study on a sub-sample/population of the original study sample/population. The REB reserves the right to require that a sub-study or extension study be submitted as a new application.
4.3C	If the study is a clinical trial, Health Canada must be notified of the rejection/disapproval of the study.
4.3D	Definition of Biological Material: Genetically modified organisms that may be hazardous to humans or the environment, biological products, microorganisms, human/animal tissues, cells, blood and bodily fluids. The term 'infectious' includes biological toxins, viruses, bacteria, fungi, parasites and other organisms/genetic systems that, by virtue of their replicative properties, are potentially harmful to humans, animals and the environment. To verify if a biosafety permit is required or for more information, please contact the Research Safety Manager of your institution's Risk Management Services.
4.4	Click here for information on minimal risk.
4.5A	Article 2.7 of the TCPS 2 stipulates that the REB must review the ethical implications of the methods and design of a research project. Peer review is required by all Research Ethics BC-affiliated REBs for research projects that pose more than minimal risk to participants. Enter peer review information in this box and attach any relevant documentation to box 9.8 of the RISe application. If your study is not minimal risk, DO NOT leave this box blank or state "not applicable." Your application will be sent back to you if appropriate information is not provided. If a peer review has not been conducted, the Scientific / Peer Review document can be used as a template. If your protocol has not received External or Internal peer review, please provide a scientific review [i.e. from a recognized independent authority in your field OR from your trainee's supervisory committee] using the Peer – Scientific Review Template here.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
	Page 4C Clinical Study Review Type (Q4.7, 4.8, 4.9)
4.7A	This does **NOT** apply to: i) a database that will be created for the sole purpose of routine data analysis of a project. ii) instances where the industry sponsor will be the custodian of data or biospecimen for future research. iii) secondary use of existing data or biospecimen which have already been collected clinically or under a previous research project that you plan to re-analyze for a different purpose. This applies to situations where the registry/biobank team is creating a registry of data or biobank that is specifically intended to be accessed by the researcher and/or other researchers for future use over an extended period of time. **Definitions:** **Registries** are repositories that collect and store information about humans specifically for use in subsequent research. The information may or may not include personally identifying information, clinical files, clinical test results, x-rays, MRIs, information about race, age, or place of origin, etc., that is collected retrospectively or prospectively. **Biobanks** (also known as biorepositories) An organized collection of searchable human biological materials stored for one or more specific or future unspecified research purposes. It may also include associated information about individuals from whom biological materials were collected. Registries and biobank can be of any size. Please note that once your application has been approved, then this box cannot be revised via an amendment.
4.8A	Please note that once your application has been approved, then this box cannot be revised via an amendment.
4.8B	Applications that are retrospective chart or database records reviews are applications that are seeking to access data that is currently/already in existence. In order to qualify as a retrospective chart review, no information or records that are dated subsequent to the date of the initial ethics approval can be requested. If you are conducting a prospective chart review, you must answer “no” to this question and complete the full application.
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Box	Guidance Notes
4.8C	**Retrospective data:** Data collected from charts/records dated on or before the date of initial ethics approval. **Prospective data:** Data collected on an ongoing basis (i.e. chart information is taken from patients who are seen after the date of ethics approval). If the study involves any other component such as biospecimen collection, or prospective data/biospecimen collection, or direct contact with participants, mark "No" to this question.
4.8D	Mark "Yes" if researchers will have access to personal identifiers. If researchers will be the ones that pull records/charts, or review records in the Electronic Medical Records (EMR) system then please mark "Yes". Mark "No" if researchers will be provided with de-identified data Only (i.e personal identifiers are remove from the dataset provided by another party such as Popdata) Personally identifiable information is information that could reasonably be expected to identify an individual, alone or in combination with other available information. Directly identifying information is information that identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number) Indirectly identifying information is information that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
4.8E	If a retrospective chart review is retaining personal identifiers, participant consent may be required. Similarly, if a retrospective chart review is being conducted on a small set of charts, looking at a rare disease, consent may be required as there is potential for participants to be identified. Please note that once your application has been approved, then this box cannot be revised via an amendment.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
4.9A	Biospecimens- human biological materials which include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials. Examples of studies that can use this truncated form: • Research on pre-existing biospecimens (for e.g., samples from the hospital Pathology Dept) • Research using biospecimens obtained from a dedicated biobank. • Research conducting new analyses on biospecimens collected in a different research study. • Cadaveric studies • Stem cell research “Previously collected biospecimen” is in regards to retrospective biospecimen: Biospecimen collected before the date of initial ethics approval. Please note that once your application has been approved, then this box cannot be revised via an amendment.
4.9B	Prospective study wherein BC researchers are only involved in sample analysis. For e.g., A study is enrolling in Montreal and Paris only. Biospecimens are transferred to BC researchers for analysis. No enrollment in BC. This study would answer “Yes” to this question. Please note that once your application has been approved, then this box cannot be revised via an amendment. Prospective: Biospecimen and data collected on an ongoing basis (i.e. collected after the date of ethics approval).
4.11	**Attach Complete AI/ML checklist to section 9.8 of the application** For BC Cancer, please see Checklist found here For the UBC - Children’s and Women’s REB, please review the AI Application Checklist found here (under Guidance Notes) For UBC Clinical Research Ethics Board, please find checklist here
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
	Page 5. Summary of Study and Recruitment
5.1B	5.1.B: Summarize the research proposal using the following headings: **Purpose:** Include the following where applicable: - Name of the investigational drug(s) used in this study - Name of any marketed drug(s) used outside of its approved indication - Name and description of any positron-emitting radiopharmaceuticals to be used - Name and description of any new investigational device(s) to be used - Name and description of any marketed device to be used in an experimental mode. **Justification:** Include the rationale for the study and the following when applicable: - A description of the standard treatment - A description of alternative treatments (other than standard treatments) - Justification of the use of placebo, if applicable. Research Design: Enter a brief description (e.g. “This is a cross-over design involving 3 study visits”). Detailed study procedures should be listed in Box 5.7. **Statistical analysis:** - A summary of the primary and secondary end-points - Statistical analysis planned - Planned sample size If this study involves more than one participant group please clearly state how many participants will be in each group (for e.g., 30 patients and 15 physicians). A copy of the research protocol/proposal must be attached to Box 9.1.A. Please ensure to include the reference list in the Protocol document.
5.2	Please enter the inclusion criteria as an itemized list and justify, if applicable. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research. Refer to TCPS 2, Article 4.1 for information on appropriate inclusion.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
5.3	Describe which potential participants will be excluded from participation, list the criteria for their exclusion, and justify the grounds for their exclusion. As TCPS 2, Chapter 4 cautions against research that excludes particular populations, it is important to ensure that a justification is provided if participants are excluded on the basis of such attributes as culture, language, religion, race, mental or physical disability, sexual orientation, ethnicity, gender, age, or being HIV positive. Please enter the exclusion criteria as an itemized list.
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5.4A	Privacy legislation in BC states that organizations cannot provide contact information for clients without their consent, unless permission is obtained from the Provincial Privacy Commissioner or through other approved Health Authority channels. Click here for information on recruitment. Please ensure the same sites are listed on page 4 of the application. If you intend to use REACH BC as a recruitment tool, please attach recruitment posting and scripts to box 9.5. Templates available from REACH BC.
5.4B	**Control participants** are defined by the U.S. Office of Human Research Protections as "Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled." Attach copies of initial letters of contact and any other recruitment documents to view 9. If this proposal does not involve a control group, enter "N/A". See TCPS 2 Article 11.3 Justification for Control Groups. **Normal participant** refers to a randomly chosen member of the general population. Any individuals chosen for enrollment in a study based on specific baseline characteristics are, by definition, not "normal" individuals for this purpose.
5.5	Click here for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities as well such as for eg, the Deaf community. See TCPS 2 Article 2.11 Research Involving Communities.

