Clinical Research Ethics Application GUIDANCE Form V.22

Project Info.

File No: Ref No : -1
Project Title:
Principal Investigator: ()
Start Date:
End Date:
Keywords:

Question	Answer
Is the PI conducting research on behalf of Island Health or external?	
If the PI is not from Island Health, please provide the name of the Island Health collaborator. All studies must have at least one Island Health affiliated team member.	
If PI is from Island Health what is their department?	
If External Researcher, do they have Island Health affiliation/privileges?	
Study nickname or acronym (if applicable):	
Type of funding for this research study; if for-profit funded, please complete the funding tab in this application.	
Provide name of the funding agency, department or industry sponsor (clinical trials).	
For funded studies, please provide name of the institution where the funds will be held:	

Enter any applicable information about your funding which is not already included (including funding applied for but not yet received).	
Is the study funded by the US Department of Health and Human Services (DHHS)?	
If yes, please indicate which DHHS funding agency.	
If this submission is part of an academic program please provide the name of the institution, supervisor, and program.	
Please describe how you will disseminate the results of the research study. Include if and how you will target specific knowledge users, and any plans to report results back to participants. If participants will not receive a report of study results, please explain why not.	
Do you consent to being contacted by a member of the Island Health Research and Capacity Building team regarding the development of dissemination strategies?	
Identify where the research will be carried out at Island Health (hospital, department, clinical area, health centre, etc.).	
Name the Island Health hospital(s) involved:	
Name the Island Health health centre(s) involved:	
Name the Public Health Unit(s) involved:	
Will data be sent outside of Island Health? (transferred)	
Will the study require any non-standard devices to be connected to Island Health's network?	
If yes, please describe the device, its technical safeguards, and who will be using it.	

Project Team Info.

Principal Investigator

Prefix:
Last Name:
First Name:

Affiliation:
Position:
Email:
Phone1:
Phone2:
Fax:
Primary Address:
Institution:
Country:
Comments:

Common Questions

1. How to Complete the Application

#	Question	Answer
1.1	The Clinical Research Ethics Board (CREB) reviews research that involve surgery, clinical interventions, and the analysis of clinical data. The CREB will also review clinical studies involving registries and/or the linkage of databases. This does not include retrospective chart reviews.	**If you would like to apply for harmonized ethical review of a multi-jurisdictional study, please stop completing this application and go to RISe or for more information, go to Research Ethics BC website.** Please use this form for projects that include clinical interventions and/or involving registries and/or the linkage of databases. This does not include retrospective chart reviews. Clinical interventions are defined as: the administration or testing of drugs, medical devices, medical imaging or diagnostic techniques; and the taking of blood or other specimens. For all other studies, including retrospective chart reviews, please apply to the Health REB (HREB) using the appropriate form. Return to the home page, look for "Apply New" on right side under REO (Certification) and complete the HREB application. If you are applying for approval to post an advertisement or distribute recruitment materials ONLY please stop this application,

		return to Home Page, look for "Apply New" on right side and under REO (Certification) select the "Short Form Ethics and Operational Review Form" for completion.
1.2	Mandatory fields	Mandatory fields have a **red asterisk (*)** beside the number of the question. If a field doesn't pertain to your study, please mark it N/A. You will be unable to submit your study to the REB until all mandatory questions are answered.
1.3	Which tabs to complete	**All studies must complete:** All studies must complete: Principal Investigator and Study Team Funding Information Conflict of Interest Study Type and Information Review Type Summary of Study and Recruitment Participant Information and Consent Process Number of Participant and Regulatory Approvals/Registration for Clinical Study Number of Participants and Locations for Clinical Research Security of Data and Research Privacy and Confidentiality Databases, Registries or Biorepositories Funding Attestations
1.4	Who Can Submit	Because the **Principal Investigator (PI)** will have overall responsibility for the conduct of the study, they are the only ones who can see and click on the **Submit button** when the study is ready to go to the Research Ethics Office. This applies throughout the review and approval process. During the review process, you may get notified that changes are required. Just as with the original submission, any team member can make the changes and save them, but only the PI will be able to see and click on the **Re-Submit button.** Once the study is approved, any team member can submit other forms (such as annual renewals, or amendments).

