Clinical Research Ethics Application 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. 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.	
1.2	Mandatory fields	
1.3	Which tabs to complete	
1.4	Who Can Submit	
1.5	Documents	
1.6	Fee For Service	
1.7	Institutional Approval	
1.8	Timelines	
1.9	After Initial Approval	

2. 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	All Investigators and study team members are required to update their TCPS 2 training to the CORE-2022 version. Please confirm that all study team members, including the Investigator, have completed this training.	
2.4	Please describe any special training requirements or qualifications required for the study team to conduct the study	

3. 3. Funding Information

#	Question	Answer

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

4. 4. Conflict of Interest

#	Question	Answer
4.1	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?	
4.2	In the box below, please describe the conflict of interest (COI) including dollar value where applicable.	
4.3	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	If yes, please describe.	

4.5	Please advise how you propose to manage any actual, perceived, or potential COI outlined above	
4.6	If applicable, please identify mitigation for any possible 'power over' relationships.	
4.7	Please describe the conflict of interest (COI) including dollar value where applicable.	

5. 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. 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?	
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?	
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. 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.	

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.	
7.5	Recruitment of Normal/Control ParticipantsDescribe 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.	
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:	

8. 8. Participant Information and Consent Process

#	Question	Answer
8.1	How much time will a participant be asked to dedicate to the study?	
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.	
8.4	Describe any potential benefits to the participant that could arise from his or her participation in the proposed research.	
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 or not these can be fully reimbursed. If not, provide a justification.	
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, andd) 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.	
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 .	

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.	
8.11	Will every participant have the capacity to give fully informed consent on their own behalf?	
8.12	If no, please provide the details of the nature of the incapacity	
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.	
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).	
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. 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 ParticipantsHow 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 DrugsEnter 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 ApprovalsA 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)?	

10. 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.	
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. 11. Security of Data, Research Privacy and Confide ...

#	Question	Answer
11.1	Unblinding in an emergencyDescribe 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.	
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 studyb) 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. 12. Creation of a Research Registry or Bioreposito ...

#	Question	Answer
12.1	Does this study involve the creation of a registry (data or tissue bank) with a local custodian for future use in other research?	
12.2	What is the scope and purpose of the database / registry or biorepository?	
12.3	What are the anticipated public and scientific benefits of the database, registry or biorepository?	
12.4	Over what period of time will data be collected?	
12.5	For registry or database, what information source(s) are you accessing?	
12.6	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.	
12.7	For biorepositories, what are the sources of your biospecimens. Check all that apply.	
12.8	All new biorepositories (biobanks) associated with this study must be registered. Please add the registration number:	
12.9	Are you collecting personally identifiable information and/or will the biospecimens or data be linked to personally identifiable information?	
12.10	If yes to the question above, indicate the type of personally identifying information you will be collecting and include a justification for its inclusion	
12.11	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.	
12.12	If yes to the question above, describe the process for removal of direct/indirect identifiers, and anonymization.	

12.13	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.	
12.14	Will participants provide consent to be included in a database, registry, to or have their specimens included in a biorepository for research purposes?	
12.15	Specify who will explain the consent form and invite participants to contribute. Include details of where consent will be obtained and under what circumstances.	
12.16	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.	
12.17	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.	
12.18	What is the entity (custodian) or who is the person (data steward) that will have responsibility for the database?	
12.19	What steps will be taken to ensure the security of the data/biospecimens?	
12.20	What will be the address of the database, registry or the location of the biorepository?	
12.21	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.	
12.22	Will data or biospecimens be sent outside of Island Health? (transferred)	

12.23	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.	
12.24	Will there by a data transfer agreement?	
12.25	Do you plan to link the data or the biospecimens to another data source (e.g., database, biorepository)?	
12.26	Identify the data set, how the linkage will occur, and provide a list of data items in the other database.	
12.27	How long are you planning to keep the data/biospecimens?	
12.28	If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction.	
12.29	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?	
12.30	If yes to future use, provide a full description of the data stewardship process.	
12.31	Describe any commercial uses for which the data/ biospecimens may be used, including any disclaimers concerning participant remuneration for such use.	
12.32	If a clinical trial, does it fall within the definition of a clinical trial requiring registration?	
12.33	If yes above, please enter the authorized registry used and the clinical trial unique identifier.	

13. 13. Funding

#	Question	Answer
13.1	Is this a For Profit Industry Sponsored Study?	

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. 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 – TCPS 2 (2022)	
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 w ...

#	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.	