UBC Clinical Research Ethics Board – SAMPLE FORM

1. PRINCIPAL INVESTIGATOR & STUDY TEAM - HUMAN ETHICS APPLICATION	
* **1.1. Principal Investigator** *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.* *Enter Principal Investigator Primary Department and also the primary location of the PI's Institution:*	**GUIDANCE NOTES** A Principal Investigator (PI) either has 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. The PI bears the overall responsibility for the conduct of the study and is required to act within the guidelines of the TCPS2. Instructors who are applying for research ethics approval for class-based projects in courses they are teaching can be listed as a PI on their application. Please contact the REB manager if you are submitting a class project and require the capacity to list yourself as a PI on the application. 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. Primary Contact *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 categories below. Note that the PI may change the Primary Contact anytime without an amendment.
Study Team Members **Complete sections 1.3, 1.4 and 1.5 below to add Co-Investigators and additional study team members and to designate the type of online access you would like them to have.** ***To add*** *Co-Investigators and additional study team members in questions 1.3 and 1.4:* *1. Click "Add".* *2. Enter the name, or enter the first few letters of the person's name and click "Go".* *3. You can sort the returned list alphabetically by First name, Last name, or Organization by clicking the appropriate heading.* *4. Select the boxes beside ALL applicable names and click "OK".*	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.

To delete *a person from the list, select the box next to his or her name and click "Remove".* **1.3. Co-Investigators** *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 Agency Research Ethics Board certificates). If this research application is for a graduate degree, enter the graduate student's name in this section.* Last Name First Name Institution/Department Rank	If you are applying to the BC Cancer Agency (BCCA), co-investigators will not be listed on the certificates of approval; however, all participating BCCA centre PIs will be listed. You will be asked to enter the BCCA centre PI's names in View 11. For further information click here for the **BCCA Research Ethics Board policy**.
1.4. Additional Study Team Members - Online Access *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.* Last Name First Name Institution/Department Rank	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. Additional Study Team Members - No Online Access *Click "Add" to list study team members who WILL NOT have online access to the application and will NOT be listed on the certificate of approval.* Last Name First Name Institution/Department Rank/Job Title Email Address	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.
1.6. Tri Council Policy Statement (TCPS) Tutorial * ***Tri Council Policy Statement2 (TCPS2) Tutorial*** *All undergraduate and graduate students and medical residents are required to complete the TCPS2 Tutorial (CORE) before submission. This tutorial provides an essential orientation to Canadian human research ethics guidelines. The Principal Investigator and all Co-Investigators must be familiar with the TCPS2. Indicate completion of the TCPS2 (CORE) tutorial below:* **1.6.A.** *All Undergraduate/Graduate Students:* N/A (no undergraduate/graduate students participating in this study) * **1.6.B.** *All Medical Residents:* *Comments:*	All non-Faculty personnel who are associated with a research project and who will have contact with the research participants are required to complete the TCPS2 online tutorial (CORE) 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, etc. The REB requires that all Principal Investigators be familiar with the TCPS2 and recommends that Principal Investigators also complete the TCPS2 tutorial, especially when the Principal Investigator supervises or teaches classes for graduate students or medical residents. The TCPS CORE Tutorial is free and can be completed in about two hours. CORE Certificates do not need to be attached. Copies should be retained by the PI and be available on request. Click here for the **TCPS2 Document**.Click here for the **TCPS2 'CORE' Tutorial**.
* **1.7. Project Title** *Enter the title of this research study as it will appear on the certificate. If applicable, include the protocol number in brackets at the end of the title. If this is a class-based project, see guidance on the right.*	The title given in the application form must correspond to the title on all study documents, including the consent form. If the study is supported by research grant or contract funding that is being administered by the University or one of the teaching hospitals, the title should correspond to the title on the grant or contract.

	For studies that have multiple titles that correspond with multiple funding sources, please enter these titles and the respective funding sources in question 2.4. For class-based projects please ensure to include "Class Project" in the first part of the title and the project nickname (question 1.8).
* **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?*test	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. For class-based projects, include "Class Project" in the first part of the nickname. For Family Practice Residency projects, include "Family Practice Project" in the first part of the nickname. For Harmonized Review projects include "Harmonized Review Project" in the first part of the nickname.

2. STUDY DATES & FUNDING INFORMATION - HUMAN ETHICS APPLICATION

Project Period * **2.1.A.** *Please choose **ONE** of the following:* • *You plan to start collecting data immediately after obtaining ethics and any other required approvals (the start date on the ethics certificate will reflect the approval date),* ☐ ***OR*** • *You plan to start data collection at a later date i.e., 2 months or more after approvals are obtained. Click the calendar icon below to select the dates (Internet Explorer) or enter the dates manually using the format yyyy-mm-dd.Estimated start date:* * **2.1. B.** *Estimated end date:*	In multi-phase projects, include the period that involves research with human participants.
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 **2.2.B.** *For Industry Sponsored studies, please provide a sponsor contact.* **2.2.C.** *Please enter any applicable information about your funding which is not already shown in Box 2.3 or 2.4 (including funding applied for but not yet received).*	"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.
Source of Funds *Please clearly identify the application for research funding associated with this ethics application. This will ensure that awarded research funds can be made available to you once this ethics application receives approval.*	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.