Box	Guidance Notes
5.6	Where the investigator is in a dual relationship – that is the researcher maintains the records (e.g. as a clinician, educator, etc.) and is proposing to undertake research on them, steps need to be taken to ensure participants' rights are not violated. Please ensure that the access and use of the charts or data from an existing registry or database is permitted under privacy law and that the organization or department with custody and control of the information is aware of this use and access and has either approved it or explain the status of that approval.
5.7	Research procedures may include: - interview or questionnaires; - tests and assessments; - type, quantity, and route of administration of drugs and radiation, operations; - use of medical devices that are prototypes or altered from those in clinical use; - specify what procedures in this project involve an experimental approach, in that there may be diagnostic procedures or treatment dictated by the protocol differing from those required for standard patient care.
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Box	Guidance Notes
	Page 6. Participant Information and Consent Process
6.1	How much time will a participant be asked to dedicate to the project beyond that needed for normal care? Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. Ensure that you indicate the number of visits that will be required and the amount of time necessary for each visit. Ensure that you also include this information in the consent form. The amount of time stated in the application must be consistent with ALL other study documents (e.g. recruitment letters or posters, protocol, and consent forms).
6.2	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. Ensure that you indicate the number of visits that will be required and the amount of time necessary for each visit. This must be consistent with the information noted in the consent form document. Please refer to Box 5.4B for a definition of a control group. If the proposal does not involve a control group, enter "N/A".

