Health Research Ethics Application Form V.22

Project Info.

File No: Ref No :
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 Health Research Ethics Board (HREB) reviews research that is predominantly behavioural or social sciences related.	
1.2	Mandatory Fields	
1.3	Which Tabs MUST be completed	
1.4	Who Can Submit	
1.5	Documents	

2. Review Process and Timelines

#	Question	Answer
2.1	Institutional Approval	
2.2	Timelines	
2.3	After Initial Approval	

3. Principal Investigator and Study Team

#	Question	Answer
3.1	Other than the PI, list all names and primary affiliation required to be on the Certificate of Approval. (e.g. Dr. Jane Doe, UBC)	
3.2	Enter the Principal Investigator's secondary appointments or affiliations (including Post-Secondary and Health Authorities) if applicable	
3.3	Describe each study team member's (co-investigator, staff, research assistant, external supervisor, consultant, etc.) role in the study e.g. statistician, supervisor, advisor, student, etc. Ensure each individual is entered in the first box of this tab.	
3.4	Please confirm all research team members have completed the required TCPS 2 (2018) Tutorial.	
3.5	Please describe any special training requirements or qualifications required for the study team to conduct the study.	

4. Study Funding Information

#	Question	Answer
4.1	Please provide the funding title (if different than the project title). (N/A if not applicable)	
4.2	Please list the type of funding for this research study.	
4.3	If other, please describe	
4.4	Please provide the name of the funding agency, department or industry sponsor. (N/A if not applicable)	
4.5	For funded studies, please provide name of the institution where the funds will be held. N/A if not applicable	
4.6	Enter any applicable information about your funding which is not already included (including funding applied for but not yet received).	
4.7	Is the study funded by the US Department of Health and Human Services (DHHS)?	
4.8	If yes, to above, please indicate which DHHS funding agency.	

5. Conflict of Interest

#	Question	Answer
5.1	Study Related Conflict of Interest Conflicts of Interest (COIs) in research are situations where someone's personal interests (financial, career, or other) could compromise or could be perceived to compromise the objective conduct of research or integrity of the data. Conflicts of interest can arise naturally from an Investigator's engagement inside and outside the health authority, and the mere existence of a COI or the perception of a COI does not necessarily imply wrongdoing on anyone's part. Nonetheless, real and perceived COI must be recognized, disclosed, and assessed. This question asks Investigators to disclose COIs that may relate to the research study that is the subject of the REB application. Do the Principal Investigator, Co-Investigators and/or their related parties have any personal interest(s) that could compromise or reasonably be perceived to compromise the objective conduct of the research or the integrity of the data generated by the study? Personal interests may include business, commercial or financial interests, dual roles (e.g. PI and Doctor), as well as personal matters and career interests.	
5.2	You have answered yes, please complete this section. Refer to the Island Health Conflict of Interest Policy and Disclosure form for next steps and attach the Disclosure form once completed to the application.	
5.3	Please describe the conflict of interest (COI) including dollar value where applicable.	
5.4	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?	
5.5	If yes, please describe	
5.6	Please advise how you propose to manage any actual, perceived, or potential COI outlined above.	
5.7	If applicable, please identify mitigation for any possible 'power over' relationships.	

6. Study Type

#	Question	Answer
6.1	Indicate whether your application is a Retrospective Chart Review or Health-Behavioural	
6.2	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).	

7. Review Type and Risks

#	Question	Answer
7.1	Relationship to Previous Ethics Applications: If this proposal is closely linked to any other proposal previously/simultaneously submitted, enter the Institution or Health Authority name and associated Research Ethics Board study number of that proposal.	
7.2	If applicable, please describe the relationships between this proposal and the previously/simultaneously submitted proposal listed above.	
7.3	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.	
7.4	Peer Review -- Has the research proposal received any independent scientific/methodological peer review? All above minimal risk studies require a peer review.	
7.5	External peer review details including name of individual:	
7.6	Internal peer review details including name of individual:	
7.7	If this research proposal has NOT received any independent scientific/methodological peer review, explain why no review has taken place:	
7.8	After considering the level of risk your research involves and the vulnerability of your study population, please tick one box below that best represents the overall level of risk.	
7.9	Provide an explanation for the assessment of research risk and group vulnerability reported above.	
7.10	Does your application fall under minimal risk (eg. was it assigned an overall risk level of 1 on the minimal risk matrix. Please see the risk matrix included in the guidance document.	