2.3. Research Funding Application/Award Associated with the Study that was Submitted to the UBC Office of Research Services *Please click "Add" to identify the research funding application/award associated with this study. 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.* UBC Number Title Funding PI Sponsor	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).
2.4. Research Funding Application/Award Associated with the Study not listed in question 2.3. *Please click "Add" to enter the details for the research funding application/award associated with this study that is not listed in question 2.3. When you press "Add" you can do a search for your funding award by doing a search in the "Sponsor" box - over 7000 options are listed* Title Sponsor	
U.S. Funding * **2.5.A.** *Is this a DHHS grant? (To view a list of DHHS funding agencies click on "add" in 2.5.B below)* Yes No **2.5.B.** *If yes, please select the appropriate DHHS funding agency from the selection box, and attach the grant to box 9.8. of the application.* DHHS Sponsor List *Attach DHHS Grant Application for each sponsor listed above* Title	The **Department of Health and Human Services**, DHHS (US Federal Agencies), requires the Research Ethics Board to review the actual grant application to compare it to the protocol being approved, to ensure that they are the same. Your certificate of approval will not be released until this documentation is attached.
* **2.6. Conflict of Interest** *Do any of the following statements apply to the Principal Investigator, Co-Investigators and/or their partners/immediate family members?* • *Receive personal benefits in connection with this study over and above the direct cost of conducting this study. For example, being paid by the funder for consulting. (Reminder: receiving a "finders fee" for each participant enrolled is not allowed).* • *Have a non-financial relationship with the sponsor (such as unpaid consultant, advisor, board member or other non-financial interest).* • *Have direct financial involvement with the sponsor (source of funds) via ownership of stock, stock options, or membership on a Board.* • *Hold patent rights or intellectual property rights linked in any way to this study or its sponsor (source of funds).* Yes No	The REB needs to be satisfied that participants are informed of conflict of interest matters in the consent process. Note that "immediate family members" includes partners and children (whether living in the household or not). The REB does not require that the investigator identify holdings in managed mutual funds to be declared in the conflict of interest statements. If you answer yes to this question you will be asked to provide more detail on view 3 of the application.

4. STUDY TYPE - HUMAN ETHICS APPLICATION

*** 4.1. UBC Research Ethics Board**

Indicate which UBC Research Ethics Board you are applying to and the type of study you are applying for:

UBC Clinical Research Ethics Board

UBC's REBs have signed a one board of record agreement. Studies taking place at multiple UBC sites require review and approval by only one UBC-Affiliated REB. Choice of Board should be determined by the PI's primary appointment and/or the main location of the research.

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.

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

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 your research will not be carried out at an institutional site, please check the "N/A" box. Otherwise 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 Agency C for Children's and Women's Health Centre of BC P for Providence Health Care U for UBC Campus V for Vancouver Coastal Health (VCHRI/VCHA).

N/A: ☐

4.2.A. Institutions and Sites for Study

Hospital/Institution	Site

4.2.B.

Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., private physician's office, community centre, school, classroom, participant's home, in the field - provide details).

4.2 Where the research will be **"carried out under this Research Ethics Board approval"** means at sites which have a **UBC REB that is included in the "one board of record agreement", which are;**

- BC Cancer Agency sites
- Children's & Women's Health Centre of BC sites
- Providence Health Care sites
- UBC Campus sites
- Vancouver Coastal Health (VCHRI/VCHA) sites.

4.2.B Other locations that are outside of a Hospital/Institution but still under the jurisdiction of a UBC REB as noted above.
Institutional Approval: Research at UBC's affiliated hospitals 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. The Hospital Administrator for facilities/services at the hospital or centre selected will be granted viewing access to this application; however, it is the PI's responsibility to pursue and obtain the necessary approvals from the various hospitals.

4*. CLINICAL STUDY REVIEW TYPE - HUMAN ETHICS APPLICATION

4.3. Relationship with other proposals **4.3.A.** *If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal.* **4.3.B.** *If applicable, please describe the relationship between this proposal and the previously/simultaneously submitted proposal listed above.* **4.3.C.** *Have you received any information or are you aware of any rejection of this study by any Research Ethics Board? If yes, please provide known details and attach any available relevant documentation in question 9.7.* ○ Yes ○ No	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. Click here for further information on **sub-studies and extension studies**. If a study has been rejected by another UBC-affiliated REB, it may not be re-submitted to any other UBC-affiliated REB. If the study is a clinical trial, Health Canada must be notified of the rejection/disapproval of the study.
* **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	Click here for information on minimal risk.
* **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 generally require a peer review.* **4.5.A.** *External peer review details:* * **4.5.B.** *Internal (UBC or hospital) peer review details:* * **4.5.C.** *If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place.*	Article 2.7 of the TCPS2 stipulates that the REB must review the ethical implications of the methods and design of a research project. Peer review is required by all UBC- 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, please explain why this is the case**. Regardless of the circumstances of the research, the REB may always, in its discretion, determine that an independent or other peer review is required as a condition of approval. Click here for further information on the requirements for peer review.