1.5	Documents	Documents required with your submission are outlined on the Attachments tab of the application. If you do not submit the documents required for ethical review, **your submission will be rejected** and you will be asked to add them and resubmit.
1.6	Fee For Service	For Profit Studies at Island Health require a payment of $4000.00 for review. Please note: the Fee for Service tab must be completed in full.
1.7	Institutional Approval	In order to obtain Institutional Approval to conduct research at Island Health, you require both **Research Ethics approval + Operational approval** from the affected departments/units. Please ensure you complete the operational approval application. If you have any questions, please contact the Research Ethics and Compliance Office at ResearchEthics@islandhealth.ca
1.8	Timelines	Once a complete application is received and ready for review, we aim to review and have a response to you within a week of the Full Board meeting. You can find the deadlines for submission for CREB meetings on our website. Most responses from the REB will require some questions to be answered for clarity, and/or some changes to documents. Timelines depend on multiple factors.
1.9	After Initial Approval	Once your study is approved for conduct at Island Health, you will be required to submit an annual renewal form before the anniversary of the ethics approval. We will remind you! You may also wish to submit an amendment or report a safety event.

2. Principal Investigator and Study Team

#	Question	Answer
2.1	Other than the PI, list all names and their primary affiliation required to be on the Certificate of Approval (e.g. Dr. John Doe, UBC)	
2.2	Please enter any other locations where the research will be conducted under this Research Ethics Approval (e.g., Name of privately owned clinic, community centre, school, classroom, participant's home, in the field - provide details).	
2.3	Please confirm all research team members have completed the required TCPS 2 Tutorial.	TCPS 2 training is required for all researchers working with human participants in research at Island Health. Please confirm here. The PI is responsible for ensuring this training is completed for their research team members. https://www.islandhealth.ca/research-capacity-building/conduct-research-island-health/training-compliance
2.4	Please describe any special training requirements or qualifications required for the study team to conduct the study	

3. Funding Information

#	Question	Answer
3.1	1. Please provide the funding title (if different than the project title). (N/A if not applicable)	
3.2	2. Please list the type of funding for this research study	
3.3	3. If Other, please describe.	
3.4	4. Please provide the name of the funding agency, department or industry sponsor. (N/A if not applicable)	
3.5	5. For funded studies, please provide name of the institution where the funds will be held. N/A if not applicable	
3.6	6. Enter any applicable information about your funding which is not already included (including funding applied for but not yet received).	
3.7	7. Is the study funded by the US Department of Health and Human Services (DHHS)?	
3.8	8. If yes, to above, please indicate which DHHS funding agency.	

4. Conflict of Interest

#	Question	Answer
4.1	1. Do the Principal Investigator, Co-Investigators and/or their related parties have any personal interest(s) that could compromise or reasonably be perceived to compromise the objective conduct of the research or the integrity of the data generated by the study?	Conflicts of Interest (COIs) can arise naturally from an Investigator's engagement inside and outside their affiliated institution, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COI must be recognized, disclosed, and assessed. This question asks Investigators to disclose COIs that may relate to the research study that is the subject of the REB application. Personal interests may include business, commercial or financial interests, as well as personal matters and career interests.
4.2	2. In the box below, please describe the conflict of interest (COI) including dollar value where applicable.	While not exhaustive, the following are examples of potentially relevant details: - Does the COI involve a financial interest in any entity (a company, partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research? - Does the COI involve the provision of services (e.g., consulting, advisory etc) to any entity (a company, partnership, or non-profit corporation) whose financial interests could be affected by the outcome of this research? (Reminder: receiving a finder's fee for each participant enrolled is not permitted) - Does the COI involve intellectual property rights or interests linked in any way to this study (e.g., patents, copyrights, royalties or other payments etc)?
4.3	3. Do any of the researchers conducting this study occupy more than one role with respect to potential participants (e.g. acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, manager, student, or employer, etc.) that may create a real,	