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
6.3	Include any information about discomfort or incapacity that the participants are likely to endure as a result of the study participation, along with the details of any known side effects which may result from the experimental treatment if applicable. Clinical risks should be listed as bullet points. Risks should be quantified using percentages where possible. Ensure this information matches what is listed in the protocol and consent form documents. Refer to TCPS 2 Chapter 2, Section B for more information about risks.
6.4	Specify the benefits to the participant. If there are no benefits, state this explicitly. If any specific therapeutic benefits cannot be assured, but may be hoped for by the participant, state explicitly that the participant may or may not benefit from participation in the study. Ensure this information matches what is listed in the consent form.
6.5B	As per TCPS 2 , Article 3.1, incentives offered to participants should not be so large or attractive as to encourage reckless disregard of risks. Click here for further information on reimbursements and incentives.
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6.6	Refer to TCPS 2 Article 3.2 for more information about the consent process. Click here for information on the consent process.
6.7A	Please see below for the different types of waivers. Along with links to the appropriate TCPS 2 articles. **For Retrospective (pre-existing) data collection** refer to Article 5.5A; click here Address criteria (a) to (f) individually. **For Retrospective (pre-existing) biospecimens** refer to Article 12.3A click here. Address criteria (a) to (f) individually. **For Prospective data collection**, please refer to Article 3.7A please click here. Address criteria (a) to I individually. If a researcher satisfies all of the applicable conditions the REB may approve the research without requiring consent from the individuals to whom the information relates.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
6.7B	**6.7.B:** Refer to TCPS2 Article 3.8 for further information on the following criteria. a. A serious threat to the prospective participant requires immediate intervention b. Either no standard efficacious care exists or the research offers a realistic possibility of direct benefit to the participant in comparison with standard of care c. Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant d. The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project e. Third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so, and f. No relevant prior directive by the participant is known to exist.
6.8	TCPS2 Article 3.2 states "For consent to be informed, prospective participants should have adequate time and opportunity to assimilate the information provided, pose any questions they may have and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed and the setting where the information is given."
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6.9	Refer to TCPS2 Chapter 3, Section C for more information on decision-making capacity. Click here for information on capacity.
6.9.1	6.9.1(b) If capacity to consent is determined by the clinical care team please indicate as such. If capacity to consent is determined by research staff indicate experience/training of the individuals.
6.10	TCPS 2 Article 3.3 states that consent encompasses a process that begins with the initial contact (e.g., recruitment) and carries through to the end of participants' involvement in the project. Throughout the process, researchers have an ongoing duty to provide participants and REBs with all information relevant to the participants' ongoing consent to participate in the research.
6.11	What provisions are planned for participants, or those consenting on a participant's behalf, to have special assistance, if needed, during the consent process (e.g. consent forms in Braille, or in languages other than English)? Attach copies of contact letters or consent forms that have been translated into other languages to page 9. For all documents which have been translated into other languages, a document verifying the translation must also be submitted.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
6.12	For more information on the expectation of researchers to provide study results to participants, refer to TCPS 2 Article 4.7 "Equitable Distribution of Research Benefits". You will need to scroll down to Article 4.7 once in the link.
6.13	Any prohibition or undue limitation on the publication or dissemination of findings from research is ethically unacceptable. Informing participants of the research results is as important as disseminating results to the research community. See TCPS 2 Article 4.8 Include the following information as applicable: a) Have relevant knowledge users (e.g., participants, patient or community groups, researchers, people embedded within healthcare or other systems that could affect change, etc.) been consulted regarding sharing results in a culturally appropriate, accessible, and meaningful way? See TCPS 2 Chapter 1, Ethics Framework b) Have you committed to developing a plan that includes sharing results in plain language? c) How will participants be informed about the study results, and how will they access them? See TCPS 2 Article 4.8. – for *items a, b, c* d) Will there be consultation with community representatives/patient partners/peer researchers before finalizing publications? See TCPS 2 Article 9.17 e) Are there any existing conflicts, barriers, limitations, or competing priorities that could impede the timely sharing of results. If so, how will these be mitigated? See TCPS 2 Article 6.24 and TCPS 2 Chapter 7, Conflicts of Interest BC Support Unit Plain Language Guide REBC Resources
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Grey Highlighted questions appear depending on previous answer(s).
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Box	Guidance Notes
	Page 7. Number of Participants and Study Drugs
7.1A	These questions will assist the REB to consider coordination of their review with the other study sites. If your study has multiple sites within BC and those sites are listed on page 4 of this application, they do not need to be repeated here. For example, if your study is being conducted at McGill University **as well as** UBC, McGill University should be listed here.
7.2.C	Controls are people acting in a control capacity (comparison group), including normal participants. See TCPS 2 Article 11.3 Justification for Control Groups
7.3	Click here for information on obtaining regulatory approval for use of drugs outside approved indication.
7.5	Enter all Natural and Non-Prescription Health Products used. Click here for information on Natural and Non-Prescription Health Products.
7.6	Click here for information on obtaining regulatory approval for experimental devices.
7.7	Click here for information on positron-emitting radiopharmaceuticals (PERs).
7.8A	The sponsor is an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. For unfunded/investigator-initiated studies, the sponsor could be the principal/qualified investigator. The sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada. Refer to Section 5 of the GCP Guidelines by clicking here for a full description of the duties and responsibilities of the sponsor. Click here for information on regulatory approvals and registration.
7.9	If regulatory approval from a Health Canada directorate is required for this study, your certificate of ethical approval will not be released until the regulatory approval certificate, approval date and control number are received by REB administration. Click “Add” to enter the name of the regulatory agency, the date of the application (if pending) or the date of the approval, and the control number and the date of approval, for either the initial application or subsequent amendments. Applications to the Research Ethics Board (REB) and Health Canada may be concurrent, however, NO REBC Affiliated REB will issue a “Certificate of Approval” until the Health Canada Regulatory Approval is received.