*** 4.6. Harmonized review of multi-jurisdictional studies** *Please read and review the guidance note on the right prior to completing this question.* *Is this study a multi-jurisdictional study that will also require REB review/approval at one or more of the following institutions with which UBC has a collaborative review agreement?(See the guidance to the right for details about the harmonized process.)* • *Simon Fraser University* • *University of Alberta* • *University of Northern British Columbia* • *University of Saskatchewan* • *University of Victoria* ***(Note: If submitting an amendment for an already approved study, you must respond "No" to this question)*** ○ Yes ○ No	A multi-jurisdictional study is a research study that requires review and approval by more than one Canadian research ethics board (i.e. by more than one Canadian REB as well as a UBC affiliated REB) as a result of the requirements of the TCPS2 and/or UBC's and/or another institution's human ethics policies. UBC has entered into partial reciprocity and collaborative review arrangements with certain other institutions and entities in situations where a study requires review and approval by more than one Canadian Research Ethics Board. For detailed guidance on harmonization processes and requirements click here. Please note that this is not the same as question 7.1 which is specifically directed to studies that involve locations outside of those listed in 4.2 and 4.6. **If submitting an amendment for an already approved study, you must respond "No" to this question.**
4.7.A Creation of a Registry (Data or Tissue Bank) *Does this study involve the creation of a registry (data or tissue bank) for future use in other research? [if no, skip to 4.8]* ○ Yes ○ No **4.7.B** *Is the purpose of this application exclusively to obtain approval for the creation of a research database, registry or tissue bank? [Note if the creation of the database or registry or tissue repository is part of a bigger project also included in this application, you must answer "no" below.]* ○ Yes ○ No	This applies to situations where the researcher is creating a repository (bank) of data or tissue that is specifically intended to be accessed by the researcher and/or other researchers for future use over an extended period of time, and where the researcher intends to be the steward or guardian of the information. 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 sponsor will be the steward or guardian of data or tissue for future research. iii) secondary use of existing data which has already been collected clinically or under a previous research project that you plan to re-analyze for a different purpose. **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. Biorepositories (also known as biobanks) are types of repositories that collect and store human biospecimens specifically for use in subsequent research. Biospecimens are defined as human biological materials obtained from a participant and may include solid tissues, blood samples and fluids. The information associated with the biospecimen may or may not include personally identifying information. Registries and biorepositories can be of any size.

Clinical Chart Review

4.8.A.
Is this an application for research using the review of clinical charts?

Yes No

4.8.B.

Insert the date range of the charts to be included in this research.

4.8.C.

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

Yes No

4.8.D.

*Is this a retrospective chart review study that will involve the collection of **NO** personally identifiable information of any sort?*

Yes No

4.8.E.

Is this a retrospective chart review study for which you are requesting a waiver of consent

Yes No

Important Note: Studies that are **exclusively** retrospective chart reviews and where no consent is being sought and no contact with participants is being proposed **may** (depending upon the responses to questions 4.8.A - 4.8.E) be directed to View A, a branch off from the main application form which asks specific questions about the retrospective chart review and the application form **may** truncate.

A retrospective chart review for the purpose of this application includes charts that were collected before the date of ethics approval (dates in the past), e.g., Sept. 2005-Sept. 2011.

Personally identifiable information is information that could reasonably be expected to identify an individual, alone or in combination with other available information, e.g. date of birth (DOB), place of residence or unique personal characteristic. Please note that while DOB is considered a personal identifier, age is not.

A. Retrospective Clinical Chart Reviews - HUMAN ETHICS APPLICATION	
* **A.1** *Summarize the research proposal*	Summarize the research proposal using the following headings: 1) Purpose 2) Hypothesis 3) Justification 4) Objectives 5) Analysis of Data
* **A.2** *Describe how permission to access the medical records and to collect and use these records will be obtained.*	
A.3 *Briefly describe the type of data that you intend to collect (e.g., disease, diagnosis, outcome, demographic, aggregate, personal-level).*	**A.3. Important Note:** If you intend to collect personally identifiable information, a data-collection / data extraction form must be appended to Question 9.8.A. of the application.
A.4 *Number of Records/Patient Charts*	Specify the minimum number of charts / records required to conduct the study.
* **Personal Information** **A.5** *Are you collecting personally identifying information?* Yes No * **A.5.1** *Indicate the **type** of personally identifying information you will be collecting. Include a justification of why it is required.*	**A.5** 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. **A.5.1** Types of personally identifiable information include but are not limited to the examples above. For example gender, e-mail address, telephone number, healthcare provider, discharge dates, photographs, postal codes etc. can all constitute personally identifiable information.
* **Waiver of Consent** **A.6.1.** *Is the identifiable information essential to the research?* Yes No **A.6.1. Explanation:** *If this question require further explanation or justification, please enter it into the text box below.* * **A.6.2.** *The use of the identifiable information without the participants consent is unlikely to adversely affect the welfare of the participants.* Yes No **A.6.2. Explanation:** *If this question require further explanation or justification, please enter it into the text box below.* * **A.6.3.** *The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.* Yes No **A.6.3. Explanation:** *If this question require further explanation or justification, please enter it into the text box below.*	**The TCPS2 article 5.5. requires that all of these criteria must be present in order for a waiver of consent to be permitted for secondary use of data (i.e. chart reviews)**