	potential, or perceived conflict of interest that could affect the integrity of the research?	
4.4	4. If yes, please describe.	
4.5	5. Please advise how you propose to manage any actual, perceived, or potential COI outlined above	
4.6	6. If applicable, please identify mitigation for any possible 'power over' relationships.	i.e. Are any of the research team members in a perceived, actual or potential "power over" relationship (e.g. the PI or team member is the care provider for the participant, or the supervisor of any potential participants AND is also administering informed consent?) Please note this should be explained in the consent form as well.
4.7	7. Please describe the conflict of interest (COI) including dollar value where applicable.	

5. Study Type and Information

#	Question	Answer
5.1	Research Type:	
5.2	If Other, please describe:	
5.3	If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Research Ethics Board number of that proposal and briefly describe the relationship to the other proposal. (N/A if not applicable)	
5.4	Island Health sites for the study: Indicate which Island Health sites for the study (including study team members' institutional affiliations under which the research is being conducted)	
5.5	Non-Island Health sites for the study (including study team members' institutional affiliations under which this research is being conducted)	
5.6	Please enter any other locations where the research will be conducted under this Ethics Approval (e.g. name of privately owned clinic, community centre, school, classroom, participant's home, in the field – provide details)	
5.7	Will biological materials be collected or analyzed by researchers or a research lab? If yes, ensure documentation regarding approval is attached in Documents. (N/A if not applicable)	
5.8	Please describe any time sensitivities (e.g. funding or student deadline) for the conduct of the study (N/A if not applicable)	
5.9	If applicable, please explain how the data will be used for commercial purpose and indicate	

	if and how participants will benefit from commercialization. (N/A if not applicable)	

6. Review Type

#	Question	Answer
6.1	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 under Attachments.	
6.2	After reviewing the minimal risk guidance notes and the criteria for minimal risk, does this study qualify for minimal risk review?	Minimal risk is defined in the TCPS2 as follows: "....research in which the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participants in those aspects of their everyday life that relate to the research." **Note** that all studies which do not fall into the minimal risk category will undergo full board review.
6.3	Explain/justify the level of risk and group vulnerability reported above.	
6.4	Describe what is known about the risks of the proposed research for participants	
6.5	Has the research protocol received independent scientific/methodological peer review?	Peer review is required for all above minimal risk studies. Student research must have appropriate academic supervisory approval.
6.6	Scientific or methodological peer review details:	
6.7	Please attached a copy of the review if available and/or applicable to the attachments tab.	
6.8	If the research protocol has NOT received any independent scientific/methodological peer review, explain why no review has taken place	

6.9	9. Please describe any risks to researchers, including how you will mitigate the risks (e.g. injury, emotional distress, economic, etc.)	

7. Summary of Study and Recruitment

#	Question	Answer
7.1	Study summary - Summarize the research proposal: Purpose, Hypothesis, Justification, Objectives, Research Design, and Statistical Analysis.	The protocol/study proposal must be attached. Provide a short summary of the study written in lay language suitable for non-scientific REB members. DO NOT exceed 2000 words and do not cut and paste from the protocol.
7.2	Inclusion Criteria: Describe the participants being selected for this study. List the criteria for their inclusion, and justify the grounds for their inclusion. For research involving human pluripotent stem cells, provide a detailed description of the stem cells being used in the research.	
7.3	Exclusion Criteria: Describe which potential participants will be excluded from participation, List the criteria for their exclusion, and justify the grounds for their exclusion.	
7.4	Provide a detailed description of the method of recruitment for the local (Island Health) sites. For example, describe who will contact prospective participants and by what means this will be done.	Privacy legislation in BC states that organizations cannot provide contact information for clients for recruitment purposes without their express consent, unless the researchers have obtained permission from the Provincial Privacy Commissioner. Ensure that any letters of initial contact and other recruitment materials are amended to meet local requirements and attached to this submission on the Attachments page.
7.5	Recruitment of Normal/Control Participants Describe how prospective normal/control	