Box	Guidance Notes
7.10	Click here for information on human pluripotent stem cell research. Certain types of research involving the use of human pluripotent stem cells conducted under the auspices of institutions receiving Tri-Council funding are required to apply to the CIHR SCOC for approval.
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7.11	Refer to TCPS 2 Chapter 11, D. Registration of Clinical Trials If there is any possibility of the intent to publish results of the study it must be registered BEFORE the study is started (but not necessarily before ethical approval is granted). The International Committee of Medical Journal Editors (ICMJE) requires registration for all clinical trials. The ICMJE accepts registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP) or in ClinicalTrials.gov, which is a data provider to the WHO ICTRP. The ICMJE defines a clinical trial as "any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. **There is a requirement for researchers to submit study results for registered Clinical Trials.** Please ensure you submit your study results to the Authorized Registry upon study completion. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration. For more information concerning registration requirements, click here.
7.12A	**7.12.A:** Mark "yes" if this study is: a) conducted or funded by the US Department of Health and Human Services (DHHS) (see link below), or b) is required to comply with either the U.S. FDA or any other U.S. regulations. The PI is responsible for ensuring that the study complies with the applicable U.S. regulations. Click here for a listing of the DHHS operating and staff divisions.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
7.12B	7.12.B: The Office of Research Ethics is responsible for reporting Unanticipated Problems to the DHHS Office For Human Research Protections (OHRP) or the U.S. FDA. In the latter case, the IND or IDE number must be referenced in the report(s). If a U.S. FDA IND or IDE number is applicable, the Ethical Certificate of Approval will not be released until a valid number is entered in Box 7.12B and if available, appropriate documentation is attached to Box 9.1.C.
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Box	Guidance Notes
	Page 8. Data Monitoring and Storage
8.1	Click here for information on unblinding in the event of an emergency.
8.2	For clinical trials, the researcher is responsible for providing the REB with an acceptable plan for monitoring the safety of participants, including a plan for the tabulation, analysis and reporting of safety data, and the sharing of other new information in a form that permits REBs to interpret and respond appropriately (TCPS 2, Chapter 11 C. Safety Monitoring and Reporting New information).
8.3	See TCPS 2 Chapter 11 A. Key concepts “stopping rules”
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Box	Guidance Notes
8.4A	REBs require the use of a unique study code. Information is considered de-identified if the following conditions are met: 1. the unique study code is not derived from or related to the information about the individual (i.e., name, SIN, PHN, hospital number, DOB, address, or unique characteristic); 2. the unique study code could not be translated to identify the individual, and; 3. the investigator or their institution could not use OR disclose the unique study code for other purposes OR disclose the mechanism for re-identification. Refer to TCPS 2 , Article 5.3 for more information on safeguarding participant information. Please note specific institutional privacy considerations will be addressed on page 11. While it may be necessary to collect participant personal identifiers (e.g., names, MRN) for linkage to administrative databases, it is highly unusual to have both participant names and study ID on forms. Personal identifiers with the corresponding study ID numbers should be stored on a separate linking document
8.4.B.2	"Personally identifying information is any information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g. name, SIN, PHN, date of birth, address, or unique personal characteristic etc. IF personal identifiers will be retained as a part of the dataset, please provide justification in Box 8.4.B.2"
8.5A	Study documents must be kept in a secure locked location/filing cabinet. Computer files should be password protected and encrypted, and data should not be stored or downloaded onto an unsecured computer or a portable laptop.
8.5.B.1	Masterlist - key that links the study ID to the identifiers.
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Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
8.6A	Please include the following information: Final disposition/storage of all research-related study documents. According to UBC Policy SC6 (formerly Policy 85), study data should be kept for a minimum of 5 years after publication. Effective February 11, 2022 Clinical trials data must abide by Health Canada's regulations regarding data retention and generally must be kept for 15 years. Final disposition of any electronic data. The procedure that will be followed in response to additional requests for access to the study data (after the study has been completed and analyzed). Note: The REB requires at a minimum an annual report for multi-year projects, and an end-of-study report for all studies at study completion. A completion of study notice must be submitted via RISe.
8.6B	Please complete Box 8.6B if your study involves the handling of biospecimens (e.g. blood samples)
8.7A	If information will be sent outside of the local site, please indicate the type of information to be transferred and in what form it will be in when transferred. TCPS 2, Chapter 5, identifies 5 different categories of data collected from research participants, each with different implications for the privacy of participants. When sending data off site, the data should be coded. Justification for sending directly identifying information or indirectly identifying information off site must be provided and approved by the REB before data is transferred. • **Directly identifying information** - the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number). • **Indirectly identifying information** - the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic). • **Coded information** - direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the Principal Investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary). • **Anonymized information** - the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low. **Anonymous information** - the information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low.
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Box	Guidance Notes
	Page 9. Documentation
9.1A	**Clinical Applications:** • Clinical trial protocol • Clinical research proposal • Amendments to full protocols • History or Summary of Changes to Amendments Please ensure to include the reference list.
9.2	Attach all consent forms for the research, including the following: • Participant consent form • Normal/Control participant consent form • Tissue blood banking consent form • Substitute decision maker consent form • Other consent forms Click here for the BC Common Clinical Informed Consent Form Template. Refer to the appropriate REBs' website for other consent form templates, e.g. optional, tissue banking etc. (Click on name for link: BC Cancer Research Ethics Board, Children's and Women's Research Ethics Board, and Providence Health Care Research Ethics Board.) For BC Cancer Studies, please see website for template here
9.3	Attach all assent forms for the research, including the following: • Participant assent form • Normal/Control participant assent form • Tissue blood banking assent form • Other assent forms