* **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:** *If this question require further explanation or justification, please enter it into the text box below.* * **A.6.5.** *It is impossible or impracticable to seek consent from individuals to whom the information relates.* Yes No **A.6.5. Explanation:** *If this question require further explanation or justification, please enter it into the text box below.* * **A.6.6.** *The researchers have obtained any other necessary permissions for secondary use of the information for research purposes.* Yes No **A.6.6. Explanation:** *If this question require further explanation or justification, please enter it into the text box below.*	
* **A.7.** *Describe the risks associated with the possible disclosure of the data. Include any foreseeable circumstances where disclosure of identifying data may be required by law.*	
* **A.8.** *Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms.*	**Unique 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, SIN, PHN, hospital number, DOB, or unique characteristic.
* **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.*	
* **A.10.** *Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio-recording, personal digital device, other)*	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.
* **A.11.** *Describe the safeguards in place to protect the confidentiality and security of the data.*	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.** *Describe what will happen to the data at the end of the study, including how long the data will be retained and where, when and how the data will be destroyed, and what plans there are for future use of the data, including who will have access to the data in the future and for what purpose.*	

* **A.13. Data Transfer** *Will data be transferred outside of UBC or its affiliated hospitals?* Yes No	Note that if this changes in the future an amendment must be submitted before data is transferred.
* **Data Linking** **A.14.A.** *Do you plan to link the data to any other data?* Yes No **A.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.*	Note that if this changes in the future an amendment must be submitted before data is linked.

C. Creation of a Research Database, Registry or Biorepository - HUMAN ETHICS APPLICATION

* **C.1.** *What is the scope and purpose of the database, registry or biorepository?*	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. In addition to other attributes, biorepositories may be considered as: a) mono-user biobanks (i.e., a collection aimed at supporting a specific, single research project; b) an oligo-user biobank (i.e., a collection aimed at supporting several research projects, a research group or a research consortium); or c) a poly-user biobank (i.e., a collection aimed at supporting undetermined, multiple users with REB-approved research projects, through a defined access/application mechanism).
* **C.2.** *What are the anticipated public and scientific benefits of the database, registry or biorepository?*	
C.3. *Over what period of time will data be collected?*	Include a clear date range of the information that will be included in the registry or biorepository. If data will be collected indefinitely, clearly indicate that data will be collected indefinitely or until the participant withdraws, if applicable.
C.4.A. Sources *What information source(s) are you accessing?* **C.4.B.** *Provide specific details about the source(s), i.e., including name of the database or type of health records, location etc.* **C.4.C.** *What are the sources of your biospecimens, check all that apply.*	**Answer C.4.A. and B if your project involves creation of a database or registry.** **Answer C.4.C. if your project involves creation of a biorepository.** Tissue biospecimens are any human biospecimens or biological material comprised of whole solid tissues, cells isolated from solid tissues and fluids other than blood.

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

* **C.5.A. Confidentiality** *Are you collecting personally identifying information/will the biospecimens be linked to personally identifiable information? [If not, skip to C.9]* ○ Yes ○ No **C.5.B.** *Indicate the type of personally identifying information you will be collecting that will be linked to the specimens. Include a justification for its inclusion in the registry or database and/or retention of the link.* **C.5.C.** *How long will data remain identifiable/ specimens be linked (i.e., when, if ever, will it be irreversibly anonymized). Justify why data/specimens 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/specimens.* Name Degree Affiliation Role on project Email	**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. Important Note: For databases or registries, a data collection form should be attached to question 9.8. of the application** **C.5.C. Irreversibly 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.6.A. Consent** *Will participants consent to be included in the database or registry? Have their specimens been included in the biorepository? [If no, skip to C.7.]* ○ Yes ○ No **C.6.B.** *Specify who will explain the consent form and invite participants to contribute. Include details of where consent will be obtained and under what circumstances. For biorepositories, please explain whether the consent process is pre-procedure or post-procedure.*	**Important Note: Attach a copy of the consent form to Box 9.2. of the application.** Pre-procedure consent is consent obtained prior to the individual undergoing a medical procedure (e.g., surgery or biopsy to remove a tumour). Post-procedure consent is consent obtained after the individual has undergone a medical procedure. For additional information click here.
* **C.7.** *If you are collecting personally identifying information or if you are collecting biospecimens that will be linked to personally identifiable data and do not plan to obtain individual participant informed consent, please provide justification for not doing so following the criteria outlined on the right. Please address each criterion individually.*	Refer to TCPS2 5.5 **D. Consent and Secondary Use of Identifiable Information for Research Purposes:** Article 5.5 Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that: a. identifiable information is essential to the research; b. the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

	c. the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information; d. the researchers will comply with any known preferences previously expressed by individuals about any use of their information; e. it is impossible or impracticable to seek consent from individuals to whom the information relates; and f. the researchers have obtained any other necessary permission for secondary use of information for research purposes. If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.
* **C.8.A. Participant access to data and withdrawal** *Will individual participants have the right to access their data, or right to amend or withdraw their information?* ○ Yes ○ No **C.8.B.** *Provide details of the process for accessing and/or withdrawing data, including what data can be withdrawn.*	
* **C.9.** *What is the entity or who is the person that will have custodianship of the database or registry/bio-repository?*	A **data/biorepository custodian** is an entity or person who is responsible for overseeing the management and use of the data/biorepository, including the main rules governing use of the database/ biorepository, 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.** *What will be the address of the database, registry or the location of the biorepository?*	This should be a mailing address; however, if there is a URL, please also provide it.
* **C.11.** *What steps will be taken to ensure the security of the data/biospecimens?*	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.12.** *For databases and registries, describe the risks associated with the possible disclosure of the data. Include any foreseeable circumstances where disclosure of identifying data may be required by law.*	