	participants will be identified, contacted, and recruited, if the method differs from the above.	
7.6	Use of records: If existing records (e.g. health records, clinic databases, registration details, etc.) will be used to IDENTIFY potential participants, please describe how permission to access the information, and to collect and use the information, will be obtained.	If a Permission to Contact (PTC) program has been used to identify potential participants, ensure you clearly describe whether this is internal or external to Island Health, who owns the PTC database, and who from the study team will have access to the PTC details. Also describe if accessing information from a database maintained by an external organization (such as BCCDC).
7.7	Summary of Procedures	
7.8	If deception will be used, please provide a thorough justification, the anticipated impacts on your participants once they learn of the deception, and describe the plans to debrief participants at the end of the study:	Describe in a step-by-step manner the research procedures. If the study involves an experimental approach, specify how the procedures differ from normal practice.

8. Participant Information and Consent Process

#	Question	Answer
8.1	How much time will a participant be asked to dedicate to the study?	Include how many minutes/hours over how many weeks/months the participant will be asked to dedicate to the project. If your study involves no direct interaction with participants you would respond “N/A”. Ensure that you also include this information in the consent process and that the amount of time stated is consistent in the application, recruitment letters or posters, and consent information.
8.2	How much time will Normal/Control participants be asked to dedicate to the study?	
8.3	Describe what is known about the risks/harms of the proposed research for participants.	Include information about any physical, social or psychological risks that the participants are likely to experience as a result of taking part in the study.
8.4	Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	Specify the benefits to the participants. 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.
8.5	Are there any costs participants can reasonably be expected to incur in order to participate (e.g. transportation, parking, child care, etc.? Specify what they are and whether	In accordance with TCPS2 (2018), the REB takes a neutral stance on the use of incentives. However, "where incentives are offered to participants, they should not be so large or attractive as to encourage reckless

	or not these can be fully reimbursed. If not, provide a justification.	disregard of risks... The offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement"
8.6	Describe any remuneration (payments/incentives/gifts-in-kind) to be offered to participants. Provide full details for the amounts, form of payment, payment schedules, and value of the gifts-in-kind.	
8.7	Obtaining Consent - Please specify: a) Who will explain the consent form, b) who will consent participants, c) details of where the consent will be obtained and under what circumstances, and d) the relationship between the person obtaining consent and the participant.	
8.8	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 confirm that the study meets the criteria below in yellow box. Ensure you address each criterion individually.	The REB must be 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 (see Glossary) 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. https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html

8.9	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. Ensure that your address each criteria individually. Include the corresponding letter (a, b, c, d, e, f) before each answer .	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 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. f. No relevant prior directive by the participant is known to exist. TCPS 2, Article 3.8 https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html
8.10	How long after being provided with detailed information about the study will the participant have to decide whether or not to participate? Provide your rationale for the amount of time given.	TCPS2 (2018), Article 3.2 that 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".
8.11	Will every participant have the capacity to give fully informed consent on their own behalf?	Please note that being under the legal age of majority in BC (19 years) does not necessarily mean that the participants are unable to provide their own consent as long as they clearly understand the risks and benefits.
8.12	If no, please provide the details of the nature of the incapacity	For instance, young age, cognitive or physical condition.
8.13	If a participant does not have the capacity to give fully informed consent, who will consent on their behalf?	