Box	Guidance Notes
9.5	This includes any type of communication (e.g. flyer, email recruitment message, Internet posting, radio/television script, poster, newspaper ad) that is directed to potential participants for the purpose of recruitment. The purpose of this documentation is to ensure that the recruitment measures are appropriate and do not cause undue influence on potential participants. Click here for **UBC C&W Research Ethics Board** policies regarding participant handouts and advertisements.
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9.6	All questionnaires, surveys, tests, interview scripts etc. must be attached as a separate document to this box even if they are included in the protocol or research proposal.
9.7	The letter of initial contact should contain a brief overview of the study and include the following: • Why the participant is being contacted and invited to participate • How the participant's contact information was obtained • If a follow-up phone call will happen, when it will happen, by who, and how the participant can opt-out of being contacted The PI's name and study title should be referenced on the letter. If you are doing research in Vancouver Costal Health, ensure to use the following template for initial contact see here .
9.8A	Examples of other types of documents: • Peer review report • Clinical Trial Agreement • Other institutional ethics approvals and associated documents not attached above • CIHR Stem Cell oversight approval letter • Transcript of Audio Visual item • Data transfer agreement • Website content • Data collection sheet If applicable, please attach a transcript (the document must include a version date) of any video or audio file. **For UBC Clinical REBs only:** If this is an application using the streamlined process as indicated in Box 4.6, please append ALL relevant documentation from the other approving REB, including the application form, all correspondence from and to the approving REB (including changes requested), the protocol approved, the certificate of approval, the other REB approved informed consents, etc.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
9.9	REBs at times, request reference documents during the review process to inform their decisions. These documents however, are not being approved by the BC REB. Such as: • Consent forms from non-BC sites • Certificate of Ethics approval-from non BC sites • Material transfer agreement. • Purchase agreement *Documents attached in this box will NOT be listed in the BC Certificate of ethics approval.
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CREB Box 10.1	For a video tutorial on the invoice feature in RISe please see here. 10.3 Sponsor name must be entered if the selected method of payment is not N/A.
10.3	Sponsor name must be entered, this will be included on the invoice issued by the REB

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

Box	Guidance Notes
	Page C. Creation of a Registry or biobank
C.0	Select "Biobank" if you will be collecting and storing biospecimens and data. Select "Data registry" if you will be collecting and storing data only, this may include imaging (MRI, X-Ray) and medical chart/record data. Some institutions may request that a Privacy Impact Assessment (PIA) be completed when creating a research database or registry. Consult your hospital or institutional privacy office for more information.
C.1	Scope and purpose– what kind of research will be supported, types of biospecimen/data that will be collected, services offered, design of the biobank/registry, target enrollment.
C.3	Include a clear date range of the collection period. If collection will be indefinite, clearly indicate that data and/ or biospecimen will be collected indefinitely or until the participant withdraws, if applicable.
C.3.B	Click here for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities as well such as for eg, the Deaf community. Please see Article 9.19 to 9.22 regarding Collection of Human biological materials involving First Nations, Inuit and/or Métis People

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
C.4.C	Biospecimens - human biological materials which include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.
C.5.A	**Personally identifying information** is any information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g. name, SIN, PHN, date of birth, address, or unique personal characteristic etc.
C.5.B	For databases or registries, a data collection form should be attached to Box 9.8.A.
C.5.C	**Anonymized data** are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low to very low.
C.5.D	Include the name, degree, affiliation, role on the project, and email address of **ALL** individuals who have access to personally identifying information.
C.6A	Attach a copy of the consent form to Box 9.2.
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C.6B	If participant will not have capacity to consent, please include the following information: A. Provide details of the nature of the incapacity (for instance, young age, mental or physical condition). B. How capacity to consent will be evaluated. Please see here C. Who will consent on their behalf? D. Will they be able to give assent to participate? E. If yes, explain how assent will be sought.
C.7	Please see below for the different types of waivers. Along with links to the appropriate TCPS 2 articles. Include the corresponding letter (A, B, C, D, E, etc.) before each answer. **For Retrospective (pre-existing) data collection** refer to Article 5.5A; click here Address criteria (a) to (f) individually. **For Retrospective (pre-existing) biospecimens** refer to Article 12.3A click here. Address criteria (a) to (f) individually. **For Prospective data collection**, please refer to Article 3.7A please click here. Address criteria (a) to (e) individually. If a researcher satisfies all of the applicable conditions the REB may approve the research without requiring consent from the individuals.