* **C.13.A. Data/Biospecimen Transfer** *Will data/biospecimens be sent outside of the institution? [If no, skip to C.14]* ○ Yes ○ No **C.13.B.** *Explain why it is necessary to send the data/biospecimens outside of the institution, and indicate what data/biospecimens will be sent, where it/they will be sent, who it/they will be sent to, how it/they will be transferred (faxed, emailed, couriered, encrypted electronic transfer etc.) and where it/they will be stored.* **C.13.C.** *Will there be a data transfer/material transfer agreement?* ○ Yes ○ No	Note that if this changes in the future an amendment must be submitted before data is transferred. **C.13.C.** Attach a copy of the data transfer agreement to box 9.8. of the application.
* **C.14.A. Data Linking** *Do you plan to link all or some of the data or the biospecimens to another data source (e.g., database, biorepository)?* ○ Yes ○ No **C.14.B.** *Identify the data set, how the linkage will occur, and provide a list of data items in the other database. Also, identify what personal information will be used to link the databases and how confidentiality regarding this shared information will be preserved.*	Note that if this changes in the future an amendment must be submitted before data is linked.
* **C.15.A. Data Retention** *How long are you planning to keep the data/biospecimens?* **C.15.B.** *If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens.*	
* **C.16.A. Future Use** *Will the information in the database/biorepository be retained as an ongoing database/biorepository (or as part of an ongoing database/biorepository) for future research? [If no, skip to C.17]* ○ Yes ○ No **C.16.B.** *Provide a full description of the data/biospecimen stewardship process, including whether the dababase/biorepository will have formalized standard operating procedures.*	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 biorepositories to consider certification of their biorepository with the Canadian Tumour Repository Network (CTRNet) Biobank Certification Program or accreditation with the College of American Pathologists (CAP) Biorepository Accreditation Program.

* **C.17.** *Describe any commercial uses for which the data/biospecimens may be used, including any disclaimers concerning participant remuneration for such use.*	
C.18. Registration for Publication of Clinical Trials **C.18.A.** *Does this clinical study fall within the definition stated on the right (in the guidelines)?* ○ Yes ○ No **C.18.B.** *If "Yes", click "Add" to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available.)* Has it been registered? | Authorized Registry used | Clinical Trial unique identifier	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) now require registration for all clinical trials as defined by *"Any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".* Health related interventions include any intervention used to modify a biomedical or health-related outcome; for example, drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. 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.

E. Harmonized Review of Multi-Jurisdictional Studies - HUMAN ETHICS APPLICATION

* **E.1.** *Is this the first/initial application for review of the multi-jurisdictional study at any of the sites where the research is going to be conducted?* ○ Yes ○ No	The first/initial application for review is the first application for ethical review of the research submitted to any of the Institutions with which UBC has a signed reciprocity agreement. UBC has entered into partial reciprocity and collaborative review arrangements with certain other institutions and entities in situations where a study requires review and approval by more than one Canadian Research Ethics Board. For detailed guidance on harmonization processes and requirements click here. For a list of institutions with which UBC has a reciprocity or collaborative review agreement click here.
* **E.2.** *Are you the Lead Investigator for this multi-jurisdictional study? (See definition on right)* ○ Yes ○ No	The Lead Investigator is the only Investigator conducting the multi-jurisdictional study at various sites or the Investigator chosen from amongst numerous Investigators from various sites to lead the multi-jurisdictional study. The Lead Investigator is the Investigator who submits the first/initial application for ethical review of the multi-jurisdictional study at any of the sites where the research is going to be conducted. The Lead Investigator is required to submit the initial application for review of the research to his or her home institution's REB regardless of where the research is taking place. If this is an initial application for review of the study and you are NOT the lead investigator, you cannot continue with this submission. If you are a UBC faculty member, you cannot answer 'no' to question E.1 and 'yes' to question E.2 because UBC must perform the review of initial/first application since UBC is your home institution.
E.3. *Please indicate which institution with which UBC has an Ethics Review Agreement is your home institution.* Check the institution below	If your institution appears on this list the application will truncate to view 9, where you will need to append all UBC site specific documents as applicable. Please append to view 9 all available documentation and information from the Lead PI and his/her REB, including the Lead PI's REB Application, Certificate of Approval, Informed Consent and recruitment documents and all available correspondence between the Lead PI's REB and the Lead PI, including, if available, the minutes from the Lead PI REB's review of the study. If your institution does not appear on this list, you will be directed to 4.8 and will need to fill out the full REB application.

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:*	**For 5.1.B:** Summarize the research proposal using the following headings: 1) **Purpose** 2) **Hypothesis** 3) **Justification** 4) **Objectives** 5) **Research Method** 6) **Statistical Analysis** In the description of **purpose**, include the followin - 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 In the description of **justification** include the following: - A description of the standard treatment - A description of alternative treatments (other than standard treatments) - Justification of the use of placebo, if applicable In the description of **statistical analysis** include the following: - A summary of the primary and secondary end-points - Statistical analysis planned - Planned sample size Click here for further information on the **research proposal summary**. A copy of the research protocol/proposal must be attached to box 9.1 of the application
5.2. Inclusion Criteria *Inclusion Criteria. Describe the participants being selected for this study, and list the criteria for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.*	Please enter the inclusion criteria as an itemized list. Click here for information on **inclusion criteria for participants**. Click here for **criteria for expedited review of pluripotent stem cell research**.
5.3. Exclusion Criteria *Exclusion Criteria. Describe which potential participants will be excluded from participation, and list the criteria for their exclusion.*	Provide all exclusion criteria as described in the protocol/proposal. Otherwise, indicate how these criteria differ from those in the protocol/proposal. As the TCPS2 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.