8.14	If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate?	
8.15	If Yes, explain how assent will be sought. Please be sure to attach copies of the assent form under the Attachments tab.	
8.16	Describe any situation in which the demonstration of ongoing consent for this research might be appropriate, and how this would take place.	TCPS2(2018), Article 3.3 that states, "Consent shall be maintained throughout the research project". Demonstration of ongoing consent might be particularly appropriate in the context of longitudinal, ethnographic or other research methods involving multiple contacts with participants.
8.17	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 documents that have been translated into other languages to the attachments tab.
8.18	Describe any restrictions regarding the disclosure of information to research participants (during or at the end of the study) that the funder/sponsor has placed on investigators, including those related to the publication of results.	
8.19	Communication of study results: Indicate plans for communicating study results to participants.	

9. Number of Participant and Regulatory Approvals/ ...

#	Question	Answer
9.1	Other Study Sites -- Is this research being conducted at any sites other than those selected under Section 4 of this submission, including world-wide	
9.2	If yes, please list the other sites below:	
9.3	Is this study being submitted for ethical approval to any other Research Ethics Boards covered the by this RISe submission, including world wide?	
9.4	If yes, please provide the name of the REB(s) and if available, contact information.	
9.5	Number of Participants How many participants (including controls) will be enrolled in the entire study (world wide)?	
9.6	How many participants (including controls) will be enrolled at the institutions covered by this Research Ethics Approval?	
9.7	Of these, how many are controls?	
9.8	Please enter any additional comments. If your study does not involve enrollment of human participants, please enter the number of records or samples to be obtained:	
9.9	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.	

9.10	Marketed Drugs Enter the name of any marketed drug(s) used within its approved indication.	
9.11	Natural and Non-Prescription Health Products	
9.12	Experimental Devices -- Enter the name of any new investigational devices, or marketed devices used in experimental mode, that will be used outside of their approved indication.	
9.13	Health Canada Regulatory Approvals -- Is this study a clinical trial or investigational test requiring Health Canada regulatory approval.	
9.14	If Yes, please check all that apply:	
9.15	Name the sponsor/institution/investigator responsible for filing a Clinical Trial Application (CTA) or Investigational Testing Authorization (ITA) with Health Canada or Other.	
9.16	Details of the Health Canada Regulatory Approvals A copy of the approval (NOL, ITA, NOA) must also be attached in Attachments.	
9.17	Name of Regulatory Agency:	
9.18	Date of Approval:	
9.19	Date of Pending Application:	
9.20	Health Canada NOL Control Number:	
9.21	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)?	
9.22	If yes, provide details	
9.23	Registration for Publication of Clinical Trials -- Does this clinical study fall within the definition stated on the yellow box (in the guidelines)?	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 relationshipbetween 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: https://clinicaltrials.gov/ct2/manage-recs/background

10. Number of Participants and Locations for Clini ...

#	Question	Answer
10.1	Does this research focus on Indigenous peoples, communities or organizations? If no, please skip to the next tab.	If "Yes", ensure that you are familiar with the guidance documents. Please see: TCPS2(2018) Chapter 9 on Research Involving the First Nations, Inuit and Metis Peoples of Canada. Also attach a copy of the research agreement with the community (if available) on the Attachments tab.
10.2	Will the research be conducted on Indigenous reserves, Métis settlement(s), or lands governed under a self-government agreement or an Inuit or First Nations land claims agreement?	
10.3	Do any of the criteria for participation include membership in an Indigenous community, group of communities, or organization, including urban Indigenous populations?	
10.4	Does the research seek input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics?	
10.5	Will Indigenous identity or membership in an Indigenous community be used as a variable for the purposes of analysis?	
10.6	Will the results of the research refer to Indigenous communities, peoples, language, history or culture?	

10.7	Community Engagement have you initiated or do you intend to initiate an engagement process with the Indigenous collective, community or communities for this study?	
10.8	If you answered Yes to question #7 please describe the process that you have followed or will follow with respect to community engagement. Include the role or position of those consulted, including their names if appropriate. Attach any documentation of consultations (i.e. formal research agreement, letter of approval, email communications, etc.) below.	
10.9	No community consultation or engagement If you answered no to question #7, briefly describe why community engagement will not be sought and how you can conduct a study that respects Indigenous communities and participants in the absence of community engagement.	
10.10	If your research involves an identified group or community, outline the likely impacts of the research on the community.	
10.11	If applicable please describe the community consent process. If no community consent is being sought, please justify.	