Grey Highlighted questions appear depending on previous answer(s).
Guidance notes, click on icon to jump to guidance note

Box	Guidance Notes
C.8	TCPS Article 3.1: If a participant withdraws consent, the participant can also request the withdrawal of their data or biospecimens *TCPS Article 12.2: The process for requesting withdrawal of Biospecimens shall be clearly explained, along with an explanation of the conditions under with researchers would NOT be able to remove a participant's data from the project (information already derived from the biospecimens and aggregated cannot be withdrawn, or anonymized data)
C.9	A **data/biobank custodian** is an entity or person who is responsible for overseeing the management and use of the data/biobank, including the main rules governing use of the database/ biobank, the process by which access requests will be reviewed, and the organization to whom the researcher is accountable for the proper management of the data/biospecimens.
C.10	Biospecimens/data will be stored in facilities overseen by the institution under the supervision of the <PI, department x and name of institution>.
C.11	Reference procedural measures, technical measures, and physical measures planned for the protection of data. If a coding procedure is being used, describe the procedure in detail in this box.
C.11.1	Masterlist - key that links the study ID to the identifiers.
C.13A	Note that if this changes in the future an amendment must be submitted before data are transferred.
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C.13.B	Note that if this changes in the future an amendment must be submitted before biospecimens are transferred.
C.13.C	Material/data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached to Box 9.9 after initial approval via an amendment
C.14.A	Note that if this changes in the future an amendment must be submitted before data/ biospecimens are linked.
C.16.B	Reference who will have access to the database in the future and under what circumstances, what will happen if an individual data custodian leaves the institution, where the ongoing database will be stored or maintained, and what security measures will be in place. UBC's REBs encourage researchers who are creating biobank to consider certification of their biobank with the 1. Canadian Tumour Repository Network (CTRNet) Biobank Certification Program 2. or accreditation with the College of American Pathologists (CAP) biobank Accreditation Program or 3. The international biobanking standard - ISO 20387:2018 - https://www.iso.org/standard/67888.html

Box	Guidance Notes
C.18	Researchers have an ongoing duty to provide participants and REBs with all information relevant to the participants' ongoing consent to participate in the research. The biobank/registry may choose to provide participants with access to information within a reasonable timeframe via a website or newsletter.
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Please note that Page A will only appear depending on how Boxes 4.8 are answered.

Box	Guidance Notes
	Page A. Retrospective Clinical Chart Reviews
A.1	Retrospective data: Data collected from charts/ records dated on or before the date of initial ethics approval. Prospective data: Data collected on an ongoing basis (i.e. chart information is taken from patients who are seen after the date of ethics approval).
A.1.B	Click here for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities as well such as for eg, the Deaf community.
A.2	"Please ensure that the access and use of the charts/records or data from an existing registry or database is permitted under privacy law and that the organization or department with custody and control of the information is aware of this use and access and has either approved it or explain the status of that approval. Note that data, such as medical records, under the custody of health authorities require Institutional/Operational approval. Example: 1. a) STEMI database at DHCC, St. Paul's and Privately owned Clinic ABC. b) Custodians: VCH, PHC and Clinic ABC director"
A.3	Please attach a data collection/ data extraction form to Question 9.8A of the application for review.
A.4	Specify the minimum number of charts / records required to conduct the study.
A.5.1	Personally identifiable information is information that could reasonably be expected to identify an individual, alone or in combination with other available information. Directly identifying information is information that identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number) Indirectly identifying information is information that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
A.6.1	The TCPS2 Article 5.5 A mandates that the criteria in A.6.1. through to A.6.6. be satisfied in order for the REB to consider approval of the research without requiring the consent of the individuals to whom the information relates. The TCPS2 defines impracticable in this context as being put into practice due to a degree of "hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience."

Box	Guidance Notes
A.6.5	The TCPS2 defines impracticable in this context as being put into practice due to a degree of "hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience."
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A.8	**Unique Participant Study Code**: UBC REBs require the use of a unique study code not derived from or related to the information about the individual, i.e., name, initials, SIN, PHN, hospital number, DOB, or unique characteristic. See Guidance Note 8.4 for further directions on coding that is consistent with de-identification of data.
A.10	For example, study documents must be kept in a secure locked location/filing cabinet, computer files should be password protected and encrypted and data should not be stored or downloaded onto an unsecured computer or a portable laptop. For further information on encryption requirements and useful tools and resources on how to do this, please see here. Please note that personal devices should not be used to store research data.
A.10.1	Masterlist - key that links the study ID to the identifiers.
A.11	Reference procedural measures, technical measures, and physical measures planned for the protection of data. If a coding procedure is being used, describe the procedure in detail in this box.
A.12	Please include the following information: Final disposition/storage of all research-related study documents. According to UBC Policy SC6 (formerly Policy 85), study data should be kept for a minimum of 5 years after publication. Final disposition of any electronic data. The procedure that will be followed in response to additional requests for access to the study data (after the study has been completed and analyzed). **Note:** The REB requires at a minimum an annual report for multi-year projects and an end-of-study report for all studies at study completion. A completion of study notice must be submitted via RISe.
A.13	Note that if this changes in the future an amendment must be submitted before data is transferred. Data transfer agreements may be required by the institution receiving or sending data. Please verify with the institutions. Completed agreements can be attached to Box 9.9 after initial approval via an amendment.