5.4. Recruitment *Provide a detailed description of the method of recruitment. For example, describe who will contact prospective participants and by what means this will be done. Ensure that any letters of initial contact or other recruitment materials are attached to this submission on Page 9.*	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. Click here for information on **recruitment**. UBC policy does **not** allow initial contact by phone, unless prior consent to be contacted has been given or in the research involves emergencies. Click here for information on **obtaining consent in emergency situations**. Click here for information on **initial contact** by a participant's personal physician or caregiver.
5.5. Recruitment of Normal/Control Participants *Describe how prospective normal/control participants will be identified, contacted, and recruited, if the method differs from the above.*	**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". **Normal** participant refers to a randomly chosen member of the general population. Any individuals chosen for enrollment in a trial based on specific baseline characteristics are, by definition, not "normal" individuals for this purpose.
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, please describe how permission to access this information, and to collect and use this information will be obtained.*	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.
* **5.7. Summary of Procedures**	Describe any specific manipulations: type, quantity, and route of administration of drugs and radiation, operations, tests, use of medical devices that are prototypes or altered from those in clinical use, interviews or questionnaires. Also, 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. When applicable, also outline or describe standard of care or standard procedure.

6. PARTICIPANT INFORMATION AND CONSENT PROCESS - HUMAN ETHICS APPLICATION	
* **6.1. Time to Participate** *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 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. Time to Participate - Normal/Control Participants *If applicable, how much time will a normal/control volunteer be asked to dedicate to the project?*	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. This must be consistent with the information noted in the consent document. Please refer to Box 5.5 for a definition of a control group. If the proposal does not involve a control group, enter "N/A".
6.3. Risks/Harms *Describe what is known about the risks (harms) of the proposed research.*	Include any information about discomfort or incapacity that the participants are likely to endure as a result of the experimental procedure, along with the details of any known side effects which may result from the experimental treatment. Quantify risks using percentages where possible. Click here for information on **risks (harms)**.
6.4. Benefits *Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.*	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.
6.5. Reimbursement *Describe any reimbursement for expenses (e.g. meals, parking, medications) or payments/incentives/gifts-in-kind (e.g. honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.*	As per the TCPS2 (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**.
6.6. Obtaining Consent *Specify who will explain the consent form and consent participants. Include details of where the consent will be obtained and under what circumstances.*	Include the following details:1. Who will approach the participants to obtain consent.2. Who will inform and take the consent from the participant.3. What is the relationship of the person obtaining consent to the participant. Click here for information on the **consent process**.

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 on the right. Please address each criterion on the right individually.* **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 on the right. Please address each criterion on the right individually.*	**6.7.A.** Refer to TCPS2 Article 3.7 for further information on the following criteria. a. The research involves no more than minimal risk to the participants b. The waiver or alteration is unlikely to adversely affect the welfare of the participants c. It is impossible or impracticable to carry out the research and to answer the research question properly, given the research design, if the prior consent of the participant is required d. Whenever possible and appropriate, after or during the study, participants will be debriefed and provided with additional pertinent information as per Articles 3.2 and 3.4 of the TCPS2, at which point they will have the opportunity to refuse consent e. The research does not involve a therapeutic intervention, or other clinical or diagnostic interventions. **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. 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.*	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." Click here for further information about time given to consent.

* **6.9. Capacity to Consent** *Will every participant have the capacity to give fully informed consent on his/her own behalf? Please click "Select" to complete the question and view further details.*	Click here for information on **capacity**.
6.10. Renewal of Consent *Describe any situation in which the renewal of consent for this research might be appropriate, and how this would take place.*	The TCPS2, 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. Provisions for Consent *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 view 9 of the application.
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. Also, indicate any plans for communicating study results to participants.*	Click here for information on **UBC's Conflict of Interest policy**.

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

7.1. Multi-Centre Studies **7.1.A.** *Is this a multi-centre study (involves centres outside of those applied for under this Approval?)* Yes No *If known, please list the other sites below:* **7.1.B.** *Is this study being submitted for ethical approval to any other BC or Canadian Research Ethics Board?* *If yes, please provide the name of the REB(s) and if available, contact information:*	These questions will assist the REB to consider coordination of their review with the other research sites. Please note that this is not the same as question 4.2 or 4.6 which are specifically directed to studies involving Institutions/sites with which UBC has a collaborative review, reciprocity or one board of record agreement. These lists should include; • Sites outside of Canada and • Sites within Canada
7.2. Number of Participants **7.2.A.** *How many participants (including controls) will be enrolled in the entire study? (i.e. the entire study, world-wide)* **7.2.B.** *How many participants (including controls) will be enrolled at institutions covered by this Research Ethics Approval? (i.e. only at the institutions covered by this approval)* *Of these, how many are controls?*	Controls are people acting in a control capacity including normal participants.
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.*	Click here for information on **obtaining regulatory approval for use of drugs outside approved indication.**
7.4. Marketed Drugs *Enter the name of any marketed drug(s) used **within** its approved indication.*	
7.5. Natural Health Products *Enter the name of any Natural Health Products used:*	Click here for information on **Natural Health Products.**
7.6. Experimental Drugs and 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.*	Click here for information on **obtaining regulatory approval for use outside approved indication.**