11. Security of Data, Research Privacy and Confide ...

#	Question	Answer
11.1	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.	
11.2	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.	
11.3	Study Stoppage -- Describe the circumstances under which the ENTIRE study could be stopped early. Should this occur, describe what provisions would be put in place to ensure that the participants are fully informed of the reasons for stopping the study.	Safeguards can be: Administrative (policies, agreements, training) Technical (virus protection, firewalls, encryption, passwords) Physical (locked doors and drawers, alarms and identity badges)
11.4	Personal Identifiers -- 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.	
11.5	Will any personal health information or personal identifiers be collected?	
11.6	If yes above, please describe what personal identifying information will be collected, and justify the need for it to be collected.	

11.7	If a study code/key/master list will be created to link each participant to the data being retained, please describe who is keeping the list, where, and what safeguards there are to protect the list.	
11.8	Data Access and Storage -- Explain who will have access to the data at each stage of processing and analysis.	
11.9	Indicate whether a current list of the names of study personnel (including co-investigators and research staff) and their delegated tasks will be maintained in the study file.	
11.10	If a list will not be maintained, please explain:	
11.11	Describe how the data will be stored (e.g., computerized files, hard copy, video-recording, audio recording, personal electronic device, other). Please confirm that any digital data will be stored on an encrypted, password protected computer, storage device, or hospital network server.	
11.12	Describe the safeguards in place to protect the confidentiality and security of the data:	
11.13	If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?	
11.14	Disposition of Study Data and Biospecimens -- please describe: what will happen to the data at the end of the study:	
11.15	Please describe how long the study data will be retained:	
11.16	Please describe when and how the data will be destroyed:	
11.17	Please describe what plans there are for future use of the data:	
11.18	Please describe who will have access to the data in the future and for what purpose:	
11.19	If applicable: a) describe what will happen to the study biospecimens at the end of the study b) how long the study biospecimens will be retained; c) where, when and how the biospecimens will be destroyed; and d) what plans there are for future use of the	

	biospecimens, including who will have access to the biospecimens in the future and for what purpose.	
11.20	Data and/or Biospecimen Transfer to Other Institutions -- Will data and/or biospecimens be sent outside of the Institution where it is being collected?	
11.21	If yes, please describe: a) the type of data to be transferred; b) who the data will be transferred to; c) where the data will transferred, and; d) how the data will be sent.	
11.22	Data and/or Biospecimen Transfer to Other Institutions -- Will data and/or biospecimens be sent outside of the Institution where it is being collected?	
11.23	If yes, please describe: a) the type of data and/or biospecimens to be transferred; b) who the data and/or biospecimens will be transferred to; c) where the data and/or biospecimens will be transferred (list institution & location); and d) how the data and/or biospecimens will be sent.	
11.24	Data and/or Biospecimen Transfer to Institution -- Will the researchers be receiving data and/or biospecimens from other sites?	
11.25	If yes, please describe: a) the type of data and/or biospecimens to be received; b) who the data and/or biospecimens will be received from; c) where the data and/or biospecimens will be received from (list institution and location); and d) how the data and/or biospecimens will be received.	
11.26	Data Linkage -- Will the data be linked to any other data source (including a biorepository)?	
11.27	If yes: a) identify the data set; b) how the linkage will occur; and c) explain how confidentiality regarding the shared information will be preserved.	
11.28	If there any plans for future use of either data or audio/video recordings please provide details, including who will have access and for what purposes, below.	
11.29	Is this application for research requiring access to clinical charts OR data from	

	registries or databases such as PopDataBC or Pharmanet?	
11.30	If data will be collected from health records at Island Health, please identify who will be accessing the health record.	
11.31	Insert the date range of the charts/data to be included in the research:	