7.11	Does this study require review and approval by another Canadian REB outside of Research Ethics British Columbia (REBC)?	

8. Summary of Study and Recruitment

#	Question	Answer
8.1	Provide a brief statement about the project written in lay language. Do not exceed 100 words and do not cut and paste directly from the study proposal.	
8.2	Summarize the research proposal including study purpose, hypothesis, study population, and research method.	
8.3	Inclusion Criteria - Describe the participants being selected for this study, and list the criteria for their inclusion.	
8.4	Exclusion Criteria - Include details if otherwise eligible participants will be excluded due to other characteristics. If no exclusion criteria are applicable, enter n/a.	
8.5	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: Who will contact the prospective participants	
8.6	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: By what means will recruitment be done (e.g., public posting, third party recruitment etc.)?	
8.7	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: How will prospective participants be identified	
8.8	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: all site specific information.	
8.9	Recruitment -- Provide a detailed description of the steps you will use to recruit participants. Include: Attach all materials, including letters of initial contact, posters, scripts and advertisements in the attachments tab.	
8.10	Use of records: If existing records (e.g. health records, clinic databases, registration details, etc.) will be used access information about	

	potential participants, please describe how permission to access the information, and to collect and use the information, will be obtained.	
8.11	Summary of Study Procedures -- Describe briefly in a step-by-step manner what the researcher will be doing with participants, after then have been recruited and consented.	
8.12	Research Types -- Select all that apply to your study. Please review the research methods descriptions before responding. If none apply, please select 'None of these Methods'	
8.13	If other, please describe:	

9. Participant Information and Consent Process

#	Question	Answer
9.1	How much time will a participant be asked to dedicate to the project?	
9.2	Describe what is known about the risks of the proposed research for participants and how it will be mitigated.	
9.3	Describe any potential benefits to the participant that could arise from participation in the proposed research.	
9.4	If your research involves an identified group or community, outline the likely impacts of the research on the community.	
9.5	Specify how potential participants will be invited to take part in the study. Include details of where the consent will be obtained and documented, and under what circumstances.	
9.6	If applicable please describe the community consent process. If no community consent is being sought, please justify.	
9.7	Describe any reimbursement and incentives (e.g., meals, parking, medications) or payments/gifts-in-kind (e.g., honoraria, gifts, prizes, credits) to be offered to the participants. Provide full details of the amounts, payment schedules, and value of gifts-in-kind.	
9.8	Obtaining Consent - Include details of where and when consent will be obtained and how it will be documented.	
9.9	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. Please address each criterion individually.	
9.10	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.	

9.11	Will every participant have the capacity to give fully informed consent on their own behalf?	
9.12	If no, please provide the details of the nature of the incapacity:	
9.13	If a participant does not have the capacity to give fully informed consent, who will consent on their behalf?	
9.14	If a participant does not have the capacity to give fully informed consent, will they be able to give assent to participate?	
9.15	If Yes, explain how assent will be sought. Please be sure to attach copies of the assent form under the Attachments tab.	
9.16	Describe any situation in which the demonstration of ongoing consent for this research might be appropriate, and how this would take place.	
9.17	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).	
9.18	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.	

10. Number of Participants and Locations for Behavioural Study

#	Question	Answer
10.1	Does this research focus on Indigenous peoples, communities or organizations?	
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 -- If you answered yes to questions above, 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 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 the previous question, 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.	
10.12	Registration for Publication of Clinical Trials	
10.13	If yes, please enter the following information: Has the study been registered?	
10.14	Authorized Registry used:	
10.15	Clinical Trial unique identifier:	
10.16	Number of Participants -- How many participants will take part in the entire study (eg. World-Wide)?	
10.17	How many participants will take part at institutions covered by this Research Ethics approval?	
10.18	Principal Investigator and Research Team Experience:	