7.7. PERs *Enter the name of any positron-emitting radiopharmaceuticals (PERs).*	Click here for information on **positron-emitting radiopharmaceuticals (PERs).**
7.8. Health Canada Regulatory Approvals **7.8.A. Health Canada Regulatory Approvals** *Is this study a clinical trial or investigational test requiring Health Canada regulatory approval (If this study does not require Health Canada approval, skip to 7.10)* ○ Yes ○ No **7.8.B.** *If Yes, check all that apply from the list below.* **7.8.C.** *Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.*	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.* Details of Health Canada Regulatory Approvals** *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. A copy of the approval (NOL, ITA, NOA) must also be attached in question 9.1.* Name of Regulatory Agency Date of Approval Date of Pending Application Health Canada NOL Control Number Date of Approval	Applications to the Research Ethics Board (REB) and Health Canada may be concurrent, however, NO UBC AFFILIATED REB will issue a "Certificate of Approval" until the Health Canada Regulatory Approval is received.
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	Click here for information on **Stem Cell Research.** Certain types of research involve the use of human pluripotent stem cells conducted under the auspices of institutions receiving Tri-Council funding is required to apply to the CIHR SCOC for approval.
7.11. Registration for Publication of Clinical Trials **7.11.A.** *Does this clinical study fall within the definition stated on the right (in the guidelines)?* ○ Yes ○ No	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) now require registration for all clinical trials as defined by *"Any research project*

7.11.B. *If "Yes", click "Add" to enter the following information. (Please note that registration by UBC ORS administration requires the prior ethical approval of the study. In that case, registration information should be added when it becomes available.)* Has it been registered? | Authorized Registry used | Clinical Trial unique identifier	*that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes".* Health related interventions include any intervention used to modify a biomedical or health-related outcome; for example, drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health related measures obtained in patients or participants, including pharmocokinetic measures and adverse events. 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.
7.12. US Regulatory Requirements **7.12.A.** *Is there a requirement for this research to comply with United States regulations for research ethics?* Yes No **7.12.B.** *If yes, please indicate whether or not FDA (Investigational New Drug) number (drug studies) or an FDA Investigational Device Exception (IDE) is required for the research and provide documentation from the Sponsor or the FDA verifying the IND/IDE number, or explaining the study exemption status, in Question 9.1.C.*	7.12.A.: Mark 'yes' if this study is conducted or funded by the US Department of Health and Human Services (DHHS) (see link below) or is required to comply with either the US FDA or any other US regulations. The PI is responsible for ensuring that the study complies with the applicable US regulations. Click here for a listing of the DHHS operating and staff divisions. 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 US FDA IND or IDE number is applicable, the Ethical Certificate of Approval will not be released until a valid number is entered in 7.12B and if available, appropriate documentation is attached to Question 9.1.C.

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.*	Click here for information on **unblinding in the event of an emergency**.
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.*	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 (TCPS2, 11.7).
* **8.3. Study Stoppage** *Describe the circumstances under which the study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.*	
* **8.4. Personal Identifiers** **8.4.A.** *Describe how the identity of the participants will be protected both during and after the research study, including how the participants will be identified on data collection forms.* * **8.4.B.** *Will any personal health information or personal identifiers be collected?* ○ Yes ○ No *If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.*	**Unique 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, SIN, PHN, hospital number, DOB, address, or unique characteristic. Click here for information on the **protection of participant identity**.
* **8.5. Data Access and Storage** **8.5.A.** *Explain who will have access to the data at each stage of 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.* * **8.5.B.** *Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio recording, personal electronic device, other).* * **8.5.C.** *Describe the safeguards in place to protect the confidentiality and security of the data.*	For example, study documents must be kept in a secure locked location/filing cabinet, computer files should be password protected and encrypted, data should not be stored or downloaded onto an unsecured computer or a portable lap-top.

8.5.D. *If any data or images are to be kept on the Web, what precautions have you taken to prevent it from being copied?*	
*** 8.6. Disposition of Study Data** **8.6.A.** *Describe what will happen to the data at the end of the study (including how long the study data will be retained, when and how the data will be destroyed), and what plans there are for future use of the data, including who will have access to the data in the future and for that purpose. If this study involves the creation of a research database or registry for the purpose of future research, please refer to the Guidance note linked on the right and provide the requisite information.* **8.6.B.** *If applicable, describe what will happen to the study samples at the end of the study, including how long the study samples will be retained and where, when and how the samples will be destroyed, and what plans there are for future use of the samples, including who will have access to the data in the future and for what purpose.*	Please include the following information: • Final disposition/storage of all research-related study documents. According to UBC Policy 85, study data should be kept for a minimum of 5 years after publication. Clinical trials data must abide by Health Canada's regulations regarding data retention and generally must be kept for 25 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.
*** 8.7. Data Transfer to Other Institutions** *Will data be sent outside of the Institution where it is being collected?:* Yes No *If yes, please describe the type of data to be transferred, who the data will be transferred to, where the data will transferred, and how the data will be sent.*	Click here for further information about transferring data outside of the institution.
*** 8.8. Data Transfer to Institution** *Will the researchers be receiving data from other sites?:* Yes No *If yes, please describe the type of data that will be received, who it will be received from, where it will be received from, and how the data will be received.*	
*** 8.9. Data Linkage** **8.9.A.** *Will the data be linked to any other data source (including a biorepository)?* Yes No **8.9.B.** *Identify the data set, how the linkage will occur, and explain how confidentiality regarding the shared information will be preserved.*	

9. DOCUMENTATION - HUMAN ETHICS APPLICATION

Please attach the documentation for the study. The Research Ethics Office cannot change document names or dates.