12. Databases, Registries or Biorepositories

#	Question	Answer
12.1	What is the scope and purpose of the database / registry or biorepository?	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) poly-user biobank (i.e., a collection aimed at supporting undetermined, multiple users with REB-approved research projects, through a defined access/application mechanism).
12.2	What are the anticipated public and scientific benefits of the database, registry or biorepository?	
12.3	Over what period of time will data be collected?	Include a clear data 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.
12.4	For registry or database, what information source(s) are you accessing?	For example, patient records, program evaluation data, routinely collected performance data, etc.
12.5	Provide specific details about the source(s) i.e. including the name of the database or	

	type of records, location, and owner of the data.	
12.6	For biorepositories, what are the sources of your biospecimens. Check all that apply.	
12.7	All new biorepositories (biobanks) associated with this study must be registered. Please add the registration number:	**How to register:** The PI is required to register the biobank HERE **In Scope:** New biospecimen research collections that arise in the course of pursuing basic research projects, translational research studies, clinical studies and trials, (ie when creating a collection to support future health research). **Out of Scope:** - Clinical (non-research) biobanks/biospecimen collections are not included in this directive as these biobanks are required to be incompliance with clinical standards - Biospecimens collected for industry sponsored clinical studies - Biospecimens stored onsite for less than 3 months If you have questions, please contact us at 250 519 6726
12.8	Are you collecting personally identifiable information and/or will the biospecimens or data be linked to personally identifiable information?	
12.9	If yes to the question above, indicate the type of personally identifying information you will be collecting and include a justification for its inclusion	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, MRN, PHN, student ID number, date of birth, address, or unique personal characteristic etc.
12.10	If yes to the question above, how long will data remain identifiable (i.e. when, if ever, will it be irreversibly anonymized?). Explain why data needs to remain identifiable if this is the case.	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.

12.11	If yes to the question above, describe the process for removal of direct/indirect identifiers, and anonymization.	
12.12	List the individuals (who are not already listed on Project Info or Project Team Info pages) who will have access to personally identifiable information at any stage in the data collection or review/abstraction of the data/analysis of the specimens.	This includes those who will have access to master lists of keys linking identifiable participants to research data/specimens.
12.13	Will participants provide consent to be included in the database , registry or have their specimens included in the biorepository for research purposes?	
12.14	Specify who will explain the consent form and invite participants to contribute. Include details of where consent will be obtained and under what circumstances.	Attach a copy of the consent form to this application.
12.15	If you do not plan to obtain individual participant informed consent, please provide justification for not doing so following the criteria outlined here. Please address each criterion individually.	Refer to TCPS2 Articles 3.7A and 5.5 for further information on the following criteria: A. Explain why inclusion in the database involves no more than minimal risk to the participants; B. Confirm that the lack of participants' consent is unlikely to affect the welfare of the participants; C. Demonstrate that the purpose or aim of the database would be impossible or impracticable to carry out, if the prior consent of the participant is required; D. Explain why the value of conducting this research using this database exceeds the public interest in protecting the privacy of individuals; E. Demonstrate compliance with any known preferences previously expressed by individuals about any use of the information; and F. Confirm that any other necessary permission for secondary use of information for research purposes are in place.
12.16	Please describe the process for a participant to access and/or withdraw their data,	

