Contents For **Guidance Notes** for Clinical Application

Guidance Notes in Application

Box	Guidance note
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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 2014. 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.

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.
1.6	All research personnel who are associated with a research project 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 and faculty, whether they are the Principal Investigator or not. 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 and available on request. Click here for the **TCPS2 2014 Document**. Click here for the **TCPS2 'CORE' Tutorial**. This tutorial provides an essential orientation to Canadian human research ethics guidelines.
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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2.1A	In multi-phase projects, include the period that involves research with human participants.
2.1B	In multi-phase projects, include the period that involves research with human participants.
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	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. Attach DHHS Grant Application for each sponsor listed above.
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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3.1	All investigators: Click here for TCPS2, Chapter 7 - Conflicts of Interest http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/ UBC Investigators & Faculty: Click here for information on Policy 97 Conflict of Interest and Conflict of Commitment http://universitycounsel.ubc.ca/files/2012/02/policy97.pdf 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 for more information from the Canadian Medical Association on finder's fees).
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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	Page 4A (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. 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 C for Children's and Women's Health Centre of BC P for Providence Health Care V for Vancouver Coastal Health (VCHRI/VCHA) U for University of British Columbia, University of Northern British Columbia and University of Victoria S for Simon Fraser University I for Interior Health and Island Health N for Northern Health
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. Add other non-UBC affiliated research sites. Ensure that the primary affiliations of all study team members are represented here. 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.

Box	Guidance Notes
	Page 4B (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 TCPS2(2014) stipulates that the REB must review the ethical implications of the methods and design of a research project. Peer review is required by all BCEHI-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 following form: https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/Peer%20-%20Scientific%20Review%20June%202016.doc

Box	Guidance Notes
4.6	Research Ethics BC (REBC) includes the following Institutions and Health Authorities: University of British Columbia University of Northern British Columbia University of Simon Fraser University of Victoria Fraser Health Northern Health Interior Health Island Health Providence Health Vancouver Coastal Health Children and Women's BC Cancer

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	Page 4C (Q4.7, 4.8)
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 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. 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. 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.
4.8B	**Retrospective data:** Data collected from charts dated on or before the date of 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).

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C.1	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	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.3	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	**Answer C.4.A and C.4.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.
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.6A	Attach a copy of the consent form to Box 9.2.
C.6B	**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.

Box	Guidance Notes
C.7	Please see below for the different types of waivers. Along with links to the appropriate TCPS2(2014) 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 to whom the information relates.
C.9	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	This should be a mailing address; however, if there is a URL, please also provide it.
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.13A	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.A.
C.14.A	Note that if this changes in the future an amendment must be submitted before data is 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 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.

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C.18A	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.

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A.2	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.
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.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.
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 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. The researcher should determine if the institution requires a data transfer agreement and if so, a copy of the completed data transfer agreement should be attached to section 9.8 A of the application.
A.14A	Note that if this changes in the future an amendment must be submitted before data is linked.

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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 TCPS2(2014) Article 4.1 for information on appropriate inclusion. Refer to TCPS2(2014) Chapter 12, Section F for information on research involving human pluripotent stem cells.

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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 TCPS2(2014), Section B 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.
5.4A	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. Click here for information on recruitment. Please ensure the same sites are listed on page 4 of the application.
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". **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	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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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 5.5 for a definition of a control group. If the proposal does not involve a control group, enter "N/A".
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 TCPS2(2014) 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 TCPS2(2014) 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	Refer to TCPS2(2014) Article 3.2 for more information about the consent process. Click here for information on the consent process.

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6.7A	**6.7.A:** Refer to TCPS2(2014) Article 3.7A 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 (see Glossary) 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. In the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and e. The plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.
6.7B	**6.7.B:** Refer to TCPS2(2014) 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(2014) 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."
6.9	Refer to TCPS2(2014) Chapter 3, Section C for more information on decision-making capacity. Click here for information on capacity.
6.10	Describe how participants' ongoing consent will be maintained throughout the research. TCPS2(2014) 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.

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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.
6.12	For more information on the expectation of researchers to provide study results to participants, refer to TCPS2(2014) Article 4.7 "Equitable Distribution of Research Benefits". You will need to scroll down to Article 4.7 once in the link.

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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.
7.2C	Controls are people acting in a control capacity (comparison group), including normal participants.
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. For information on investigational devices, please see Health Canada's Guidance Document on Applications for Medical Device Investigational Testing Authorizations here
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. For information on investigational devices, please see Health Canada's Guidance Document on Applications for Medical Device Investigational Testing Authorizations here
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.
7.11	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.
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.

Box	Guidance Notes
	Page 8
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 (TCPS2(2014), Article 11.7)
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 TCPS2(2014), Article 5.3 for more information on safeguarding participant information. Please note specific institutional privacy considerations will be addressed on page 11.
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.
8.6A	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.
8.6B	Please complete Box 8.6B if your study involves the handling of biospecimens (e.g. blood samples)

Box	Guidance Notes
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. TCPS2(2014), 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.

Box	Guidance Notes
	Page 9
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.)
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 • Substitute decision maker assent form • Other assent forms
9.5	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 **UBC C&W Research Ethics Board** policies regarding participant handouts and advertisements.
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.

Box	Guidance Notes
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: https://www.vchri.ca/vch-letter-initial-contact-template
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 • 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 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, the protocol approved, the certificate of approval, the other REB approved informed consents, etc.

Box	Guidance Notes
	Page 11 Vancouver Coastal Health
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).
11.3	IMPORTANT: To avoid delays, researchers should simultaneously submit this application for ethical review (by selecting the "submit" button on the application homepage once the application is complete) and send the applicable forms to the Health Service Delivery Area(s) (HSDA) specified in Box 11.3 as approval from both the ethical review board and the HSDAs are required before a project may proceed.

Box	Guidance Notes
	Page 11 BC Cancer Agency
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.

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

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 Alex Trethewey (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. NOTE: Use of Anatomical Pathology If the research is being conducted by an external researcher in possession of a certificate of ethical approval issued by a UBC Research Ethics Board other than the Providence Health Care Research Ethics Board, please follow the following instructions: Requests for pathology tissue blocks/slides for new and on-going research projects should be copied to: Alex Trethewey Pre&Post Review Manager Office of Research Ethics Providence Health Care Research Institute alex.trethewey@ubc.ca (604) 682-2344 x68366 The request should include a copy of a current Certificate of Ethical Approval and a copy of the relevant approved consent form.
11.2	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 alex.trethewey@ubc.ca (604) 682-2344 x68366 Ensure that the form includes the REB File number for the research.

Box	Guidance Notes
	Page 11 Fraser Health
11.2	Please note that if Fraser Health services or access to a patient care area are required a **Department Agreement for Providing Research-Related Services [DAR]Form** will be required. For details, refer to the DAR form at: http://research.fraserhealth.ca/approvals-&-ethics/forms-and-guidance-notes/
11.3	Please note that Affiliated Investigators must also have a Fraser Health Co-Investigator submit a letter to the FHREB detailing their roles and responsibilities in the project. This document may be added to RISe Section 9.8.A. For more information about becoming an Affiliated Investigator, please visit our website at http://research.fraserhealth.ca/approvals-%26-ethics/external-researchers/ prior to the initiation of research at FH Sites, the FHREB must provide written approval of all human subject research that includes any of the following:
11.4	If Yes, please note that you are required to complete an Appendix 2 (Privacy, Confidentiality, and Data Security) form to obtain a Department Access Agreement (DAA). This form should be uploaded in Box 9.8.A.