11. Security of Data and Confidentiality of Personal Information for a Behavioural Study

#	Question	Answer
11.1	Please select all tools for data collection.	
11.2	If other, please describe:	
11.3	Please describe who on the study team will be doing the data collection:	
11.4	It is the PI's responsibility to ensure that all members of the study team who will be accessing data are made aware of their responsibilities concerning privacy and confidentiality. Explain who will have access to the data at each stage of processing and analysis.	
11.5	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.	
11.6	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.	
11.7	Will any personal health information or personal identifiers be collected?	
11.8	If yes, please describe what personal identifying information will be collected, and justify the need for it to be collected.	
11.9	How and where will data be stored? (E.g., computerized files, hard copy, videotape, audio recordings, personal electronic communications device, other.)	
11.10	If data will be sent outside of the Institution where it originated, please describe the type of data to be transferred, who the data will be transferred to, where the data will transferred, and how the data will be sent.	
11.11	If data will be received from other sites, please describe the type of data, where it will be received from, and how the data will be received.	

11.12	If data will be linked to any other data source (including a biorepository) please identify the data set, how the linkage will occur, and explain how confidentiality regarding the shared information will be preserved.	
11.13	Describe any data that will be sent to, accessed from, or stored outside of Canada. Include details of where it will be sent to or accessed from, and the purpose.	
11.14	Describe the safeguards in place to protect the confidentiality and security of the data:	
11.15	If any data or images are to be kept on the Web, what precautions have been taken to prevent them being copied?	
11.16	Describe what will happen to the data at the end of the study (including how long the study data will be retained, when and how the data will be destroyed)	
11.17	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.	
11.18	Is this application for research requiring access to clinical charts OR data from registries or databases such as PopDataBC or Pharmanet?	
11.19	If data will be collected from health records at Island Health, please identify, by name, who will be accessing the health record.	
11.20	Insert the date range of the charts/data to be included in the research:	

12. Retrospective Chart Review

#	Question	Answer
12.1	Is this a retrospective chart review study for which participant consent will be obtained?	
12.2	Describe how permission to access the medical records and to collect and use these records will be obtained.	
12.3	Briefly describe the type of data that you intend to collect (e.g., disease, diagnosis, outcome, demographic, aggregate, personal-level).	
12.4	Number of Records/Patient Charts	
12.5	Are you collecting and retaining personally identifiable information to be a part of the data set?	
12.6	Indicate what personally identifying information you will be collecting and retaining as part of the dataset. Include a justification of why it is required.	
12.7	Please explain if and why the identifiable information essential to the research.	
12.8	Please explain how the use of the identifiable information without the participants consent is unlikely to adversely affect the welfare of the participants to whom the information relates.	
12.9	Please explain how the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information.	
12.10	Please explain how the researchers will comply with any known preferences previously expressed by individuals about any use of their information.	
12.11	Please explain why it is impossible or impracticable to seek consent from individuals to whom the information relates.	
12.12	Please describe how the researchers will obtain any other necessary permissions for secondary use of the information for research purposes.	

12.13	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.	
12.14	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.	
12.15	Explain who will have access to the data at each stage of collection, processing and analysis, and indicate whether a current list of the names of study personnel (including co-investigators) and their delegated tasks will be maintained in the study file. If a list will not be maintained, please explain why.	
12.16	Describe how and where the data will be stored (e.g., computerized files, hard copy, video-recording, audio-recording, personal digital device, other)	
12.17	Describe what will happen to the data at the end of the study, including how long the data will be retained and where, when and how the data will be destroyed, and what plans there are for future use of the data, including who will have access to the data in the future and for what purpose.	
12.18	Will data be transferred out of the custody and control of Island Health?	
12.19	If data will be transferred out of Island Health, please describe a) the type of data to be transferred, b) who the data will be transferred to, c) where the data will be transferred d) how the data will be sent.	
12.20	Do you plan to link the data to any other data?	
12.21	If yes to data linkage: a) Identify the data set, b) how the linkage will occur, c) provide a list of data items in the other database. d) identify what personal information will be used to link the databases e) how confidentiality regarding this shared information will be preserved.	

13. Attestations

#	Question	Answer
13.1	I attest that the information provided in this form is accurate and up to date at the time of submission.	
13.2	I agree to conduct the study in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition (2018)	
13.3	I agree to conduct the study in accordance with the REB approved documents.	
13.4	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	
13.5	I agree that Island Health may conduct a compliance audit of this study.	
13.6	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.	

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

#	Question	Answer
14.1	If Island Health staff/physicians will be involved in the recruitment of participants for the study, please describe what the involvement will entail.	
14.2	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.	
14.3	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.	