INSTRUCTIONS

View the guidelines to the right of each section to see where the document should be attached. Documents will appear on the certificate of approval with the information that you enter when you attach the document. Please check that version dates, document names etc. are accurate and match those on the attached documents. Submit final versions only (i.e. not "drafts") except that blanks can be included for names and addresses in documents to be sent to specific individuals or organizations. Revisions required by the Board should be highlighted.

New Applications: Attach the documents to the applicable section (refer to guidelines on right)

Response to Proviso, Deferral, Changes Required by REBA, or Amendments: If you are submitting a revised version of a document that is already attached, delete only the document that you are replacing and attach the revised version of the same document (Do NOT delete any of the other documents). You may add a new document but you must indicate in your response or PAA coversheet that you have added a new document for review.

9.1.A. Protocol

Examples of types of protocols are listed on the right. Click "Add" to enter the required information and attach the documents.

Document Name	Version	Date	Document	Password (if applicable)

9.1.B.

Health Canada regulatory approval (receipt will be acknowledged)

Document Name	Version	Date	Document	Password (if applicable)

9.1.C.

FDA IND or IDE letters (receipt will be acknowledged)

Document Name	Version	Date	Document	Password (if applicable)

Clinical Applications

- Clinical trial protocol
- Clinical research proposal
- Amendments to full protocols
- History or Summary of Changes to Amendments

NOTE: If this application is part of the streamlined review process outlined in question 4.6, UBC specific documents must be appended in Sections 9.1 - 9.7, as applicable.

9.2. Consent Forms

Examples of types of consent forms are listed on the right. Click "Add" to enter the required information and attach the forms.

Document Name	Version	Date	Document	Password (if applicable)

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 Consent Form Guide and Template for UBC Clinical REBs.

Refer to the appropriate REBs' website for other consent form templates, e.g. optional, tissue banking etc. (Click on name for link: BC Cancer Agency (BCCA) Research Ethics Board, UBC C&W Research Ethics Board, and Providence Health Care.)

9.3. Assent Forms *Examples of types of assent forms are listed on the right. Click "Add" to enter the required information and attach the forms.* Document Name Version Date Document Password (if applicable)	Attach all assent forms for the research, including the following: • Participant assent form • Normal/Control participant assent form • Tissue blood banking assent form • Substitute decision maker assent form • Other assent forms
9.4. Investigator Brochures/Product Monographs *Please click "Add" to enter the required information and attach the documents.* Document Name Version Date Document Password (if applicable)	
9.5. Advertisement to Recruit Participants *Examples are listed on the right. Click "Add" to enter the required information and attach the documents.* Document Name Version Date Document Password (if applicable)	**Advertisement to Recruit Participants.** This includes any type of communication (e.g., flyer, radio/television script, poster, newspaper ad, Internet message) 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 **BCCA Research Ethics Board** policies on participant handouts and advertisements. Click here for **UBC C&W Research Ethics Board** policies on participant handouts and advertisements.
9.6. Questionnaire, Questionnaire Cover Letter, Tests, Interview Scripts, etc. *Please click "Add" to enter the required information and attach the documents.* Document Name Version Date Document Password (if applicable)	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. Letter of Initial Contact *Please click "Add" to enter the required information and attach the forms.* Document Name Version Date Document Password (if applicable)	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
9.8. Other Documents **9.8.A.** *Other documents: Examples of other types of documents are listed on the right. Click "Add" to enter the required information and attach the documents.* Document Name Version Date Document Password (if applicable)	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

9.8.B. *If a Web site is part of this study, enter the URL below. Since URL's 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.*	• Website content • DHHS Grants • Data collection sheet If applicable, please attach a transcript (the document must include a version date) of any CD, tape or audio file and send the hard copy to the Research Ethics Office. If this is an application using the streamlined process as indicated in Question 4.6, please append ALL relevant documentation from the other approving REB, including the application form, all correspondence from and to the approving REB, the protocol approved, the certificate of approval, the other REB approved informed consents, etc.

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

Industry For-Profit Sponsors *Send the $3000.00 fee to the Clinical Research Ethics Board (CREB) OR enter details below stating that the fee will be sent and by when. It is the investigator's responsibility to communicate this requirement to the sponsor and collect the payment prior to CREB submission if possible.* ***** *Please indicate which of the following methods of payment will be used for this application.* ***OR*** *Enter information stating when the fee will be sent:*	Please click here for information on **requirements for fee refund.**

12. SAVE APPLICATION - HUMAN ETHICS APPLICATION

You have reached the end of the Human Ethics Application.

OPTIONS

1) submit application (PI only) -*click the "Continue" button and "Submit application" on the next page.* ***NOTE: the "Submit application" button is only visible to the PI****.*

2) work on this application later - *click the "Continue" button. Your application will be in "Pre Submission" and saved in your inbox.*