	including what data can be withdrawn. If data cannot be amended or withdrawn, please provide justification as to why not.	
12.17	What is the entity (custodian) or who is the person (data steward) that will have responsibility for the database?	**Custodian:** This is the institution that will have custody and control of the data maintained in the database. **Data Steward:** This is the person who is responsible for overseeing the management and use of the data, including the main rules governing use of the database, and the process by which access requests will be reviewed for the proper management of the data.
12.18	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 the data. If a code procedure is being used, describe the procedure in detail here.
12.19	What will be the address of the database, registry or the location of the biorepository?	
12.20	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.	
12.21	Will data or biospecimens be sent outside of Island Health? (transferred)	Note that if this changes in the future an amendment must be submitted before the transfer.
12.22	Explain why it is necessary to send data outside of the institution, and indicate what data will be sent, where it will be sent, who it will be sent to, how it will be transferred (emailed, couriered, electronic encrypted transfer, etc.) and where it will be stored.	
12.23	Will there by a data transfer agreement?	
12.24	Do you plan to link the data or the biospecimens to another data source (e.g., database, biorepository)?	Note that if this changes in the future an amendment must be submitted before data or specimens are linked.
12.25	Identify the data set, how the linkage will occur, and provide a list of data items in the other database.	Identify what personal information will be used to link the databases and how confidentiality regarding this shared information will be preserved.

12.26	How long are you planning to keep the data/biospecimens?	
12.27	If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction.	
12.28	Will the information in the database/biorepository be retained as an ongoing database/repository (or as part of an ongoing database/repository) for future research?	
12.29	If yes to future use, provide a full description of the data stewardship process.	Reference who will have access to the database in the future and under what circumstances, what will happen if an individual data steward or custodian leaves the institution, where the ongoing database or biorepository will be stored or maintained, and what security measures will be in place.
12.30	Describe any commercial uses for which the data/ biospecimens may be used, including any disclaimers concerning participant remuneration for such use.	
12.31	If a clinical trial, does it fall within the definition of a clinical trial requiring registration?	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 of 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, behavioral treatments, dietary intervention, and process-of-care changes). Health outcomes include any biomedical or health related measure 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.
12.32	If yes above, please enter the authorized registry used and the clinical trial unique identifier.	Please note that registration information can be submitted to our office when it becomes available.

13. Funding

#	Question	Answer
13.1	Is this a For Profit Industry Sponsored Study?	Industry For-Profit Sponsors The review fee is $4000 for the initial review and $750 for the annual renewal. Please wait for the invoice from the Research Ethics Boards (REBs) to submit payment. The invoice will detail payment instructions and wire transfer information.
13.2	If yes, please provide the following information: Organization name; Department or branch; Mailing address (including City, Province/State, Postal/ZIP Code); Invoice to be sent to the attention of; Email address; Office/Cell phone number.	
13.3	Mailing address (including City, Province/State, Postal/ZIP Code)	
13.4	Invoice to be sent to the attention of:	
13.5	Email address:	
13.6	Office/Cell phone number:	

14. Attestations

#	Question	Answer
14.1	I attest that the information provided in this form is accurate and up to date at the time of submission.	
14.2	I agree to conduct the study in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition (2018)	
14.3	I agree to conduct the study in accordance with the REB approved documents.	
14.4	I have read, understood, and agree to abide by the Island Health policies and procedures regarding the conduct of research: specifically Policy 25.2 Free and Informed Consent in Research, Policy 25.3 Research Integrity Policy, and (if applicable) 705 Research Finance Policy	
14.5	I agree that Island Health may conduct a compliance audit of this study.	
14.6	Principal Investigator Signature: By signing this application electronically, I understand that my electronic signature has the same legal effect and can be enforced in the same	

	way as a written signature. Please enter your name.	

15. Please submit an operational application to pair with this ethics application. If you have any questions, please contact the office at ResearchOperations@islandhealth.ca

All research at Island Health must have both research ethics approval AND approval from the facilities/services impacted by the conduct of the research (operational approval).

Ethics Approval + Operational Approval = Institutional Approval.

#	Question	Answer
15.1	If Island Health staff/physicians will be involved in the recruitment of participants for the study, please describe what the involvement will entail.	
15.2	If Island Health staff/physicians will be involved in any other part of the conduct of the study, please describe what that involvement will entail.	
15.3	Please identify all departments where personnel will be requested to support the study. If department name is unknown, please identify the type of support required.	