Box	Guidance Notes
A.14A	Note that if this changes in the future an amendment must be submitted before data is linked.
A.15	Data collection/extraction form is almost always required. See example here
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Please note that Page M will only appear depending on how Boxes 4.9A &4.9B are answered.

Box	Guidance Notes
	Page M. Analysis of Biospecimen
M.1	Please summarize study details. This would be similar to a Journal Abstract. The Protocol attached to 9.1A would contain more details regarding the study.
M.2	Biospecimens under the custody of health authorities require Institutional/Operational approval. Contact the health authority for more details. Please ensure that the access and use of biospecimens is permitted under privacy law and that the organization or department with custody and control of the information is aware of this use and access and has either approved it or explain the status of that approval.
M.3A	Biospecimens can include: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, fecal matter and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.
M.3B	Leftover biospecimens should only be used for research if they are in excess of that required for any clinical diagnosis.
M.5A	Include participant, clinical and biospecimen data that will be provided along with the samples, for e.g., age, sex, disease type, date of specimen collection. Note that data, such as medical records, under the custody of health authorities require Institutional/Operational approval. Contact the health authority for more details.
M.6	If applicable, please ensure to include the study application number of the associated study or biobank in Boxes 4.3A and 4.3B Attach previously used consent form template to Box 9.9.
M6.A	As per UBC policy LR9 "Genetic material shall not be considered Anonymous unless a REB determines otherwise". As such, if consent was not obtained for the proposed research, waiver criteria must be meet. Note that this will be determined by the REB.
M6.1	Researcher must address all the waiver conditions listed in Boxes 6.1-6.6, for the REB to consider approving the research without requiring consent from the individuals from whom the biological materials were collected. Please see TCPS2 Article 12.3A
M6.5	Impracticable – Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it **does not** mean mere inconvenience. Please provide a justification as to why it is impracticable or impossible to consent.
M6.6	Biospecimens under the custody of health authorities require Institutional/Operational approval. Contact the health authority for more details.

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M.7	Mark "Yes" if listed researchers will be the ones that pull records/charts/ or review records to retrieve the biospecimens. Mark "No" if researchers will be provided with de-identified data Only (i.e. personal identifiers are removed from the dataset provided by another party) Personally identifying information is any information that may reasonably be expected to identify an individual, alone or in combination with other available information, e.g. name, SIN, PHN, date of birth, address, pathology accession number, or unique personal characteristic etc.
M7.1	Consent was not obtained for the use of identifiable information. Researchers must address all the waiver conditions listed in Boxes 7.1-7.6, for the REB to consider approving the research without requiring consent from the individuals from whom the information relates. Please see TCPS2 Article 5.5A
M7.5	Impracticable – Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research; it **does not** mean mere inconvenience. Please provide a justification as to why it is impracticable or impossible to consent.
M.8	Click here for TCPS 2 Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. While Chapter 9 is designed for Indigenous research, the guiding principles can also be applied for distinct communities as well such as for eg, the Deaf community. Secondary use of human biological materials identifiable as originating from a specific First Nations, Inuit or Métis community, or a segment of the Indigenous community at large, is addressed in TCPS2 Articles 9.20 to 9.22.
M.9	REBs require the use of a unique study code. Information is considered de-identified if the following conditions are met: 1. the unique study code is not derived from or related to the information about the individual (i.e., name, SIN, PHN, hospital number, DOB, address, or unique characteristic); 2. the unique study code could not be translated to identify the individual, and; 3. the investigator or their institution do not currently or in the future use OR disclose the unique study code for other purposes OR disclose the mechanism for re-identification. Refer to TCPS2, Article 5.3 for more information on safeguarding participant information.
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M.12	Please note that future use of biospecimens may require a separate ethics application. Please consult your REB regarding future use.
M.13	Study documents must be kept in a secure locked location/filing cabinet. Computer files should be password protected and encrypted, and data should not be stored or downloaded onto an unsecured computer or a portable device.
M.14A	Please include the following information: Final disposition/storage of all research-related study documents. According to UBC Policy SC6, study **data** should be kept for a minimum of 5 years after publication Final disposition of any electronic data. The procedure that will be followed in response to additional requests for access to the study data (after the study has been completed and analyzed).
M.14.B	Material incidental findings: Researchers should refer to the guidance in TCPS2 here, which addresses material incidental findings.
M.15	Please note that future use of data may require a separate ethics application. Please consult your REB regarding future use.
M.16	Please indicate the type of biospecimens/data to be transferred and in what form it will be in when transferred. Material Data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached to 9.9 after initial approval via an amendment. Note that if this changes in the future an amendment must be submitted before biospecimen/data are transferred.
M.16.B	Please indicate the type of biospecimens/data to be transferred and in what form it will be in when transferred. Material Data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached after initial approval via an amendment. Note that if this changes in the future an amendment must be submitted before biospecimen/data are transferred.
M.17	Click here for information on human pluripotent stem cell research. Certain types of research involving the use of human pluripotent stem cells conducted under the auspices of institutions receiving Tri-Council funding are required to apply to the CIHR SCOC for approval
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M.18	Please attach these documentations for the **previously collected** biospecimen/data. Note that in some instances when biospecimens/data were collected over a period of time, there may be more than one applicable document in each category. Consent form, if applicable, should be from when the biospecimens/data were originally collected. **Do not** create an example or potential new consent form. Data collection forms includes variables that are provided along the biospecimen, such as: sex, date of collection and disease type. A data collection form should also be attached if data will be extracted from medical records. Material/data transfer agreements may be required by the institution receiving or sending biospecimen/data. Please verify with the institutions. Completed agreements can be attached after initial approval via an amendment.
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Box	Guidance Notes
	Page 11. Vancouver Coastal Health Research Institute
11.1	If you have not yet received hospital approval to conduct this study an email will be sent to the PI listed in Box 1.1 and the primary contact listed in Box 1.2 on submission to the ethical review board listing the steps required to receive approval by the appropriate VCHA Health Service Delivery Area(s).
11.2A	In order for a research project to be undertaken at VCHA, either a VCHA employee or a member of the VCHA medical staff needs to be designated as the "Site Investigator at VCHA". This individual must have actual responsibility with respect to the project. If you have a faculty appointment at a post-secondary institution that has a research agreement with VCHA, but do not have an appointment at VCHA, you must either: Obtain a VCHRI Affiliated Investigator Appointment. This person will assume the role of “Site Investigator at VCHA”. To apply for VCHRI Affiliated Investigator Appointment, please contact the Associate Director, VCHRI at 604-875-4111 Ext 66687. Designate a VCHA person as the “Site Investigator at VCHA”. If a co-investigator on the study is a VCHA employee or is a member of VCHA medical staff, this person may assume the role of "Site Investigator at VCHA". If you choose this option, please ensure that the "Site Investigator at VCHA" is listed as a co-investigator on the UBC ethics certificate (you would still remain the Principal Investigator on the UBC Research Ethics Certificate of Approval).
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Box	Guidance Notes
	Page 11. BC Cancer
11.1	Additional participating centre PIs listed in this section WILL be listed on the certificate of approval and WILL have online access to read, edit, and track this application. (Only the PI named in View 1 can submit an application or amendment etc. to the REB). Click here for the BC Cancer policy on listing Principal Investigators and Co-investigators (see "BCC & non-BCC Researchers"). If a centre PI is on a leave of absence longer than 6 months they should be replaced with a new centre PI. If the PI on a leave wishes to have access while they are away so they can continue to monitor the study, they should be added to Box 1.3 as a co-investigator.
11.2	The Certificate of Approval will not be released until BC Cancer has received a copy of the signed contract, which should be attached in Box 9.8. All industry-related and "for-profit" sponsored studies require a Clinical Trials Agreement between the sponsor, BC Cancer and the Investigator.
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Box	Guidance Notes
	Page 11. Children's and Women's 
11.1	If you cannot find the PI's name in the list, have it added by clicking here. Include the name, department, rank (or affiliation with the University), email, UBC employee number (if applicable), and phone number of the PI. Once added to RISe, new user will receive their researcher number by email.
11.2	Completion of this form is not required by those affiliated with a UBC academic department. This form is intended for those in professional departments (e.g. Occupational Therapy, Social Work, Nursing).
11.3	Send the applicable forms listed in Box 11.3 to the Research Ethics Board Office at the Children's and Women's Health Centre. If you have any questions, please email the Children's and Women's Research Ethics Board office at cwreb@bcchr.ubc.ca.
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Box	Guidance Notes
	Page 11. Providence Health Care 
11.1	Once each hospital service or area has granted approval for use of services or facilities, please forward a copy to the Office of Research Ethics c/o Paula Piper (Ethics Review Coordinator). Note that each letter or email must include the title of the research, the name of the principal investigator, and the UBC PHC REB ethics file number.
11.2A	Please note that the Providence Health Care Certificate of Final Approval to commence the research will not be released until the Office of Research Services receives all relevant hospital services/areas approval letters, the contract (if applicable) has been finalized, and the ethics review fee (if applicable) has been paid.
11.3	Send the completed PHC declaration form to: Alex Trethewey Pre&Post Review Manager Office of Research Ethics Providence Health Care Research Institute mailto:alex.trethewey@ubc.ca (604) 682-2344 x68366 Ensure that the form includes the REB File number for the research
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